

NHS dictionary of medicines and devices (dm+d)

Editorial policy

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July 2020

This document is produced and maintained by NHS Prescription Services (provided by NHS Business Services Authority) in partnership with NHS Digital.

The dm+d NHS Medicines Standard is approved by the Data Coordination Board.

Document control since 2016

Date Issued	NHS dm+d	Change summary
May 2016	Release 2.0 Version 3.2	<p>Appendix II VMP Prescribing Status – order of information in this section changed for clarity.</p> <p>Appendix II Controlled Drug Prescribing Information included reference to: Ketamine having changed to Schedule 2 (CD) status on 30/11/2015 Temazepam having changed status to Schedule 3 (CD no register) on 1/06/2015</p> <p>Appendix II Examples of SNF Patterns – Strength expression and Appendix XIV Injections and Infusions sections - inclusion of mannitol as an example of where dual representation is applied</p> <p>Appendix V VMP Form table updated</p> <p>Addition of Appendix XX VMP and AMP Strength Description Differences providing examples of strength mismatches and reasons.</p>
May 2017	Release 2.0 Version 3.3	<p>dm+d – the NHS Medicines Standard. Section reworded with updated information regarding the Standardisation Committee for Care Information (SCCI) standard. SCCI logo added to front page too.</p> <p>HSCIC name change to NHS Digital throughout</p> <p>dm+d enquiries/issues – link added for diagram representation online</p> <p>Appendix II:</p> <ul style="list-style-type: none"> • Virtual Medicinal Product Name: minor updates • New subsection – reference to the inhaled delivered dose in a VMP description • New subsection – reference to the British Pharmacopoeia ('BP') in a VMP description • Actual Medicinal Product Note: updating the policy for generic AMPs listed by wholesalers • Actual Medicinal Product Pack Note: adding clarity to discontinued packs and the supply chain • Strength expression – inclusion of trichloroacetic acid as an example where dual expression is used <p>Appendix V VMP Form table updated</p> <p>Appendix VI VMP Route table updated</p> <p>Appendix XI Abbreviations – minor updates and table updated of products unable to be abbreviated to 60 characters or less</p> <p>Appendix XX VMP and AMP Strength Description Differences – inclusion of the variation of eye product strengths in the transition of SmPC regulated product name descriptions.</p> <p>Addition of Appendix XXI British Pharmacopoeia ('BP') reference in a Virtual Medicinal Product (VMP) description includes a decision tree that demonstrates the decision making process for whether or not to include the suffix BP in the VMP name</p> <p>Addition of Appendix XXII Medical Devices that may be prescribed in</p>

		<p>Secondary Care explaining the policy about authoring of these products</p> <p>Addition of Appendix XXIII Representation of diluents for Special Order cytotoxic infusions – SACT (Systemic Anti-Cancer Therapies)</p> <p>Glossary of terms – minor updates</p>
December 2018	Release 2.0 Version 3.4	<p>Appendix II VTM Name. Note added following safety concerns about prescribing / dispensing of Peppermint Oil and Peppermint water</p> <p>Appendix II VMP Prescribing Status text updates following the consultation November 2016.</p> <p>Appendix II VMP Basis of Strength Substance (BoSS). Inclusion of parenteral dexamethasone products authored to include reference to base in brackets following safety concerns.</p> <p>Appendix II Semantic Normal Form Patterns used in NHS dm+d. Note added clarifying dm+d authoring style of expression per ml / per 5ml for oral solutions and oral suspensions.</p> <p>Appendix II Schedule 1 and ACBS Indicators. Note added that flags updated in line with the 'gluten-free' update to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 (effective from 4th December 2018).</p> <p>Appendix V and Appendix VI VMP Forms and Routes tables updated</p> <p>New Appendix XXIII added on Radiopharmaceuticals</p> <p>Addition of Appendix XXV Authoring of Biosimilar Systemic Anticancer Therapy (SACT) dose banded SACT products</p>
July 2020	Release 2.0 Version 3.5	<p>dm+d – the NHS Medicines Standard. Reference to responsibility for Information Standards transferring to the Data Coordination Board.</p> <p>Inclusion of the email address for enquiries specifically concerning secondary care: nhsbsa.dmdsecondarycare@nhs.net</p> <p>Appendix II VTM and VMP word order. Clarification that the source manufacturer SmPC documentation now tends to guide the dm+d editorial style rather than the BNF.</p> <p>Appendix II VMP Prescribing Status minor text updates to the tense following the implementation of the changes March 2016.</p> <p>Appendix II Controlled Drug Prescribing Information included reference to: Gabapentin and pregabalin changing status to Schedule 3 (CD no reg, exempt safe custody).</p> <p>Appendix II Restrictions on Availability. Individual patient supply, Sandimmun capsules and oral solution removed as an example.</p> <p>Appendix V VMP Forms table updated (including a form of 'Herbal material' to support authoring of cannabis based products for medicinal use [CBMP]).</p> <p>Appendix VI VMP Route table updated.</p> <p>Appendix VII Units of Measure updated.</p> <p>Appendix IX AMP Flavours table updated.</p> <p>Appendix XVIII Global Trade Item Numbers. Text updated to read more clearly. A caveat added to support the dm+d user community.</p> <p>Appendix XXV Authoring of SACT dose banded products. Section updated to included editorial policy on authoring of products with a strength equal to or over 1g/1000mg.</p>

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NHS dictionary of medicines and devices and its governance structure

dm+d — the NHS Medicines Standard

Following recommendation by the Standardisation Committee for Care Information (SCCI), the Department of Health has provided authority to publish the [SCCI0052 Dictionary of Medicines and Devices \(dm+d\)](#) information standard under section 250 of the Health and Social Care Act 2012. This information standard was formerly approved by the Standards Board for Health and Social Care (ISB). SCCI published the updated SCCI0052 information standard in April 2017; it is a conversion from the original ISB 0052 information standard. In 2017, the responsibility for the approval of Information Standards transferred to the [Data Coordination Board \(DCB\)](#).

The information standard is a dictionary for use in the National Health Service (NHS) of medicines licensed in the United Kingdom. The scope of the standard in terms of content is for medicines only; medical devices/appliances are currently excluded in terms of complying with the Standard although users can use all the content within dm+d should it support their needs.

The primary purpose is to support interoperability. Therefore electronic systems that exchange or share information about medicines relating directly to a patient's care must conform to the standard by using dm+d identifiers and descriptions when transferring information.

This Notice does not extend this conformance date from the previous ISB 0052 information standard.

dm+d Content Committee

The Content Committee is accountable to the dm+d Programme Board and is responsible for:

- Defining and maintaining the editorial policy to ensure the safe and usable delivery of the clinical content.
- Ensuring the dm+d is maintained in accordance with its policy.
- Approving major content changes such as those necessary to support new use-cases.
- Changes in dm+d that impact on the suppliers' ability to implement dm+d systems.
- Changes that impact on the dm+d Team's capacity to deliver the products and services.
- Overseeing structural changes and extensions or adjuncts to dm+d.
- Overseeing the technical changes that may be required to meet authoring and user requirements.

The dm+d Content Committee is made up of representatives from Department of Health, NHS England, NHS Business Services Authority, NHS Digital, Medicines and Healthcare products Regulatory Agency and Clinical safety. However the committee will draw from a wide variety of stakeholders and interested parties to identify or clarify issues and solutions relating to the maintenance of dm+d. These may include but are not limited to:

- Clinical system suppliers
- Other NHS Digital work streams
- Clinical Safety Representatives
- Practicing Clinicians
- UK Terminology Centre Implementation Forum
- Users of dm+d

The dm+d Content Committee meets quarterly.

Approach to and the re-visiting of issues

- General dm+d enquiries should be raised in the first instance via the dm+d help desk:
- Email:
 - nhsbsa.dmdenquiries@nhs.net
 - nhsbsa.dmdsecondarycare@nhs.net
- An issue's form is available for raising a potentially serious safety concern or clinical issue. For more information see:
 - <http://www.nhsbsa.nhs.uk/1121.aspx>
- Papers for the Content Committee to consider will be submitted via the Content Committee Secretariat and will detail the proposal plus alternative options and an assessment of the impact on the use cases as well as the physical structure or editorial policy where appropriate.
- Decisions made by the Content Committee will only be revisited when there is additional relevant information to be considered that was not available to the Content Committee at the time of their decision. Examples could be Department of Health policy changes, new patient safety issues, changes in clinical practice etc.
- For a diagram of the processes for handling enquiries and issues see: https://www.nhsbsa.nhs.uk/sites/default/files/2017-02/dmd_issues_process_18.05.16.pdf

Appendix I

UKCPRS Programme

The NHS dictionary of medicines and devices (NHS dm+d) was developed and delivered through the UK Clinical Products Reference Source (UKCPRS) programme — a partnership between NHS Digital (formerly the Health and Social Care Information Centre) and the NHS Business Services Authority (NHSBSA).

Phase 1 covered the release of the Primary Care Drug Dictionary component.

Phase 2 extended the use of the dictionary into secondary care with the inclusion of the Secondary Care Drug Dictionary component.

Further development of the NHS dm+d, Phase 3, will cover the extension of the dictionary to include medical devices/appliances.

The UKCPRS programme's aim was to deliver a standard electronic vocabulary (terminology) and identifiers for clinical products (medicines, appliances and personal medical devices). This dictionary of medicines and devices will facilitate electronic transfer of data on clinical products between systems and provide a route by which knowledge to assist decision making can be accessed for the relevant product.

The successful implementation of the dm+d underpins a number of the key objectives outlined in the drive to deliver an 'information aware' National Health Service focused on the patient at its centre. These include:

- Providing an integral component of electronic health records
- Inter-sector clinical messaging
- Electronic transfer of Electronic Patient Records (EPRs) by GP's
- Electronic transfer of prescriptions (ETP) between GP, Community Pharmacy and NHSBSA
- Data aggregation for performance assessment, Clinical Governance and management from clinical systems
- National Care Record Service (NCRS)
- Interoperability between decision support systems

Background to primary care drug dictionary (NHS dm+d release 1.0)

Benefits

The benefits of a primary care drug dictionary will be attainable with rollout across all primary care prescribing and dispensing systems. These benefits are:

- Common drug data used in prescribing and dispensing processes facilitating:
 - Reduction in ambiguity for dispensers of prescribers' intent and resulting improvement in service to patients.
 - The avoidance of human and machine transcription errors and increased patient safety.
 - Automated feedback from dispensers to prescribers on the results of the prescribing process.
- Closer correlation of information on prescribing and dispensing systems providing support for:
 - Pharmacist managed repeat dispensing
 - Pharmacist managed repeat prescribing
 - Common use of detailed drug properties in the reimbursement process undertaken by the NHS Business Services Authority (NHSBSA) thus increasing the level of service to dispensing contractors
 - Increased automation of the prescription processing processes undertaken by the NHSBSA and a minimisation of human intervention in those processes
- The common identification of categorical drug information in primary care electronic patient records facilitating:
 - Reliable recreation of prescribing information on transfer of those records (e.g. GP-GP)
 - The use of sophisticated machine-level prescribing decision support mechanisms
 - Unambiguously shared views of prescribing information across different Primary Care Team systems facilitating shared care and common care pathways.

- A common identification of prescribing information between custodians of primary care EPRs and providers of feedback and other added-value services (e.g. NHSBSA) supporting:
 - Local clinical governance
 - Improved management of prescribing budgets in primary care
 - Improved NSF attainment
 - Professional accreditation mechanisms
 - The reliable sharing of prescribing information between prescribers, dispensers and patients thus allowing for patient access to prescribing information generally and ownership of their own records specifically.

Use cases

The drug dictionary supports the following activities:

- Prescribing — the issue of a machine-generated prescription.
- Dispensing — against a prescription
- Electronic data interchange of prescription and dispensing information with a minimum need for human or machine mapping
- The act of administration of a medicinal product
- Application of other aspects of drug knowledge including evidence-based prescribing via an ontology.
- Reimbursement against dispensed medicinal products

Appendix II

Fields and sources for identifiers and other attributes

Virtual Therapeutic Moiety

A Virtual Therapeutic Moiety (VTM) is the abstract representation of the substance(s), formulated as a medicinal product, intended by an authorising health care professional for use in the treatment of the patient

The virtual therapeutic moiety (VTM) is the abstract conceptual representation of the material defining the prescriber's therapeutic intent, divorced from formulation, dose or strength.

Examples of VTMs include:

Atenolol

Co-amoxiclav

Paracetamol

Metoclopramide

For combination names e.g. Paracetamol + Metoclopramide, before 2016, the dm+d word order for VTM and VMP combination names was authored in-line with the British National Formulary word order. Since 2016, the source manufacturer SmPC documentation has tended to be used to guide the dm+d editorial style in an attempt to join up the word sequence used in the company literature and packaging with the dm+d descriptions.

Virtual Therapeutic Moiety Identifier & Previous VTM identifier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the VTM.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. If at a future date a SNOMED CT International Release term is created, this core identifier will replace the SNOMED CT UK Drug extension code which will be kept under the previous product identifier.

Virtual Therapeutic Moiety Identifier Date

Field Population:

Date

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid

The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Management of invalidity flag

Where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will provide notification of any replacement concept (where possible), and explain one of the following reasons for the invalidation i.e.

- Duplicate – a concept representing the identical item has been found to already exist.
- Outdated – where policy changes mean that the concept no longer fits with the dm+d Editorial policy.
- Ambiguous – a concept is deemed to be poorly described by either coded data or its term. There may be one or more replacement concepts.
- Erroneous – a concept has been created to represent something that is subsequently found not to exist. It may not be possible to identify a replacement concept for these.
- Reason not stated – invalidation of a concept due to a different reason.

Note: this will apply to all the appropriate concepts that contain the Invalidity Flag.

Virtual Therapeutic Moiety Name, Virtual Therapeutic Moiety Abbreviated Name

Field Population:

- rINN — recommended international non-proprietary name
- INN — modified recommended international non-proprietary name
- pINN — proposed international non-proprietary name
- BAN — British approved name
- BANM — modified British approved name
- USAN — United States adopted name
- Other

Additional Information:

The recommended international nonproprietary name (rINN) or modified recommended international nonproprietary name (INN) will be used to name a VTM. Where there is no rINN available a proposed international nonproprietary name (pINN), British approved name (BAN) or modified British approved name (BANM) will be used, followed by other approved or clinically intuitive names.

A VTM may be linked to one or many VMPs. A VMP may only link to one VTM but a VMP is not required to link to a VTM. For example the following groups of VMP concepts would not normally be linked to a VTM.

- Invalid concepts (although VMP concepts that are subsequently invalidated would not have the linkage removed)
- Drug Tariff appliance/medical device concepts
- Medical gases

- VMPs that have a VMP name of the format 'generic xxxx'
- VMPs that have more than 3 active ingredients
- VMPs that are non-specific in format used for unlicensed medicines (see type D VMPs in Appendix XIII of the dm+d Editorial Policy)

Exceptions to the above are where a well-defined use case for VTM has been identified for these products e.g. use in datasets to support disease state management. For example the antiretrovirals dataset contains a VTM (Abacavir + Lamivudine + Zidovudine) for the VMP Generic Trizivir tablets.

The VTM abbreviated name is a 60 character name field.

The likelihood of a VTM name needing to be abbreviated is very rare.

Note: following safety concerns regarding concatenation of dm+d VTM and VMP concept terms into a prescribable entity, in order to avoid the risk of Peppermint Oil being dispensed when Peppermint Water is intended or vice versa, Peppermint Oil containing VTM names have been updated with the word oil removed i.e.

Former VTM name	New VTM name
Menthol + Peppermint oil	Menthol + Peppermint
Morphine + Peppermint oil	Morphine + Peppermint
Peppermint oil	Peppermint

Virtual Medicinal Product

A Virtual Medicinal Product (VMP) is an abstract concept representing the properties of one or more clinically equivalent Actual Medicinal Products, where clinical is defined as relating to the course of a disease.

A virtual medicinal product (VMP) is an abstract concept representing a template of the properties which constitute one or more actual medicinal products.

The VMP describes a generic product without supplier or trade name information. The only **exception** being food supplement products available in a range of flavours where no flavour is specified e.g. Ensure liquid – these are virtual concepts with brand information.

Drug VMPs will usually follow the format of name + strength + form. Modification(s), unit dose and 'freeness' information will be provided where applicable. Further information on how VMPs are named is provided under VMP name. Examples of drug VMPs include:

Paracetamol 500mg tablets

Paracetamol 250mg/5ml oral suspension sugar free

Heparin sodium 25,000units/5ml solution for injection vials

Aqueous cream

Generic Ensure powder

Sometimes there is a difference in how the strength is described in a VMP description compared with its linking AMP description(s). For more information, see Appendix XX VMP and AMP Strength Description Differences.

Appliance/medical device VMPs will be assigned VMP names consistent with Drug Tariff headings where possible. Incontinence and stoma type appliances will not usually have size at VMP level, other appliances like bandages, dressings and catheters will have size at VMP level. Examples of appliance VMPs include:

Colostomy bags

Colostomy sets

Cotton crepe bandage 10cm x 4.5m

Alginate dressing sterile 10cm x 15cm

Nelaton catheter female 14Ch

For an explanation of how medical devices/appliances that may be prescribed in secondary care that are not listed in the Drug Tariff are considered in dm+d, see Appendix XXII Medical Devices that may be prescribed in Secondary Care.

For combination names e.g. Paracetamol + Metoclopramide, before 2016, the dm+d word order for VTM and VMP combination names was authored in-line with the British National Formulary word order. Since 2016, the source manufacturer SmPC documentation has tended to be used to guide the dm+d editorial style in an attempt to join up the word sequence used in the company literature and packaging with the dm+d descriptions.

Unless the virtual product prescribing status is set to the contrary VMPs are prescribable. A new VMP will be created for each different strength of a licensed medicinal product.

If an existing product has a change of ingredient such that it does not conform to the ingredients of the original VMP then a new VMP will be created for the new product.

Unlicensed products that are prescribed within primary care, for example herbal and health supplements and dietary and toiletry products, are populated depending upon which category or types they fall into — see Appendix XIII, unlicensed products.

Virtual Medicinal Product Identifier & Previous Product Identifier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the VMP.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. If at a future date a SNOMED CT International Release term is created, this core identifier will replace the SNOMED CT UK Drug extension code which will be kept under the previous product identifier.

Virtual Medicinal Product Identifier Date

Field Population:

Date

Combination Product Indicator

Used to provide information about combination products and the packs that are contained within them.

A combination product contains two or more components each of which is a virtual medicinal product in its own right although it may not be available or prescribable.

Field Population:

- Combination product
- Component only product

Additional Information:

Combination product identifies a VMP that is a combination product e.g. Clotrimazole 500mg pessary and Clotrimazole 2% cream (Canesten Combi), Conjugated oestrogens 625microgram tablets and Norgestrel 150microgram tablets (Prempak-C).

Component only product identifies a combination product component that is not available separately, i.e. it identifies those entities which cannot be prescribed in their own right e.g. Norgestrel 150microgram tablets or Norethisterone 250micrograms/24hours / Estradiol 50micrograms/24hours patches (Estragest TTS patches) are only encountered as a part of a combination pack and are therefore not prescribable in their own right.

For appliances/medical devices that are combination products, these should be populated in a similar way to a combination medicinal product pack.

Virtual Medicinal Product Name, Virtual Medicinal Product Abbreviated Name, Basis of Preferred Name, Previous Name, Basis of Previous Name

Field Population:

- rINN — recommended international non-proprietary name
- INN — modified recommended international non-proprietary name
- pINN — proposed international non-proprietary name
- BAN — British approved name
- BANM — modified British approved name
- USAN — United States adopted name
- Other

Exceptions to this rule include certain inhaled medicines where a Summary of Product Characteristics (SmPC) reports the strength in terms of the active moiety (e.g. tiotropium, compared with tiotropium bromide which is the rINN). In these instances dm+d will follow the SmPC in order to be consistent with the product labelling and literature.

Products for which no generic title available will be named as follows:

- Two active substances:
 - Populate with generic name of active substances in-line with the British National Formulary (BNF) word order for the active substances which should, where practicable, follow the SmPC.
 - In the event of more than one AMP being attached to a VMP and the AMPs having different word orders in their SmPCs, dm+d will follow the word order of the first product to market.
- More than two active substances — populate with title 'generic xxxx'.

Exceptions to the more than two active substances rule include:

Parenteral products that are vaccines or large volume parenteral fluids, containing three or more active ingredients, and for which no current approved generic name is in existence, a true VMP name will be supplied.

Scenarios where the clinical advantage of referring to three or more active ingredients outweighs the disadvantages e.g.

- VMP Timolol 10mg / Amiloride 2.5mg / Hydrochlorothiazide 25mg tablets, reflecting the SmPC product description
- VMP Generic Dermovate-NN cream was changed to VMP Clobetasol 500 microgram / Neomycin 5mg / Nystatin 100,000units/g cream where no brand named product version is available.

Note: VMPs for food supplements that are not derived from the Drug Tariff and include the brand in the VMP name have been reverted to 'Generic XXXX' in line with the dm+d Technology Reference

Data Update Distribution Service (TRUD) communications to stakeholders in May 2012 and July 2012.

Abbreviated name (short name or label name) - 60 character maximum name — previously applicable to medicines only but in 2008, the scope was widened (see Appendix XI).

Additional Information:

A VMP will always be issued with a name, even if the product is non-prescribable. A new VMP may be allocated a temporary name that is replaced at a later date.

A VMP will utilise an approved generic name where one is available. This will be the rINN or INN, with the **exception** of adrenaline and noradrenaline only. If there is no rINN the BAN will be used. If there is no BAN then another approved name will be used providing it is 'clinically intuitive' (The name basis field will specify which of the above has been used for population — 'British Approved Names 2002', a list of drug names for regulatory use in the UK, incorporates rINNs. This will be used as the prime source for allocation of name basis).

If a VMP is available in one form as two or more salts and the rINN is insufficiently precise the INN will be used. Except where a BP monograph or the MHRA has determined that the preparations are clinically equivalent e.g. amlodipine tablets etc.

Examples:

rINN	INN	Populate with
Acebutolol capsule	Acebutolol hydrochloride	rINN
Thyroxine tablet	Thyroxine sodium tablet	rINN
Promethazine tablet	Promethazine hydrochloride tablet	INN
	Promethazine teoclate tablet	INN

For drugs with narrow therapeutic indices (phenytoin, theophylline etc.) the VMP name will reflect the strength i.e. Phenytoin sodium 50mg capsules – (Epanutin) contain 50mg Phenytoin sodium. Phenytoin 50mg tablets – (Epanutin infatabs) contain 50mg Phenytoin.

In circumstances where a rINN or a BAN is not available another approved name will be used. It is important that the name is 'clinically intuitive'. For example Slow Lithium Carbonate tablet (BP Monograph) or Lithium Carbonate (USAN) is clinically known as Lithium Carbonate Modified release tablet and in this example the clinically intuitive name will be used.

With reference to the release time (e.g. 12-hour for a twice a day modified release dose, and 24-hour for a once a day modified release dose) of a product will not be included in the VMP name unless there is an established European or British standard for duration of action for the modified release products.

The naming convention followed will be NAME, STRENGTH then FORM.

Fucidin H cream is Hydrocortisone acetate 1% / Fusidic acid 2% cream

Canesten HC cream is Hydrocortisone 1% / Clotrimazole 1% cream

Gaviscon tablets contain more than two active substances and will be populated as 'Generic Gaviscon', Ensure as 'Generic Ensure' etc. Where there is more than one proprietary product that

would fit the 'generic proprietary' description the proprietary that is first to the market place will be used in the title.

The Content Committee (formerly Editorial Group) will pursue the allocation of an official approved name for such products via the British Pharmaceutical Commission.

The VMP name for appliances/medical devices will be based upon Drug Tariff (England & Wales) headings where possible. For some appliances the dimension details will be included in the virtual product name, for example, width of bandages, dressings. Incontinence and Stoma appliances use a variety of 'sizings' e.g. SI units (mm), descriptions (small) or a mixture of both. A small incontinence sheath may have a diameter ranging from 22mm to 28.5mm – size will therefore not be included in the title.

Note: for information about the use of concentrate / concentrated terms, see Appendix V

VMP abbreviated name (also known as short or label name) — The VMP name will be abbreviated to 60 characters or less as detailed in Appendix XI (LIST I). Where the VMP name is already 60 characters or less or is invalid as a prescribable product, never valid to prescribe as a VMP or not recommended to prescribe as a VMP there is no requirement to provide an abbreviated name.

For further information and examples see Semantic Normal Form Patterns used in NHS dm+d at the end of Appendix II.

Reference to the inhaled delivered dose in a VMP description

Following an update to British Pharmacopoeia (BP) policy, inhalers are now being listed with their delivered dose in line with the European Pharmacopoeia. Manufacturers' SmPCs for inhaled medicines submitted to the Medicines and Healthcare Products Regulatory Agency (MHRA) now include the actual dose and the delivered dose.

For new inhaled medicines (where there are no brands already on the market) that are added to dm+d, the VMP name will be described using the delivered dose(s) and the AMP name will reflect the naming in the SmPC (which ideally should reflect the product packaging too).

In line with editorial policy, where appropriate the dm+d will use the recommended international non-proprietary name (rINN) in the VMP name. However, where SmPCs report the delivered dose strength of the active moiety, to keep dm+d more consistent with the product literature/packaging, the delivered dose of the active moiety will be used. VMP names will also include '(delivered dose)' in the name of the new VMPs where appropriate.

Reference to the British Pharmacopoeia ('BP') in a VMP description

The suffix BP is referred to in the VMP name where it may influence (assist) the prescribing decision when selecting a product to use.

The principles that will be applied to determine whether or not 'BP' should be used in the VMP name are outlined in a decision tree in Appendix XXI. Reference to 'BP' will not usually be appropriate for inclusion in a VMP name where a linking AMP is a licensed medicinal product. For licensed products, the Summary of Product Characteristics (SmPC) is available for reference; the decision making process will therefore only usually be of consideration for an unlicensed products.

In communications with the British Pharmacopoeia Commission that publishes the BP, we have been made aware that the publication is moving away from providing a specific formula in a Formulated Specifications: Specific Monograph therefore Specific Monographs are increasingly applicable to more products. Where a BP monograph contains a formula, this is provided to assist extemporaneous preparation. This does not mean that only products made to the formula comply with the monograph. Formulations can be changed for bulk manufacture and a product will still conform to the monograph so long as the change in formulation does not change the fundamental characteristics of the product.

In the VMP name dm+d does not routinely include information to identify the diluent used. Exceptions are the Special Order products within scope of the support the Systemic Anti-Cancer Therapies (SACT) dataset. See Appendix XXIII for further details.

Date of Name Applicability

Date from which the name became the preferred name for the medicinal product

Field Population:

Date

Reason for Name Change

If a new approved name has to be allocated to an existing VMP the dictionary maintainer will ensure the history and reason for the change is maintained.

Field Population

List A contains the reason options.

Sugar Free Indicator, Gluten Free Indicator, Preservative Free Indicator and CFC Free Indicator

Field Population

Confirms absence. The setting of this flag only confirms that the substance is absent from the VMP; a null value does not necessarily indicate that it is present.

Additional Information:

This provides a means of identifying that an ingredient substance is absent (as in sugar free or CFC free). This flag will be used routinely in four circumstances only to denote

- absence of sugar in sugar free products (further defined below)
- absence of CFC in CFC free products (applies to pressurised inhalers)
- absence of gluten in gluten free products
- absence of preservative in preservative free eye preparations.

In addition sugar free, CFC free, gluten free and preservative free will be included in the VMP name where appropriate.

The definition of absence of sugar has been defined in the BNF — oral liquid preparations that do not contain fructose, glucose or sucrose are described as sugar free. Preparations containing hydrogenated glucose syrup, mannitol, maltitol, sorbitol or xylitol are also marked sugar free since there is evidence that they do not cause dental caries. As the marking of oral liquid preparations is designed to identify those products that do not contain cariogenic sugars those products that have a prolonged contact in the mouth will be annotated sugar free where appropriate. (Note: where there is a clinically insignificant presence of sugar such as a low level of sucrose in an excipient, then this may also be described as sugar-free e.g. in the BNF, Fybogel Granules are referred to as sugar free).

Virtual Medicinal Product Prescribing Status

Further to the consultation 'Proposal to change values for VMP prescribing status' which closed in November 2016, the revised text below has been endorsed by the Content Committee. The following VMP Prescribing Status values have been retired:

- VMP not recommended to prescribe - brands not bioequivalent,
- VMP not recommended to prescribe - patient training required,
- VMP not recommended to prescribe -no published specification

These 3 values have been combined and replaced by the following single new value:

- Caution – AMP level prescribing advised

It is anticipated that these changes will feature in dm+d over the next quarter by March end 2019:

Field Population:

- valid as a prescribable product,
- invalid to prescribe in NHS primary care,
- never valid to prescribe as a VMP
- caution – AMP level prescribing advised

Additional Information:

Valid as a prescribable product — all products that do not fall into the following three numbered categories will be valid as a prescribable product:

1. Invalid to prescribe in NHS primary care:
 - VMPs included in Schedule 1 of the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 and VMPs where all of the AMPPs are Schedule 1 will be annotated as invalid unless the VMP is a recognised official title.
 - Components of a multipack that are not individually marketed will also be annotated as invalid to prescribe,
 - e.g. Terazosin 1mg x 7 tablets is a component of the combination 'Hytrin tablets starter pack' but Terazosin 1mg tablets are not available on their own and so are invalid to be prescribed.
 - Appliances where all of the AMPPs are no longer reimbursable (i.e. not included in the Drug Tariff (for England and Wales) then the VMP will be set to invalid.

Note: Even though some products (e.g. Yellow Fever Vaccine) should not be prescribed on an FP10 prescription form, they can be prescribed and administered in primary care and are valid as a prescribable product.

2. Never valid to prescribe as a VMP:

- Products for which the VMP is not prescribable by a generic name i.e. there is no approved non-proprietary name (e.g. Generic XXXX) will be annotated never valid to prescribe as a VMP.
- Investigational Medicinal Products (IMPs) will have a prescribing status of never valid to prescribe as a VMP.
- Historically Drug Tariff approved medical devices with no official DT specification (or not specified by a BP or EP monograph) will be never valid to prescribe as a VMP (see also VMP not recommended to prescribe –no published specification).

3. The value 'Caution – AMP level prescribing advised' will be applied to licensed medicinal products and to medical devices in the following circumstances:

- A. the VMP represents AMPs that are licensed medicinal products where there may be issues with interchangeability between innovator and generic products, or where continuity of supply is desirable for clinical reasons
- B. the VMP is a medical device (including appliances) where the VMP name is an approved non-proprietary name but it cannot be assumed that devices prescribed using the VMP name will be equivalent

Explanatory notes

A. Licensed medicinal products

Under European medicines legislation, a medicinal product can be granted a Marketing Authorisation on the basis of demonstrating equivalence to an existing 'reference medicinal product', these are so called generic medicinal products. A "generic medicinal product" is defined as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product (innovator), and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. This entails establishing through studies on human volunteers, that comparable blood levels of the generic and innovator product are achieved thus demonstrating comparable efficacy and safety (Article 10(1) of Directive 2001/83/EC). Where the "generic medicinal product" is fully interchangeable with the innovator reference product for all indications and patient populations, it can be licensed with a generic name and prescribed under a generic name.

European law also allows for cases where bioequivalence of the medicinal product cannot be demonstrated through comparable blood levels. Therefore additional results of appropriate pre-clinical tests or clinical trials are required. In such cases, MHRA requires that therapeutic equivalence to the innovator product is demonstrated in the intended patient population and for the indications claimed. Licences for these types of products are granted under a specific legal basis (Article 10(3) of Directive 2001/83/EC); they are not considered to be true generics and, in the UK, may be required to have a brand name, unless they are considered to be interchangeable for all indications and patient populations.

An example of the above is inhaled products on the UK market that are not considered wholly interchangeable with the innovator for all the indications and patient populations and which have been licensed with differences in potency, indications, restricted populations, available strengths, or with an administration device which requires different techniques of administration and training. These differences may require the products to have a brand name.

However, the European Medicines legislation also allows for the licensing of a product referring to an innovator product without including all of the indications or patient populations that have been approved for the innovator product, provided that there are no associated safety concerns.

For the reasons above for some VMPs, prescribers and pharmacists/dispensers need to be able to identify which AMP is appropriate for a particular patient for continuity of treatment and these VMPs will be assigned the status 'Caution – AMP level prescribing advised'. This may be established through review of the Summary of Product Characteristics (SmPC) and/or the BNF. Where the release characteristics and therapeutic index mean that the clinical effect may differ between brands and so the relevant authorities (Commission on Human Medicines, British National Formulary, National Institute for Health and Care Excellence) recommend brand name prescribing, the VMP prescribing status 'Caution – AMP level prescribing advised' will also be assigned.

However where only one licensed AMP is/has been available and the VMP has an 'approved' generic name, then that product should not be marked with 'Caution – AMP level prescribing advised'.

A biosimilar medicine (Article 10(4) of Directive 2001/83/EC) is a biological product that has been demonstrated as similar in terms of Quality, Safety and Efficacy to a medicine that has already been authorised to be marketed (the biological reference medicine) in the EU product. The BNF advises that when prescribing 'biosimilar medicines', it is good practice to use the brand name, and therefore the value 'Caution – AMP level prescribing advised' will be assigned.

B. Medical Devices

This value is used for medical devices that are appliances listed in Part IX of the Drug Tariff where the VMP name is an approved non-proprietary name but there is no official Drug Tariff specification. Medical devices do not have to demonstrate that they meet Drug Tariff specifications unless they are prescribed on an FP10 prescription when Drug Tariff Part 1 Clause 2 requires products listed in Part IX to conform to the specifications shown in Part IX.

Non-Availability Indicator and Non-Availability Status date

Field Population:

- 0 = actual products available (though not necessarily prescribable in primary care)
- 1 = actual products not available

Additional Information:

A flag indicating that there are currently no actual medicinal products which correspond to this VMP

This attribute is optional. When absent the VMP shall be considered to have corresponding actual product(s) (although these may not be generally prescribable in Primary care).

When present with a value of 1 (actual products not available) this shall indicate that the VMP has previously been available as one or more actual products but has now ceased to be. The non-availability status date may be used to indicate when this status change occurred.

When present with a value of 0 (actual products available) this shall indicate that the VMP has previously 'not been available as an actual product' but which now has at least one associated product. The non-availability status date may be used to indicate when this status change occurred.

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid

The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept.

Dose Form Indicator, Unit Dose Form Size, Unit Dose Form Units and Unit Dose Unit of Measure

Field Population:

Dose form indicator has 3 values:

- discrete
- continuous
- not applicable

Unit dose form size is represented by a numerical value

Unit dose form units is the unit of measure relating to the size (units of measure as in List E)

Unit of measure is a description of the 'thing' that can be handled (units of measure – List E)

Where the dose form indicator has the value 'continuous' or 'not applicable' there is no requirement to populate information in unit dose form size, unit dose form unit or unit of measure.

Additional Information:

The unit dose is an elemental and numeric machine-readable representation or description of what the single unit dose or 'each' is for a VMP. There are some groups of products for which a unit dose cannot be substantiated e.g. continuous solids, semi-solids and liquids, because a consistent, physically measurable unit or sub-unit cannot be defined.

The dose form indicator will identify if a product has a unit dose form (discrete), if the product is regarded as a continuous substance (continuous) or if the product belongs to a category where the identification of dose form is not appropriate e.g. urinary catheters, colostomy bags, etc. (not applicable).

All oral liquids described in their Summary of Product Characteristics as having a strength expressed in whole multiples of 5ml will be described as 'discrete' with a unit dose form size and

unit dose form units of 5ml. All oral liquids described in their Summary of Product Characteristics as having a strength expressed other than in whole multiples of 5ml will be described as continuous. Where a VMP has more than one AMP associated with it and where the respective Summary of Product Characteristics differ in their expression of strength, some in multiples of 5ml and others not, then the VMP will be described as continuous.

Examples:

VMP	DFI	UDFS	UDFU	UOM
Atenolol 50mg tablets	Discrete	1	tablet	tablet
Furosemide 80mg/2ml solution for injection ampoules	Discrete	2	ml	ampoule
Diamorphine 30mg powder for solution for injection ampoules	Discrete	1	ampoule	ampoule
Hydrocortisone 1% cream	Continuous			
Mesalazine 1g/actuation foam enema	Discrete	1	actuation	actuation
Metronidazole 200mg/5ml oral suspension	Discrete	5	ml	spoonful
Digoxin 50microgram/ml oral liquid	Continuous			
Amoxicillin 500mg powder for solution for injection vial	Discrete	1	vial	vial
Tobramycin 80mg/2ml solution for injection vials	Discrete	2	ml	vial
Chloramphenicol 0.5% eye drops	Continuous			
Salbutamol 100microgram/dose inhaler	Discrete	1	dose	dose
Gluten Free Bread	Not applicable			
Crepe bandage 10cm x 4.5m	Not applicable			

Form and Route Information

Information relating the VMP to its form and route(s) of administration, both as a combined concept and also as a separate concept. For a combination pack, VMP route, form and unit dose should all be marked as not applicable and no entry should be made for ingredients. The route not applicable will be used for combination products.

In the autumn of 2008 a change was made to add route information to ACBS (and non-ACBS) liquid and powder food products on dm+d in order to assist with secondary care prescribing of these products. Where this information cannot be confidently obtained, then this attribute will be set to not applicable.

In September 2009, the Editorial Group approved a proposal that dose forms for products that move from medicine to medical device status (and new medical devices that share similar features to some conventional licensed medicines) should be populated in dm+d with the dose form.

Examples of medical devices populated with the dose form:

Carmellose 0.5% eye drops
 Dextranomer paste 10g sachets
 Emulsifying wax 30% / Yellow soft paraffin 30% ointment

Generic Balneum cream
Glucose 25% in glycerol nasal drops
Hydrocolloid paste
Hylan B 4.125mg/0.75ml solution for injection pre-filled syringes
Sodium chloride 0.9% irrigation solution 200ml cans
Sodium hyaluronate 0.18% eye drops preservative free
Synovial fluid 20mg/2ml injection vials
Water for irrigation 2litre bottles

Ontology Form & Route Information

Virtual Medicinal Product Form and Route

Field Population:

Combined route and form list provided by decision support domain

Additional Information:

The VMP form and route (ontology form/route) is required by decision support domain and will represent the form/route at administration. A specific list for field population is provided. The dictionary maintainers will populate according to the list. (LIST B)

Form Information

Virtual Medicinal Product Form

The Dose Form of a concept in the NHS dm+d is the representation of the orderable physical form of the AMP from which the concept derives.

Field Population:

European Directorate for the Quality of Medicines & HealthCare (EDQM) List of Standard Terms as amended.

Additional Information:

This is a list of pharmaceutical dosage form terms drawn up in response to a request from the European Commission and utilised in the licensing of medicines.

Combination products may have a mixture of forms. For example tablets and capsules or cream and pessaries. The form 'not applicable' will be used for combination products.

Route Information

Virtual Medicinal Product Route

The Route of Administration of a concept in the NHS dm+d is the representation of the place in or on the body where the product is introduced in order to achieve the desired therapeutic effect.

Field Population:

European Directorate for the Quality of Medicines & HealthCare (EDQM) List of Standard Terms as amended.

Additional Information:

This is a list of pharmaceutical route of administration terms drawn up in response to a request from the European Commission and utilised in the licensing of medicines (LIST D)

For licensed medicinal products licensed routes only will be included in the dictionary, this will be a super set of the linked AMP licensed routes. Unlicensed products will be allocated a route based upon the manufacturer's literature when applicable or will have the route 'route of administration not applicable'.

Virtual Medicinal Product Ingredient

The Ingredient Substance of a concept in the NHS dm+d is the representation of any component that is intended to furnish a direct effect, pharmacological or other, in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of the patient.

At the VMP level only ingredient substances deemed to be 'significant' to the prescribing act are detailed. In general this will always include 'active' ingredients.

Ingredient Substance Identifier

Field Population:

SNOMED CT code

Additional Information:

A unique identifier for the ingredient substance.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier.

Specific NHS terms will be used only where SNOMED terms do not exist.

Ingredient Substance

Field Population:

- rINN
- INN
- INN
- pINN
- BAN
- BANM
- USAN
- Other

Additional Information:

All active ingredients declared in SmPC, BNF and BP as appropriate will be included in the dictionary wherever possible however the strengths or quantities of the ingredients will be included

if of clinical or reimbursement significance only. Homeopathic preparations will not have ingredients expressed.

As far as is practicable records without full details of ingredients will be kept to a minimum. As with the VMP name the ingredient substance will utilise the rINN where possible.

When two or more actual medicinal products are clinically equivalent but the ingredient substance stated on the SmPC differs then the BoSS will be used as the ingredient substance. Examples: Lisinopril 5mg tablets are available as 2 brands Carace and Zestril. Both contain 5mg of lisinopril and are regarded as clinically equivalent. The ingredient substance stated for Carace is lisinopril whilst that for Zestril is lisinopril dihydrate. In this situation the ingredient substance will be lisinopril. Amlodipine tablets may be manufactured using different salt forms that are clinically and therapeutically equivalent. Again the BoSS of Amlodipine will be used as the ingredient substance.

Basis of Strength Substance Identifier

Field Population:
SNOMED CT code

Additional Information:

A unique identifier for the ingredient substance (a Basis of Strength Substance or BoSS is an ingredient substance).

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist.

Basis of Pharmaceutical Strength

Field Population:

The following options are available:

- ingredient substance
- 'base' substance

Additional Information:

The strength of the active ingredient(s) of a product can be expressed as a complete substance (e.g. amitriptyline hydrochloride) or by part of the complete substance, the 'base' (e.g. acebutolol). The basis of the strength included in the dictionary will be determined by the description within the British Pharmacopoeia (BP), the British National Formulary (BNF) or in the Summary of Product Characteristics (SmPC). For example:

'Acebutolol 100mg capsules' contain acebutolol hydrochloride – the strength of 100mg refers to acebutolol. (Basis of Pharmaceutical strength = 'base')

'Amitriptyline 10mg tablets' contain amitriptyline hydrochloride – the strength of 10mg refers to amitriptyline hydrochloride, (Basis of Pharmaceutical strength = ingredient substance)

For drugs with narrow therapeutic indices (phenytoin, theophylline etc.) the VMP title will reflect the strength i.e. Phenytoin sodium 50mg capsules — (Epanutin) contain 50mg Phenytoin sodium. Phenytoin 50mg tablets — (Epanutin infatabs) contain 50mg Phenytoin

This attribute is mandatory when a value is present in the attribute 'pharmaceutical strength'

Basis of Strength Substance (BoSS)

Field Population:

'Base' substance or part of the complete substance upon which the strength is based.

Additional Information:

When the pharmaceutical strength is not based upon the ingredient but upon the 'base' (or basis of strength substance – BoSS) then the 'base' will be identified. The 'base' may be any part of the complete substance including an element.

Examples:

VMP	Ingredient	BoSS
Dexamethasone Oral Soln	Dexamethasone Sodium Phosphate	Dexamethasone
Dexamethasone Injection Phosphate	Dexamethasone Sodium Phosphate	Dexamethasone

Where there is a patient safety issue, that the VMP could be misinterpreted then the VMP and AMP names may be described with further clarity. For example, in noradrenaline solution for infusion ampoules, the ingredient is noradrenaline acid tartrate but the VMP name is expressed using only the base noradrenaline. However, this can lead to confusion as it is not immediately apparent what the strength refers to i.e. salt or base. Therefore to minimise any confusion, the VMP and AMP in this instance is authored in the following style in dm+d:

- Noradrenaline (base) 20mg/20ml solution for infusion ampoules
- Noradrenaline (base) 20mg/20ml solution for infusion ampoules (Hospira UK Ltd)

Similarly safety concerns have been raised regarding parenteral dexamethasone, that some prescribing guideline resources present dosing guidance expressed as the dexamethasone phosphate (salt) and others (including the manufacturer's packaging) as the 'base'. Authoring of parenteral dexamethasone VMPs and linking AMPs has now been updated to include reference to base in brackets e.g.

- Dexamethasone (base) 3.8mg/1ml solution for injection vials
- Dexamethasone (base) 3.8mg/1ml solution for injection vials

Pharmaceutical Strength

The amount of ingredient substance.

This attribute indicates the quantity of the substance per defined unit of measure in the VMP (e.g. one tablet, one ml) measured by weight or volume per unit or concentration. An ingredient may be present without a strength.

For homeopathic products ingredient details (except for ingredient name) will not be populated but the expression of potency within the name will be based upon the common, accepted expressions of dilution issued in the homeopathic community. See Appendix XII.

Strength Value Numerator, Strength Value Numerator Unit, Strength Value Denominator, Strength Value Denominator Unit

Field Population:

Strength value numerator and strength value denominator are numerical values. Strength value denominator (SVD) is used to express 'per' strengths. Ingredient strengths are usually expressed per 1 'unit of measure' (per 1 gram, per 1ml), however the expression of strength for patches will reflect the VMP e.g. Estradiol 100micrograms/24hours patches – SVD is 24.

Strength value numerator unit and strength value denominator unit are units of measure as listed in Appendix VII List E.

Additional Information:

Pharmaceutical strength has 4 components, where a strength is provided the strength value numerator (SVN) and strength value numerator unit (SVNU) are mandatory. Strength value denominator (SVD) and strength value denominator unit (SVDU) are used to fully express 'per' strengths.

Examples:

Paracetamol 500mg tablets

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Paracetamol	500	mg		

Paracetamol 250mg/5ml oral suspension

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Paracetamol	50	mg	1	ml

Hydrocortisone 1% cream

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Hydrocortisone	10	mg	1	g

Hyoscine 1mg/72hours patches

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Hyoscine	1	mg	72	hours

Furosemide 20mg/2ml solution for injection ampoules

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Furosemide	10	mg	1	ml

Controlled Drug Prescribing Information

Information relating to VMP where these are drugs and in particular where the drug is controlled under the Misuse of Drugs Act.

Controlled Drug Category, Controlled Drug Category Change Date, Controlled Drug Category Prior to Change Date

Field Population:

The following options will be available:

- No CD status
- Schedule 1 (CD Lic)
- Schedule 2 (CD)
- Schedule 2 (CD exempt safe custody)
- Schedule 3 (CD no reg)
- Schedule 3 (CD no reg, exempt safe custody) — From 1st April 2019 gabapentin and pregabalin are Schedule 3 controlled drugs under the Misuse of Drug Regulations 2001, and Class C of the Misuse of Drugs Act 1971.
- Schedule 3 (CD no reg, exempt safe custody)
- Schedule 3 (CD no reg Phenobarbital)
- Schedule 3 (CD no reg Temazepam)—The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 amended the prescription writing requirements for Temazepam to Schedule 3 (CD no register) from the 1 June 2015
- Schedule 4 (CD Anab)
- Schedule 4 (CD Benz)
- Schedule 5 (CD Inv)

Note: updates will be made to dm+d in tandem with timescales defined in The Misuse of Drugs (Amendment) (No. 2) England, Wales and Scotland) Regulations 2015 laid before Parliament in March 2015 and the Editorial Policy will be updated in due course.

Additional Information:

- 0 = No CD status
- 1 = Schedule 1 (CD Lic) – drugs with virtually no therapeutic use e.g. LSD
- 2 = Schedule 2 (CD) – Schedule 2 controlled drugs where full requirements apply e.g. morphine and cocaine. 30 November 2015 ketamine moved from Schedule 4 (CD Benz) to Schedule 2 (CD) status
- 3 = Schedule 2 (CD exempt safe custody) – as 2 but exempt from safe custody requirements e.g. secobarbital

- 4 = Schedule 3 (CD no reg) – Schedule 3 CD requirements apply but supply not required to be recorded in register
- 5 = Schedule 3 (CD no reg, exempt safe custody) – as 4 but exempt from safe custody requirements.
- 6 = Schedule 3 (CD no reg Phenobarbital) – as 5 but exempted from handwriting requirements and emergency supply allowed for epilepsy
- 7 = Schedule 3 (CD no reg Temazepam) – as 4 but exempted from handwriting and prescription requirements — 1 June 2015 Temazepam changed to Schedule 3 (CD no register)
- 8 = Schedule 4 (CD Anab) – Schedule 4 drugs liable to misuse including most anabolic steroids and some growth hormones
- 9 = Schedule 4 (CD Benz) – Schedule 4, contains most benzodiazepines and zolpidem
- 10 = Schedule 5 (CD Inv) – Contains preparations of certain controlled drugs e.g. codeine which are exempt from full control when present in medicinal products of low strength

The controlled drug category will be allocated according to the Misuse of Drugs Act 1971 and the restrictions of the Misuse of Drugs Regulations.

The data will be collated from the SmPC, Medicines, Ethics and Practice, and Medicines and Healthcare products Regulatory Agency (MHRA) as appropriate.

The date at which the category of the controlled drug changed will be included. The dictionary will be populated from a specified date and updated from that date. The full past history prior to population will not be included.

Actual Medicinal Product

An Actual Medicinal Product (AMP) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form), attributable to an identified supplier that contains a specified amount of an ingredient substance.

Examples of single dose units of a finished dose form include tablets, capsules, suppositories, pessaries, sachets — this category covers discrete entities that have a consistent physically measurable dose.

Examples of continuous dose forms include creams, ointments, gels, pastes, foams, liquids — this category covers those products where a consistent physically measurable dose cannot be defined.

An Actual Medicinal Product is a medicinal product that has been made available by a manufacturer / supplier.

AMPs that are drugs will follow the format of AMP name + Supplier.

For generic drugs the AMP name will usually be exactly the same as the VMP name, the **exception** to this is where the AMP name uses the form of 'caplet' to represent a capsule shaped tablet in this case dm+d will use caplet at AMP level e.g. VMP = Paracetamol 500mg tablets, AMP = Paracetamol 500mg caplets or where the AMP has been licensed with an alternative official generic title e.g. VMP = Hamamelis Water but AMP licensed name = Distilled Witch Hazel.

For proprietary drugs this will be the 'trade name' of the product (expanded when necessary – see below under AMP name) + Supplier.

Examples: Tenormin 100mg tablets (AstraZeneca)
Atenolol 100mg tablets (Almus Pharmaceuticals Ltd)
Aqueous cream (Approved Prescription Services)

AMPs that are appliances/medical devices will follow the format of AMP name + order number + size + colour + Supplier.

Examples: Elastocrepe bandage 10cm x 4.5m (BSN medical Ltd)
Ileodress ileostomy bag small S852 25mm opaque

The Actual Medicinal Product shall provide sufficient information to uniquely identify the product but not the size of pack that the supplier makes available for dispensing. There are occasions when the supplier does not reflect the liveried pack – these AMPs are required to support the reimbursement use case and the supplier is the company 'supplying' the AMP. In situations where the licensed medicinal product is manufactured by one company and supplied by another and there are two manufacturer/supplier names on the pack then the dictionary will be populated with the manufacturer name that is most prominent on the AMP packaging i.e. the 'supplier', e.g.. Salbutamol Inhaler CFC free (Cox Pharmaceuticals) – manufacturer of 3M Health Care Ltd also on pack, Calprofen 100mg/5ml oral suspension (Pfizer Consumer Healthcare) – manufacturer/PL holder on pack is Pinewood Laboratories Ltd.

In the AMP name description dm+d does not routinely include information to identify the diluent used unless it is judged to be part of the product name in the SmPC. Exceptions are the Special Order products within scope of the support the Systemic Anti-Cancer Therapies (SACT) dataset. See Appendix XXIII for further details.

Each AMP is associated with an identifiable manufacturer or supplier.

Note: where the supplier is a wholesaler, dm+d will only author AMPs with generic names where a generic product is available. Where a wholesaler supplies a licensed branded product that is in patent, or the licensed medicine is required by the MHRA to have a brand name, these will not be listed on dm+d. This also applies to the 'Basket List suppliers' cited in the introductory section of Part VIIIA of the NHS England and Wales Drug Tariff, namely AAH, Alliance Healthcare (Distribution) Ltd, Teva UK and Actavis.

Actual Medicinal Product Identifier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the AMP.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist.

Combination Product Indicator

Used to provide information about combination products and the packs that are contained within them.

Field Population:

- Combination product
- Component only product

Additional Information:

As VMP combination product indicator

Actual Medicinal Product Name, Actual Medicinal Product Abbreviated Name, Date of Name Applicability, Previous Name

Field Population:

In the case of generic medicines this field will be populated in the same manner as the virtual product name field above.

In the case of proprietary medicines as far as is practicable the name on the SmPC will be utilised. Where a food supplement VMP has attached more than one flavoured AMP, an unflavoured AMP concept (and linked AMPPs) is authored in dm+d.

Example:

VMP

Generic Electrolade oral powder sachets

AMPs

Electrolade oral powder sachets banana

Electrolade oral powder sachets blackcurrant

Electrolade oral powder sachets lemon and lime

Electrolade oral powder sachets multiflavour

Electrolade oral powder sachets orange

Electrolade oral powder sachets

Abbreviated name (short name or label name) -60 character maximum name — previously applicable to medicines only but in 2008, the scope was widened (see Appendix XI).

Additional Information:

There will be instances where the proprietary name does not specify name, strength and form clearly. In cases where there could be ambiguity additional data will be added to the proprietary name as it appears on the SmPC or manufacturer literature to produce the actual medicinal product name.

For example: 'Adalat Retard' has no indication of strength consequently '20mg' will be added, it has partial indication of form consequently tablet will be added.

'Adalat Retard 10' has partial indication of form consequently tablet will be added.

Generic AMP names will be specified in the order name, strength, form.

Note: for information about the use of concentrate / concentrated terms, see Appendix V.

If the name of an AMP changes the dictionary maintainer will ensure a history of the change is maintained.

The AMP name will be abbreviated to 60 characters or less as detailed in Appendix XI (LIST I). Where the AMP name is already 60 characters or less there is no requirement to provide an abbreviated name.

Actual Medicinal Product Description

Field Population:

A description or full name that is used to uniquely describe the actual medicinal product.

Additional Information:

The AMP description will consist of the following:

AMP name + product order number + size + colour + (Supplier)

Note: product order number, size and colour are applicable for appliances/medical devices only.

Examples:

Paracetamol 500mg tablets + (Alpharma Ltd)

Mandanol 500mg tablets + (M & A Pharmachem Ltd)

Biotrol Elite colostomy bag + 36-825 + 25mm + Beige + (B Braun Medical)

Note: unflavoured AMP concepts authored in dm+d from August 2012 have an associated supplier name of 'Flavour Not Specified'. No indicative price will be published at AMPP level.

Supplier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the manufacturer/supplier/distributor.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. (LIST F)

Licensed Route

Field Population:

Populated in the same manner as the route field for the virtual medicinal product.

i.e. Expanded European Directorate for the Quality of Medicines & HealthCare (EDQM) List of Standard Terms.

Additional Information:

This is a list of pharmaceutical route of administration terms drawn up in response to a request from the European Commission and utilised in the licensing of medicines.

Licensed routes only will be included at this level (AMP) in the dictionary. An unlicensed medicine/product will not have a licensed route. The route or routes must correspond to or be a sub set of the routes associated with the corresponding VMP.

Flavour

Field Population:

dm+d List

Additional Information:

Used where different flavours are available. (See List G).

Examples:

Fybogel Orange 3.5g effervescent granules sachets

Fybogel Lemon 3.5g effervescent granules sachets

Ensure Plus liquid strawberry

Ensure Plus liquid raspberry

Ensure Plus liquid vanilla

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid

The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept.

EMA Additional Monitoring Indicator

Field Population:

EMA monitoring

Additional Information:

Indication as to whether the drug is on the list(s) issued by the European Medicines Agency (EMA) (black triangle)

Note: in April 2013, the MHRA Intensive Monitoring Scheme was replaced by the EMA additional monitoring scheme.

Parallel Import Indicator

Field Population:

Parallel Import

Additional Information:

This is a flag indicating that an Actual Medicinal Product has been procured and imported from within the European Union and has a parallel import licence – PL(PI)

Product Availability Information

Current Licensing Authority, Previous Licensing Authority, Date of Change of Licensing Authority

Field Population:

- None — unlicensed, lapsed/expired/withdrawn licensed products, clinical trial drugs.
- Medicines – MHRA / EMA — medicinal products having a valid marketing authorisation (MA) or PL issued by MHRA or EMA. Note: this value was formerly Medicine Control Agency.
- Devices — products that are CE marked under the Medical Devices Directive 93/42/EC or custom made appliances and deodorants, as well as chemical reagents CE marked under the In Vitro Diagnostic Medical Devices Directive 98/79/EC.
- Traditional Herbal Medicines – MHRA — currently available traditional herbal medicines having a traditional herbal registration (THR) issued by the MHRA.
- Unknown — where licensing info is unavailable for any reason. This value will also cover those products that have been discontinued by a manufacturer for commercial reasons and which may or may not have a valid product licence.

Additional Information:

Licensed Medicines and Medical Devices i.e. appliances and devices included in Part IX and X of the Drug Tariff will be annotated accordingly. In cases where products are known to be neither licensed by the MHRA nor registered by the MHRA the field will be annotated as None. Licensing authority 'Unknown' will be used in circumstances where it is not possible to allocate one of the other four terms.

This information will be obtained directly from the manufactures/distributor.

Licensing Authority Change Reason

Field Population:

- Licence granted
- Licence transferred
- Withdrawn manufacturer
- Withdrawn CHM
- Suspended CHM
- Discontinued/expired/lapsed
- Reintroduced
- No reason available

Additional Information:

The value of 'withdrawn manufacturer' will be used where the product has been withdrawn voluntarily by the manufacturer on grounds of safety.

Restrictions on Availability

Field Population:

- None
- Restricted availability
- Individual patient supply
- Imported
- Clinical trial
- Special
- Extemp
- Hospital only
- Not available

Additional Information:

None – there are no restrictions on the availability of this AMP. This value will be applicable to the majority of prescribed products

Restricted availability – used to denote products that have restrictions upon their prescribing and dispensing e.g. Clozaril tablets where the patient, prescriber and pharmacist must all be registered with the Clozaril monitoring service

Individual patient supply– a medicinal product that has been available, its licence may have been withdrawn or discontinued, but the product is still supplied by the manufacturer for specific clinical reasons to named patients. These are available on a named patient basis only for patients who cannot be transferred to another brand. Phenylbutazone is another example of where the product is no longer available but can be obtained from the manufacturer for an individual patient

Imported – imported products are unlicensed medicinal products sourced from outside the UK under an importers licence issued by the MHRA. These products have been specially sourced to meet a prescription ordered for individual patients without the need for the importer to hold a marketing authorisation for the medicinal product concerned.

Clinical trial – A medicinal product undergoing a clinical trial. This could be a phase 2 or 3 clinical trial drug that may become a licensed product in due course or may be withdrawn or a drug imported for the trial and licensed elsewhere

Special – specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.

Extemp – Extemporaneously prepared products made under the supervision of a Pharmacist against a prescription for a particular patient

Hospital only – This is a medicinal product where the manufacturer has stated that the product should only be used in hospitals e.g. Dantrium Intravenous 20mg vial

Not available – Used to denote medicinal products that have been withdrawn or discontinued by the company for commercial or safety reasons i.e. they are no longer supplied or distributed in the UK. These products are no longer available and cannot be acquired from the manufacturer on an ‘individual patient supply’ basis

Appliance Product Information

Size

Field Population:

A string

Additional Information:

Information relating to the size of an appliance/medical device where this information is not captured within the VMP name. Examples of this type of appliance include incontinence and ostomy equipment where size may be expressed in SI units e.g. mm, by a description e.g. small or a mixture of both.

Examples:

Jade Naturalflex sheath	25mm small
Urosheath	28.5mm small
Biotrol Elite Colostomy bag	Starter hole
Biotrol Elite Colostomy bag	25mm

Colour

Field Population:

dm+d list

Additional Information:

Occasionally colour is useful in determining which of a number of optional medical devices is appropriate. When appropriate the dictionary will be populated with the colour as specified in the Drug Tariff.

Product Order Number

Field Population:

A string

Additional Information:

Certain appliances/medical devices are associated with order numbers within the Drug Tariff (England and Wales). The Drug Tariff number will be added to the dictionary.

Actual Product Excipients

The Excipient Substance of a concept in the NHS dm+d is the representation of any substance other than an 'ingredient substance' that furnishes an effect deemed significant by the current editorial definition even though that effect may not be an event intended as a result of its inclusion in the formulated product.

Ingredient Substance Identifier

Field Population:

dm+d list

Additional Information:

A specified list of 'interesting' excipients (those that may have a biological action) will be included in the dictionary providing the excipient is declared on the SmPC. This attribute confirms the presence of an excipient. If the excipient substance identification field is not populated then this merely infers that the excipient was not stated on the SmPC, or the SmPC data was not available. If the prescriber considers that it is essential to confirm the absence of an excipient then this should be done with the manufacturer. For more information, see Appendix X, LIST H.

All interesting excipients declared in the SmPC will be included even those that may not be present in the final product.

Pharmaceutical Strength

Field Population:

Weight or volume per unit or concentration

Additional Information:

In the vast majority of circumstances the SmPC does not state the strength of the excipient. This field will be populated only for preservatives included in eye drops and in addition only in circumstances where the strength of the preservative is stated on the SmPC. (Units of measure are as LIST E).

Virtual Medicinal Product Pack

A Virtual Medicinal Product Pack (VMPP) is an abstract concept representing the properties of one or more quantitatively equivalent Actual Medicinal Product Packs (AMPP's).

Identity and amount of medicinal product within a Virtual Medicinal Product Pack expressed by mass, volume, number of entities or otherwise in a container, intermediate container(s) or package as supplied by a manufacturer or supplier.

The VMPP takes the description of the VMP and provides information about the various pack sizes or content associated with the VMP.

Virtual Medicinal Product Pack Identifier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the VMPP.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist.

Virtual Medicinal Product Pack Description

Field Population:

A description or full name that is used to uniquely identify the virtual medicinal product pack

Additional Information:

The VMPP description will consist of the following:

VMP name + VMPP Quantity and VMPP Quantity unit of measure

Examples:

Paracetamol 500mg tablets + 100 + tablet

Hydrocortisone 1% cream + 30 + gram

Cotton crepe bandage 10cm x 4.5m + 1 + bandage

Clotrimazole 10% cream and Clotrimazole 2% cream + 1 + pack

Combination Pack Indicator

Field Population:

- Combination pack
- Component only pack (not available separately)

Additional Information:

Flag denoting that the VMPP is a combination product or is only available as a component of a combination pack and is not available in its own right.

Virtual Medicinal Product Quantity

Field Population:

Quantity – numerical value
Units of Measure – dm+d list

Additional Information:

Amount of the Virtual Medicinal Product expressed by mass, volume, number of entities or otherwise in a container, intermediate container or package as supplied.

Examples:

Quantity	Unit of measure
28	tablet
10	ml
60	gram
200	dose
5	cartidge
1	bandage

Units of Measure — LIST E

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid
The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: Where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This

communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept).

Combination Pack Content

Constituent Virtual Product pack Indicator

Field Population:

SNOMED CT

Additional Information:

Used to identify the component packs within a combination product. (Rules as per VMPP identifier above)

Drug Tariff Category Information

Information relating to the categorisation of drugs, appliances/medical devices, chemical reagents and oxygen as provided in the Drug Tariff (England and Wales)

DT payment category

Field Population:

- Part VIIIA Category A
- Part VIII Category B — From 1 September 2004 the concept of Category B and all Category B products were deleted from the Drug Tariff.
- Part VIIIA Category C
- Part VIII Category E — From 1 November 2011 the concept of Category E and all Category E products were deleted from the Drug Tariff.
- Part VIIIA Category M
- Part IXA
- Part IXB
- Part IXC
- Part IXR
- Part X
- Part IXB & IXC
- Part VIIIB

Additional Information:

The dictionary will be populated according to the Drug Tariff (England and Wales).

DT Price, DT Price Date, DT Price Previous

Field Population:

Price in pence, sterling, and a date.

Additional Information:

The price included in the dictionary is indicative only.

Actual Medicinal Product Pack

An Actual Medicinal Product Pack is the packaged product that is supplied for direct patient use or from which AMP's are supplied for direct patient use. It may contain multiple components each of which may or may not be an AMPP in their own right.

An Actual Medicinal Product Pack contains information concerning a medicinal product that has been made available by a manufacturer and/or supplier as a packaged entity

Actual Medicinal Product Pack Identifier

Field Population:

SNOMED CT

Additional Information:

A unique identifier for the AMPP.

The identifier will not be re-used and given to another concept (e.g. VTM, VMP, AMP, VMPP, AMPP, ingredient, form, route, unit of measure or supplier).

The identifier will not be deleted, although there will be circumstances in which it could be marked as no longer valid.

The NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist.

Actual Medicinal Product Pack Description

Field Population:

A description or full name that is used to uniquely identify the actual medicinal product pack

Additional Information:

The AMPP description will consist of the following:

AMP name + Product order number + size + colour + (supplier) + VMPP Quantity and VMPP Quantity unit of measure + Subpack information + Pack order number.

Note: product order number, size, colour and pack order number, are applicable for appliances/medical devices only.

Examples:

Paracetamol 500mg tablets + (Almus Pharmaceuticals Ltd) + 100 + tablet + 10 x 10

Paracetamol 500mg tablets + (Almus Pharmaceuticals Ltd) + 100 + tablet

Mandanol 500mg tablets + (M & A Pharmachem Ltd) + 100 + tablet

Biotrol Elite colostomy bag + 36-825 + 25mm + Beige + (B Braun Medical) + 30 + device

CoaguChek testing strips + (Roche Diagnostics) + 12 + strip + 1937634

CoaguChek testing strips + (Roche Diagnostics) + 48 + strip + 1937642
Canesten Combi Internal & External cream + 1 + pack

Note: unflavoured AMP concepts authored in dm+d from August 2012 have an associated supplier name of 'Flavour Not Specified'. No indicative price will be published at AMPP level.

Sub-pack Information

Field Population:

A string

Additional Information:

Information about the composition of medicinal products that are composed of the same product packed in sub-packs. For example the number of separate strips of tablets within a pack, the number of tubes of tablets or the number of Gluten free rolls.

28 tablets, sub-pack info: 2 x 14 tablets

60 tablets, sub-pack info: 3 x 20 tablets

300gram, sub-pack info: 4 rolls

Combination Pack Indicator

Used to provide information about combination products and the packs that are contained within them.

Field Population:

- Combination pack
- Component only pack

Legal Category

Field Population:

- general sales list (GSL)
- pharmacy medicine (P)
- prescription only medicine (POM)
- not applicable

Additional Information:

Status with regard to the legal category of the medicinal product pack. The value of 'not applicable' will be used for all non-medicine packs e.g. appliances/medical devices, and Investigational Medicinal Products (IMPs) where the legal category cannot be determined. Note: In the autumn of 2008 a change was made to population of this information with respect to ACBS (and non-ACBS) liquid and powder food products in order to assist with secondary care prescribing of these

products. Route information will be added too, except where this information is unavailable, then this attribute will be set to not applicable.

Discontinued Flag, Discontinued Flag Change Date

The discontinued date is defined as the date, notified to the dictionary maintainers by the supplier, from which they will no longer be supplying the product.

Field Population:

- 0 = reinstated
- 1 = discontinued

Additional Information:

A flag indicating that this pack has been discontinued by the manufacturer. This attribute is optional. When present with a value of 1 this shall indicate that the pack has been discontinued by the manufacturer. When present with a value of 0 this shall indicate that the pack has previously been discontinued by the manufacturer but is now available (it has been reinstated). There will also be a date associated with this field showing the date the flag last changed value. A history will be kept by the dictionary maintainers.

Note: This attribute only identifies that the pack has been discontinued by the supplier, there may or may not be stock available within the supply chain.

For more information about supply problems or discontinued items, see the EPS (Electronic Prescription Service) Factsheet for prescribers and the dm+d general implementation guides.

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid

The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: Where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept).

Product Prescribing Information

Information relating to Actual Medicinal Product Packs where these contain drugs. This information is required for primary care products in the act of prescribing but is also important within dispensing, administration and the reimbursement domains.

Schedule 2 Indicator (previously known as Schedule 11)

Field Population:

Schedule 2

Additional Information:

Indication as to whether the drug is included in Schedule 2 of the NHS (General medical Services Contracts)(Prescription of Drugs etc.) Regulations 2004 (Statutory Instrument No 629) - 'Selective List Scheme' (previously known as Schedule 11).

The doctor who prescribes these products for the purpose indicated is required to endorse the prescription with the reference "SLS".

Schedule 1 Indicator (previously known as Schedule 10)

Field Population:

Schedule 1

Additional Information:

Indication as to whether the drug is included in Schedule 1 of the NHS (General medical Services Contracts)(Prescription of Drugs etc.) Regulations 2004 (Statutory Instrument No 629) - (previously known as Schedule 10).

Note: Schedule 1 indicator flags updated in line with the 'gluten-free' update to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 (effective from 4th December 2018).

Hospital Indicator

Field Population:

hospital only pack

Additional Information:

Indication as to whether this item relates to a package that is only to be made available through hospital prescribing.

ACBS Indicator

Field Population:

ACBS product

Additional Information:

Indication as to whether the product is recommended by the Advisory Committee on Borderline Substances and is included in Part XV of the Drug Tariff.

Note: ACBS status does not apply to medical devices listed in Part IX of the Drug Tariff and therefore it would be inappropriate to flag medical devices as ACBS approved.

ACBS indicator flags updated in line with the 'gluten-free' update to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 (effective from 4th December 2018).

Personally Administered Indicator

Field Population:

attracts a drug administration fee

Additional Information:

Indication as to whether the drug, when personally administered by the prescriber in primary care, attracts a fee.

FP10MDA Prescription

Field Population:

Prescribable on FP10 MDA

Additional Information:

Indication as to whether the drug can be prescribed and consequently dispensed, in instalments, on a FP10MDA form.

Nursing Formulary Indicator

Field Population:

Nurse formulary

Additional Information:

Indication as to whether the actual product pack is included in PartXVIIIB(i) of the Drug Tariff as being prescribable by nurse formulary nurses.

Nurse Extended Formulary Indicator

Field Population:

Nurse Extended formulary – From 30 April 2006 the Nurse Prescribers' Extended Formulary was discontinued

Additional Information:

This flag was previously used to indicate as to whether the actual product pack was included in PartXVII B(ii) of the Drug Tariff as being prescribable by nurse extended formulary nurses prior to 1 May 2006.

Dental Formulary Indicator

Field Population:

Dental formulary

Additional Information:

Indication as to whether the actual product pack is included in PartXVII A of the Drug Tariff as being prescribable by Dentists

Appliance Pack Information

Information relating to Virtual Medicinal Products where these are appliances/medical devices

Appliance Reimbursement Status, Appliance Reimbursement Status Date, Appliance Reimbursement Previous Status

Field Population:

- not allowed (not included in Drug Tariff)
- allowed (included in Drug Tariff)

Additional Information:

Indication as to whether the appliance/medical device is allowed for reimbursement purposes and is included in the Drug Tariff (England and Wales). Date from which the appliance reimbursement status became effective. If absent the date shall be taken as from the issue of the current version of the dictionary.

Pack Order Number

Field Population:

A string

Additional Information:

Certain appliances/medical devices are associated with order numbers within the Drug Tariff (England and Wales). The Drug Tariff number will be added to the dictionary.

Reimbursement Information

Prescription Charges

Field Population:

An integer

Additional Information:

The number of standard prescription charges attracted when this type of product pack is dispensed as defined in the Drug Tariff (England and Wales) – Part XVI.

Examples:

Microgynon 30 tablets – 0 prescription charge

Atenolol 50mg tablets – 1 prescription charge

Prempak C 1.25mg tablets – 2 prescription charges

Dispensing Fees

Field Population:

An integer

Additional Information:

Number of standard dispensing fees associated with the pack as defined in the Drug Tariff (England and Wales) – Part III.

Broken Bulk Indicator

Field Population:

eligible for broken bulk claim

Additional Information:

This indicates whether the product is eligible for broken bulk claims within primary care.

Limited Stability Indicator

Field Population:

Blank

Additional Information:

The Drug Tariff no longer identifies products as limited stability; therefore this indicator is no longer populated in dm+d. The data field will persist but will be blank.

Calendar Pack Indicator

Field Population:

calendar pack

Additional Information:

A manufacturer's calendar pack is a blister or strip pack showing the days of the week or month against each of the several units in the pack.

Note: calendar packs are no longer defined by the Drug Tariff.

Special Container Indicator

Field Population:

- special container
- sub-pack is a special container

Additional Information:

This indicates that the pack is a special container or that the sub-pack is classed as a special container as defined in the Drug Tariff (England and Wales) – Part II clause 10B.

Discount Not Deducted Indicator

Field Population:

- discount not deducted — automatic
- discount not deducted — endorsement required

Additional Information:

This indicates whether the product has been identified as a product that has not received discount and as such when reimbursed no discount deduction is applied automatically or where the contractor has to endorse the prescription if no discount has been received. Reference Drug Tariff (England and Wales) – Part II.

FP34D Prescription Item

Field Population:

allowed as a bulk vaccine

Additional Information:

This indicates whether the product is allowed as a 'Bulk Vaccine' on personal administration claims within primary care.

Medicinal Product Price

Information relating to the price (indicative only) of the actual medicinal product pack.

Price, Date of Price Validity, Price Prior to Change Date

Field Population:

A price in pence, sterling

A date

Additional Information:

An indicative price for the pack will be entered where a price list is available from a supplier. Where price information is received for products that are used only within secondary care, this will also be taken as the indicative price.

Price Basis Flag

Field Population:

- NHS indicative price
- No price available
- No price – product centrally funded
- No price – priced when manufactured

Additional Information:

Identifies where there's an indicative NHS price or the reason why the price field has no value

Where a product is centrally funded e.g. MMR vaccine a zero value will be used in the price field and the price basis flag will be 'No price – product centrally funded'. Some centrally funded products are also reimbursable in Primary care when prescribed on a FP10. In this situation if a reimbursement price is required these products will have a NHS indicative price.

Note: for disease modifying drugs (e.g. Interferon beta) that are included in a Risk Sharing Scheme between manufacturers and policy makers, the indicative price is the manufacturer's list price for these drugs (and not the NHS primary care reimbursement price).

Drug Tariff Special Order products

An NHS indicative price will be held at AMPP level only. Only those packs published in the Drug Tariff Part VIII B will be populated with a price in dm+d.

The Drug Tariff prices will be fixed prices and no discounts will be applied.

All other Special Order and Extemporaneously prepared products

These are priced as and when they are manufactured in this case the price basis flag will be 'No price – priced when manufactured'.

Combination Pack Content

Constituent Actual Product pack Indicator

Field Population:

SNOMED CT

Additional Information:

Used to identify the component packs within a combination product. (Rules as per AMPP identifier above)

Other data

Ingredient Substance File

Use to describe the substances which may act as ingredients of medicinal products. Within the file of ingredient substances will be entries relating to the following:

- Complete substances which act as actual ingredients of medicinal products. For example heparin sodium, cyclizine lactate, dexamethasone sodium phosphate. This class of substance may or may not be a salt or other type of derivative.
- Basis of Strength Substance (BoSS) which may or may not be available as actual ingredients. For example heparin, cyclizine, dexamethasone, dexamethasone sodium.
- Excipients
- Substances to support the recording of allergies in clinical systems. These are ingredients in products that are not UK licensed medicines. There is no relationship to a dm+d VMP or AMP concept for these substances.

Ingredient Substance Identifier, Ingredient Substance Identifier date, Previous Ingredient Substance Identifier

Field Population:

SNOMED CT

Additional Information:

Identification of the ingredient substance within the Ingredient Substance file. NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. Where an ingredient is not available a temporary SNOMED CT UK Drug extension will be used. If at a future date a SNOMED CT International Release term is created, this core identifier will replace the UK extension code which will be moved to the previous field.

Ingredient Substance Name

Field Population:

As Virtual Medicinal Product ingredient substance name

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid
The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: Where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept.

Form

Form Identifier, Form Identifier Date, Previous Form Identifier

Field Population:

SNOMED CT

Additional Information:

Identification of the form within the dose form file. NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. Where a dose form is not available a temporary SNOMED CT UK Drug extension will be used. If at a future date a SNOMED CT International Release is created, this core identifier will replace the UK extension code which will be moved to the previous field.

Form Name

Field Population:

Name used to describe the dose formulation e.g. tablet, cream, gastro resistant capsule etc.

Route

Route Identifier, Route Identifier Date, Previous Route Identifier

Field Population:

SNOMED CT

Additional Information:

Identification of the route of administration within the route of administration file. NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. Where a route is not available a temporary SNOMED CT UK Drug extension code will be used. . If at a future date a SNOMED CT International Release term is created, this core identifier will replace the UK extension code which will be moved to the previous field.

Route Name

Field Population:

Name used to describe the route of administration e.g. Oral use, intravenous use, cutaneous use etc.

Supplier

Supplier Identifier, Supplier Identifier Change Date, Previous Supplier Identifier

Field Population:

SNOMED CT

Additional Information:

Identification of the supplier within the supplier file. NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. Where a supplier is not available a temporary SNOMED CT UK Drug extension code will be used. If at a future date a SNOMED CT International Release term is created, this core identifier will replace the UK extension code which will be moved to the previous field.

Invalidity Flag

Additional Information:

Flag indicating that this dictionary entry is invalid

The entry will be retained in case it was used prior to its invalidation. Although it is unlikely it is possible for a concept to subsequently have the invalidity flag removed if further information proves that the concept should not have been marked as invalid.

Note: Where a concept is to be made invalid, a communication message will be issued to all license holders in the run up to the weekly publication of the database affected by the change. This communication will explain the reason for the invalidation (for more information, see page 12, and where possible provide notification of any replacement concept.

Supplier Name

Field Population:

Name used to describe the supplier e.g. C P Pharmaceuticals Ltd, GlaxoSmithKline, Novartis Pharmaceuticals UK Ltd.

Unit of Measure

Unit of Measure Identifier, Unit of Measure Identifier Change Date, Previous Unit of Measure Identifier

Field Population:

SNOMED CT

Additional Information:

Identification of the unit of measure within the unit of measure file. NHSBSA will be authorised to allocate codes as part of the NHS name space identifier. Specific NHS terms will be used only where SNOMED Clinical Terms (CT) do not exist. Where a unit of measure is not available a temporary SNOMED CT UK Drug extension code will be used. If at a future date a SNOMED CT International Release term is created, this core identifier will replace the UK extension code which will be moved to the previous field.

Taken from the dictionary code list (LIST E)

EXAMPLE mg when the strength is 200 mg.

Unit of Measure Name

Field Population:

Name used to describe the unit of measure e.g. mg, ml, cm, device, tablet.

Semantic Normal Form Patterns used in NHS dm+d

Products follow the naming convention:

Name Strength Modification(s) **Form** Unit dose xxx-free(s)

Note – name in the above refers to the recommended international non-proprietary name or equivalent (see below) e.g. Atenolol, Amoxicillin etc. A VMP name will consist of this 'name' and the form. It will usually have a strength and may have a modification, unit dose or xxx-free.

- A VMP will always be issued with a VMP name, even if the product is non-prescribable
- A new VMP may be allocated a temporary name that is replaced at a later date
- The VMP will utilise an approved generic name where one is available
- VMPs with two active substances and no approved generic name will be populated:
 - following the naming convention used by the British National Formulary.
 - the strength of each active substance will immediately follow the name i.e. Name Strength / Name Strength Form examples:
Hydrocortisone acetate 1% / Fusidic acid 2% cream
Hydrocortisone 1% / Clotrimazole 1% cream
- VMPs with more than two active substances will be populated with the prefix Generic followed by the brand name of the product
- If two or more proprietaries exist, where the name would be Generic XXXX, the name of the product marketed first will be used
- There are certain preparations containing more than two ingredients for which the British Pharmacopoeia has approved generic names e.g. Measles, Mumps and Rubella vaccine and Potassium chloride, Sodium chloride and Glucose intravenous infusion. In addition parenteral products that are vaccines or large volume parenteral fluids and for which there is no current approved generic name then a true VMP will be supplied.

STRENGTH

- A VMP name will usually have a strength, there are however occasions when this is not applicable examples of this include Calamine lotion, Vitamin B compound tablets, Aqueous cream
- Strength may be expressed in a variety of ways e.g. weight, volume, percentage, activity. The strength may represent the total amount of active ingredient in each form i.e. per tablet or may be expressed per volume or per weight i.e. liquids and semi-solids.
- Strength in the VMP name will be the clinically intuitive strength i.e. Amoxicillin 250mg/5ml oral suspension. At ingredient level strength is expressed per 1 (per 1 tablet, per 1ml, per 1 gram etc. with the **exception** of patches where strength may be expressed per hour, per 24 hours etc.). For the VMP above the strength in the ingredient field is expressed as 50 mg/ml

MODIFICATION(S) and FORM

- A VMP may only have one form
- A VMP that is of type 'drug' will generally always be associated with a form
- Although ACBS products may be regarded as drugs gluten-free products and other food supplements will generally have the form 'not applicable'. However, to assist with secondary care prescribing where:

- Any liquid food has a route of JUST oral, it will have a form of liquid.
- Any powder for liquid food has a route of JUST oral it will have a form of powder.
- If the product has a route of JUST gastrointestinal, or BOTH oral AND gastrointestinal, a form of gastrointestinal liquid OR powder for gastrointestinal liquid will be added (i.e. gastrointestinal takes priority over oral here).
- Note: Route information will be added too, except where this information is unavailable. Where unavailable, this attribute will be set to not applicable.
- Combination packs e.g. Canesten Combi (pessary + cream) will have the form 'not applicable'
- Occasionally it may be necessary to use a modification in addition to a form e.g. Peppermint oil 0.2ml gastro-resistant modified-release capsules, Glyceryl trinitrate 2mg modified-release buccal tablets
- Products containing two active ingredients where one active ingredient only is modified will have the modification after the appropriate name & strength e.g. Dipyridamole 200mg modified-release / Aspirin 25mg capsules.

UNIT DOSE

- When the form is insufficiently precise to describe the product the unit dose should be included in the name.
 - The form injection does not fully describe a product therefore the name is qualified with the unit dose form e.g. ampoules, vials, pre-filled syringes, pre-filled disposable devices etc. Furosemide 50mg/5ml solution for injection ampoules.
 - Other unit dose examples include: Budesonide 250micrograms/ml nebuliser liquid 2ml unit dose vials, Carbenoxalone 1% granules 2g sachets, Benorilate 2g granules sachets.

XXX FREE

- Where a product has a xxx free flag that 'freeness' will form part of the VMP name.
- Where a product has two or more 'freeness' then they will appear in alphabetical order.

EXAMPLES OF SNF PATTERNS – Strength expression

Solid unit dose forms

Examples include: tablets, buccal tablets, chewable tablets, dispersible tablets, effervescent tablets, gastro-resistant tablets, modified-release tablets, soluble tablets, sublingual tablets, capsules, gastro-resistant capsules, modified-release capsules, pessaries, suppositories, urethral sticks, cachet, lozenge, pastille, pillule, medicated chewing gum etc.

The strength is expressed as the amount per unit dose form. It will usually be expressed as; a weight – mg, microgram, g, nanogram

but may be expressed as;

a ratio — 8mg/500mg (this will usually be used for BP approved Co- products)

a volume — ml

a percentage — %

activity – units

other – mmol

There may be occasions where no strength is required in the VMP name e.g. Vitamin B compound tablets

Examples:

Allopurinol 100mg tablets

Chloroquine phosphate 250mg tablets

Co-amilofruse 5mg/40mg tablets

Colistin 1.5million unit tablets

Cyclopentiazide 500microgram tablets

Rifampicin 300mg / Isoniazid 150mg tablets

Vitamin B compound tablets

Glyceryl trinitrate 2mg modified-release buccal tablets

Bendroflumethiazide 2.5mg / Potassium Chloride 630mg (potassium 8.4mmol) modified-release tablets

Alfacalcidol 250nanogram capsules

Aspirin 300mg suppositories

Buprenorphine 200microgram sublingual tablets

Co-amoxiclav 250mg/125mg dispersible tablets

Diethylstilbestrol 500micrograms / Lactic acid 5% pessaries

Fentanyl 400microgram lozenges

Nicotine 2mg medicated chewing gum sugar free

Generic Anusol HC suppositories

Shark liver oil 3% / Yeast cell extract 1% suppositories

Nystatin 100,000unit pessaries

Peppermint oil 0.2ml gastro-resistant modified-release capsules

Alprostadil 125microgram urethral sticks

Liquid unit dose forms – injections and intravenous infusions (i.e. parenteral products)

Examples of liquid injections and intravenous infusions include: ampoules, vials, pre-filled syringes, cartridges, bottles, polyethylene bottles, bags. For details on the identification of infusions, see the section below.

If strength is expressed this will be the total amount of drug present in the unit dose volume as:
a weight – mg, microgram, g, nanogram or

a number of units – units, million units

Water for injection is an example of a product that will have no strength information in the VMP name.

These preparations will also specify the unit dose form itself i.e. ampoules, vials etc.

Examples:

Apomorphine 30mg/3ml solution for injection pre-filled disposable injection devices

Atenolol 5mg/10ml solution for injection ampoules

Filgrastim 48million units/1.6ml solution for injection vials

Heparin sodium 25,000units/5ml solution for injection vials

Water for injection 10ml ampoules

Exceptions

There are 3 alternative methods for a list of pre-defined **exceptions** where a clinical use case has determined the requirement to express the strength in an alternative manner. This list is detailed in Appendix XIV.

These are:

Alt method 1

The first of these allowable exceptions 'alt. method 1' being to quote the unit strength i.e. mg/ml. This method will be used for insulins and other identified multidose injections where the intention is that only a proportion of the total quantity will be administered at any one time.

Human soluble insulin 100units/ml solution for injection 10ml vials.

Alt Method 2

The second exception 'alt method 2' will be to allow for dual representation of the strength which will be represented as unit strength in both instances. This will be used for preparations such as lidocaines, adrenalines, and other preparations where the strength is quoted as biological activity, in units, or as ratios/percentages as well as in milligrams or micrograms.

Adrenaline (base) 500micrograms/0.5ml (1 in 1,000) solution for injection ampoules

Lidocaine 400mg/20ml (2%) solution for injection ampoules

Mannitol 100g/500ml (20%) infusion bags

Trichloroacetic acid 15% (150mg/1ml) solution

Alt method 3

A third exception 'alt method 3' is proposed for large volume infusion fluids, electrolyte solutions and other specified injections whereby these are quoted as a %.

Sodium chloride 0.9% solution for infusion 1litre bags

Identification of infusions

All licensed and unlicensed parenteral products meeting either of the following criteria will be defined as an infusion:

- Products intended by the manufacturer for infusion only.
- Products of at least 50ml, which are intended for both injection and infusion.

All products meeting the definition of an infusion and presented in bags or polyethylene bottles will use the following dose form:

- Infusion

This is the shortened EDQM form term and will be used in the VMP/AMP term and used as the coded form.

Whereas products meeting the definition of infusion not presented in bags and polyethylene bottles, will be described with one of the following EDQM forms (also see Appendix V, List C) in their VMP/AMP term and have an equivalent coded form:

- Solution for infusion.
- Emulsion for infusion.
- Powder for solution for infusion.
- Powder and solvent for solution for infusion.

Exceptions:

The following products are exempt from the definition because they are intended to be used as diluents rather than for direct patient administration:

- glucose 5% solution for injection – ampoules and vials
- sodium chloride 0.9% solution for injection – ampoules and vials
- water for injection – ampoules and vials

Liquid unit dose forms – others

Examples include: nebuliser liquid unit dose vials, sachets of liquids.

If a strength is expressed this is usually as the amount per ml either as:

a weight – mg, microgram, g, nanogram or

a number of units – units, million units

A number of medicinal products use a strength expressed as a percentage and in these cases this more clinically intuitive way of expressing the strength will be used.

In September 2009, a paper was approved by the Editorial Group that proposed that VMP and AMP names for liquid unit dose concepts should be described expressing the total strength based on the total volume (i.e. total dose) in-line with unit dose injectables and unit dose oral liquids. The paper also stated that the following products would be exempt here:

- Insulin injections
- Contrast media injections
- Eye drops expressed as mg/ml and not a percentage will not be changed to the total amount in the total volume whether unit dose or not
- Unit dose preparations that are expressed as a percentage e.g. Sodium chloride 0.9% nebuliser liquid 2.5ml unit dose vials
- Any multi-dose preparations e.g. Ventolin respirator solution

Examples:

Budesonide 500 micrograms/2mL nebuliser liquid unit dose vials

Diazepam 2.5mg/1.25ml rectal solution tube

Dornase alfa 2.5mg/2.5ml nebuliser liquid ampoules

Salbutamol 2.5mg/2.5ml nebuliser liquid unit dose vials*

Tobramycin 300mg/5ml nebuliser liquid ampoules

* Using the salbutamol example above, previously this description was: Salbutamol 1mg/ml nebuliser liquid unit dose vials.

Continuous solid unit doses

Examples include: sachets of granules or powder

The strength is usually expressed as the weight of 'drug' per sachet. Occasionally this strength may be expressed as a percentage in which case the weight of the sachet will be stated before 'sachets'

Examples:

Benorilate 2g granules sachets
Carbenoxolone 1% granules 2g sachets
Clarithromycin 250mg granules sachets
Colestipol 5g granules sachets sugar free
Amoxicillin 3g oral powder sachets sugar free
Cadexomer-iodine 0.9% powder 3g sachets
Beclometasone 200microgram inhalation powder blisters
Ipratropium 40microgram inhalation powder capsules
Colecalciferol 440unit / Calcium carbonate 1.25g effervescent granules sachets
Co-codamol 30mg/500mg effervescent powder sachets

Continuous semi-solid preparations

Examples include: cream, gel, ointment,

The strength will usually be expressed as a percentage. Depending upon the product this may be w/w, w/v, v/w or v/v. The percentage strength within the VMP name will not be qualified with the appropriate w/w or w/v etc.

Occasionally strength may be expressed as the amount per gram where this is more clinically intuitive. This may be:

a weight – mg, micrograms etc.

activity – units

A range of products within this grouping do not require strength information e.g. Aqueous cream

Examples:

Aciclovir 5% cream
Aqueous cream
Calcipotriol 50micrograms/g cream
Nystatin 100,000units/g cream
Choline salicylate 8.7% dental gel
Dinoprostone 800micrograms/ml vaginal gel
Metronidazole 0.8% gel
Betamethasone valerate 0.1% ointment
Polymyxin B 10,000units/g / Bacitracin 500units/g eye ointment
Polymyxin B 10,000units/g / Bacitracin 500units/g ointment
Simple eye ointment
Simple ointment
Tacalcitol 4micrograms/g ointment
Tacrolimus 0.03% ointment
Tacrolimus 0.1% ointment
Titanium ointment

Continuous liquid preparations

Examples include: oral solutions, oral suspensions, oral emulsions, liquids, eye lotion, mouthwash, paints, eye drops, ear drops, nose drops

Liquids intended for oral administration will usually express the strength per ml. The most common being per 5ml as this is the usual standard dose form. There is however a range of preparations that supply a pipette with the product and will express the strength based upon this size for example as per 1ml (digoxin and nystatin) or 1.25ml (Amoxicillin). The amount per ml will usually be a weight (mg, microgram etc.) but can be units. Again a range of BP formulations will not express a strength (Potassium citrate mixture).

External liquids will usually express the strength as either a percentage or as an amount per ml e.g. weight or activity (mg etc. or units)

Examples:

Atenolol 25mg/5ml oral solution sugar free

Colistin 250,000units/5ml oral solution

Digoxin 50micrograms/ml oral solution

Potassium citrate mixture

Amoxicillin 125mg/1.25ml oral suspension paediatric

Amoxicillin 125mg/5ml oral suspension

Erythromycin ethyl succinate 500mg/5ml oral suspension

Magnesium trisilicate oral suspension

Nystatin 100,000units/ml oral suspension

Aluminium chloride 20% solution

Betamethasone valerate 0.1% scalp application

Clotrimazole 1% solution

Tetracycline 2.2mg/ml topical solution

Surgical spirit

Salicylic acid 17% paint

Tioconazole 28.3% nail solution

Ketoconazole 2% shampoo

Benzydamine 0.15% mouthwash

Salicylic acid 12% collodion

Terbutaline 10mg/ml nebuliser liquid

Betaxolol 0.25% eye drops

Adrenaline 1% eye drops

Alfacalcidol 2micrograms/ml drops

Bimatoprost 300micrograms/ml eye drops

Polymyxin B 10,000units/ml / Trimethoprim 1mg/ml eye drops

Ketotifen 250micrograms/ml eye drops

Note: the EMA and MHRA are approving more SmPCs with oral solution and oral suspension product descriptions routinely expressed as e.g. 1mg/ml. The dm+d authoring style remains as 5mg/5ml unless there is evidence that most doses are intended to be in volumes less than 5ml (e.g. primary target population is children), in which case the expression will be as 1mg/ml e.g. Domperidone 1mg/ml oral suspension sugar free.

Continuous solid preparations

Examples include: granules, powders

Strength will usually be expressed as a percentage but may be expressed as a weight per weight or weight per volume.

Examples:

Clotrimazole 1% powder
Nelfinavir 50mg/g oral powder
Ispaghula husk 90% granules
Senna 15mg/5ml granules
Sterculia 62% / Frangula 8% granules gluten free
Silver nitrate 95% caustic pencil

Miscellaneous preparations:

Patches

Strength will usually be expressed as the amount of 'active drug' released over x hours. The amount will usually be a weight (mg, micrograms) and the time will depend upon the clinical use of the product e.g. a patch used for pain relief will often express the strength as the amount per hour whereas a HRT patch is usually over 24 hours. Some nicotine patches are designed to be worn just during the day and these preparations choose to express the strength over a 16 hour period.

Examples:

Buprenorphine 35micrograms/hour patches
Estradiol 100micrograms/24hours patches
Fentanyl 100micrograms/hour patches
Hyoscine 1mg/72hours patches
Nicotine 10mg/16hours patches
Nicotine 14mg/24hours patches
Norethisterone 170micrograms/24hours / Estradiol 50micrograms/24hours patches

Inhalers and sprays

Examples: metered dose inhalers and sprays - pressurised inhalers, dry powder inhalers, nasal spray, sublingual spray

The strength is expressed as the amount per actuation or dose. The amount will usually be expressed as a weight e.g. mg, micrograms etc.

Examples:

Beclometasone 100micrograms/dose breath actuated inhaler CFC free
Beclometasone 100micrograms/dose breath actuated inhaler
Beclometasone 100micrograms/dose inhaler
Glyceryl trinitrate 400micrograms/dose sublingual spray
Isosorbide dinitrate 1.25mg/dose sublingual spray

Implants/ Vaginal rings/ Intra-uterine systems

The strength is expressed either as the amount per implant or device or as the amount released over a given time period e.g. weight/'x'hours.

Examples:

Estradiol 100mg implant

Goserelin 10.8mg implant pre-filled syringes

Testosterone 100mg implant

Estradiol 2mg vaginal ring

Estradiol acetate 1.25mg vaginal ring

Levonorgestrel 20micrograms/24hours intrauterine system

Dry powder injections

The strength is expressed as the amount per vial. This will usually be a weight but may be expressed as a number of units.

Examples:

Amoxicillin 500mg powder for solution for injection vials

Diamorphine 30mg powder for solution for injection ampoules

Hyaluronidase 1500unit powder for solution for injection ampoules

Etanercept 25mg powder and solvent for solution for injection vials

Appendix III

List A — Virtual Medicinal Product Reason For Name Change

Reason	Example
Replacement of a temporary name	Drug dictionary populated with a temporary name which is subsequently replaced by an 'approved' name
New approved generic name available	Development of co-names
Basis of name changed	Change from a BANN to rINN
Other	

Note: there is no requirement for a reason 'new proprietary name' as this would be handled by the production of a new AMP.

Appendix IV

List B — Virtual Medicinal Product Combined Route and Form

Editorial Policy: The VMP combined route and form terms are the route and form at administration. This field is required for Decision Support use. The list and definitions have been compiled by the Ontologists

The form-route string is a single text string. It should begin with the form of a product at administration, table 1. The form may be modified with the descriptors listed in table 2. The string should end with the route of administration as defined in table 3.

e.g.

Paracetamol 500mg tablets	tablet.oral
Cimetidine 200mg/5ml suspension	suspension.oral
Indometacin 100mg suppositories	suppository.rectal
Terbutaline 500mcg turbohaler	powderinhalation.inhalation
Cocodamol dispersible tabs	suspension.oral
Cocodamol soluble tabs	solution.oral
Emulsifying ointment	ointment.cutaneous
	ointment.bathadditive
Morphine sulf 10mg injection	solutioninjection.subcutaneous
	solutioninjection.intramuscular
	solutioninjection.intravenous
Juvela GF bread	grocerysolid.oral
Ensure liquid	liquidfood.oral
	liquidfood.gastroenteral
Resource Energy pudding	grocerysemisolid.oral
PKU3	granulesfoodmix.oral
Maxijul LE powder	powderfoodmix.oral
	liquidfood.oral
Terbutaline turbohaler	powderinhalation.inhalation
Terbutaline inhaler	pressurizedinhalation.inhalation

Table– Forms and definitions

Form	Definition
Cachet	Solid disc-shaped dosage form made of wafer enclosing a unit-dose for oral use
Capsule	A solid preparation with hard or soft shells of various shapes and capacities, usually containing a single dose of active ingredient(s). The capsule shells are made of gelatin or other substance. The contents of capsules may be solid, liquid or of a paste-like consistency. For oral administration, the shell is attacked by the digestive fluids and the contents are released. Capsules can also be formulated for use via a variety of administration routes (e.g. oromucosal, rectal, vaginal) to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes.

Collodion	Liquid usually containing pyroxylin in a mixture of ether and ethanol. Forms a flexible film at the site of application.
Cream	A multiphase preparation consisting of lipophilic phase and an aqueous phase. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes.
Delivery System	A mechanism formulated for releasing a drug, and designed for administration to a specific location.
Dispersion	A system consisting of 2 or more phases. To be used only when suspension or emulsion are not appropriate.
Emulsion	This is a stabilised oil-in-water dispersion, either or both phases of which may contain dissolved solids. Solids may also be suspended in emulsions. It can contain one or more active ingredients.
Eye lotion	A sterile aqueous solution intended for use in washing or bathing the eye or for impregnating eye dressings. The term also covers solid and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use.
Foam	A foam consists of large volumes of gas dispersed in a liquid and generally contains one or more active substances. It is usually formed at the time of administration from a liquid preparation in a pressurised container. The container is equipped with a device consisting of a valve and a push button suitable for the delivery of the foam.
Gargle	An aqueous solution used for gargling. The process of gargling is intended to bring the liquid into intimate contact with membranous lining of the throat. Gargle is different from a Mouthwash in that the latter is used on the mucous membranes of the oral cavity rather than in the throat. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.
Gas	A compressed, liquefied or dissolved gas with medical use(s).
Gastroenteral liquid	A liquid administered via the enteral route (oral, nasogastric, PEG, jejunostomy etc.) used either to provide sole nutrition or to supplement other food intake. The term covers emulsions, suspensions, and solutions provided for this use case.
Gel	A semi-solid preparation consisting of liquids gelled by means of suitable gelling agents. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes.
Granules	Granules are preparations consisting of solid, dry aggregates of powder particles sufficiently resistant to withstand handling. They are intended for oral administration. Some are swallowed some are chewed. Granules are presented as single-dose or multidose preparations.
Grocerysemisolid	A food that is available for the supplementation of diet in a recognisable solid grocery semi-solid form such as yoghurt, mousse.
Grocerysolid	A food that is available for the supplementation of diet in a recognisable solid grocery form such as biscuits, cookies, bread, pasta.
Gum	Semi-solid preparation with a basis of gum and sugar that is to be sucked or chewed before swallowing. Medicated chewing gum is excluded.

Herbal tea	Herbal teas consist exclusively of one or more herbal drugs in an aqueous preparation. The preparation is prepared immediately before use
Implant	Implants are sterile, solid preparations suitable for parenteral implantation, and release the active substance(s) over an extended period of time.
Implantation suspension	Suspension to be implanted in the body.
Impregnated dressing	A piece or strip of gauze or other suitable fabric, impregnated with a liquid or a semi-solid preparation.
Insert	Medicated insert. Sterile, solid or semisolid preparations. They usually consist of a reservoir of active substance embedded or bounded by a rate-controlling membrane. The active substance is released over a determined length of time.
Intrauterine device	Insert intended to release its content over extended period of time.
Lacquer	Medicated liquid preparations of a variety of viscosities intended to be applied to the nails in order to obtain a local action.
Liquid	Term to be used for liquid preparations that are neither solutions, suspensions, oils or emulsions
Liquidfood	A food substitute product consumed in liquid form
Lozenge	Hard candy to be sucked to obtain a local effect. It can contain one or more active ingredients.
Lyophilisate	Freeze dried, fast releasing solid preparation.
Medicated chewing-gum	A solid, single-dose preparation with a base consisting mainly of gum intended to be chewed but not swallowed. They contain one or more active ingredients which are released by chewing.
Medicated plaster	Medicated plasters are flexible preparations containing one or more active substances. They are intended to be applied to the skin. They are designed to maintain the active substance(s) in close contact with the skin such that these may be absorbed slowly or act as protective or keratolytic agents.
Mouthwash	An aqueous solution intended for use in contact with mucous membranes of the oral cavity. It can contain one or more active ingredients.
Oil	Insoluble in water a liquid obtained from animals or plants or derived from petroleum. Also covers natural esters of glycerol and various fatty acids which are liquid at room temperature.
Ointment	A semi-solid preparation consisting of a single-phase basis in which solids or liquids may be dispensed. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes.
Paste	A semi-solid preparation that is much stiffer than ointments. It usually consists of finely ground insoluble powders (at concentrations of 20% to 60%) dispersed in hydrocarbon or water-miscible bases. It can contain one or more active ingredients and is intended to be used for protective, therapeutic or prophylactic purposes.
Pastille	A medicinal preparation containing gelatine and glycerine, usually coated with sugar. It can contain one or more active substances.

Patch	Patches are flexible pharmaceutical preparations of varying sizes, containing one or more active substances. They are intended to be applied to the unbroken skin.
Pessary	Moulded pessary. Pessaries are solid, single-dose preparations. They have various shapes, usually ovoid, with a volume and consistency suitable for insertion into the vagina. They contain one or more active substances dispersed or dissolved in a suitable basis that may be soluble or dispersible in water or may melt at body temperature.
Pillules	Pillules for homoeopathic use are preparations of solid consistence obtained from sucrose, lactose or a mixture of both by progressive addition of these excipients and addition of a dilution of the homoeopathic stock.
Poultice	A hydrophilic, heat-retentive basis in which solid or liquid active substances are dispersed. It is usually spread thickly on a suitable dressing and heated before application to the skin.
Powder	Preparations consisting of solid, loose, dry particles. It can contain one or more active ingredients. The term "powders" can be used to describe a solid dosage form.
Pressurized inhalation	Pressurized metered-dose preparations for inhalation in special containers equipped with a metering valve and which are held under pressure with suitable propellants or suitable mixtures of liquefied propellants, which can also act as solvents.
Ring	A silicone elastomer ring, containing a drug reservoir.
Solution	A liquid containing one or more active ingredients dissolved in a suitable vehicle. The term also covers powders, granules and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use
Sponge	Sponge impregnated with an active substance.
Stick	Sticks for medical uses are solid preparations intended for local application. They are rod-shaped or conical preparations consisting of one or more active substances alone or which are dissolved or dispersed in a suitable basis that may dissolve or melt at body temperature.
Suppository	A solid, single-dose preparation with a shape, volume and consistency suitable for rectal administration. It contains one or more active substances dispersed or dissolved in a suitable basis that may be soluble or dispersible in water or may melt at body temperature.
Suspension	A liquid containing one or more active ingredients suspended in a suitable vehicle. Suspended solids may slowly separate on standing but are easily redispersed. The term also covers powders, granules and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use
Tablet	Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volume of particles. This term is used to cover both uncoated and coated tablets as well as film-coated tablets. The excipients used are not specifically intended to modify the release of the active substance in the digestive fluids.
Tampon	A solid dosage form intended to be used to plug a cavity or canal in order to absorb blood or secretions or to deliver active substance(s). Medicated tampons

	are inserted for a limited time and usually consists of a suitable material such as cellulose, collagen or silicone impregnated with one or more active substances.
Vapour	Preparations converted into vapour and the vapour generated inhaled.

Table – Modified forms and definitions

Bath additive	Added to the bath water for protective, therapeutic or prophylactic purposes (e.g. for moisturising and cleansing).
Buccal	Applied to the buccal cavity (pouch) to obtain a systemic effect.
Chewable	An oral preparation designed to be broken down rapidly in the buccal cavity by the action of teeth.
Dispersible	To be dispersed in liquid before being swallowed.
Drops	Administered in small volumes by means of a suitable device. It may contain one or more active substances.
Effervescent	Upon administration, the active ingredient(s) is released by an effervescent-like reaction between the product and body fluids.
Enema	The term “enema” is used to cover liquid preparations intended for rectal use. The enema is usually supplied in single-dose containers and contains one or more active substances dissolved or dispersed in water, glycerol or macrogols or other suitable solvents.
Foodmix	To be consumed when mixed with food.
Gastro-resistant	Gastro-resistant is the intention to resist the gastric fluid and to release their active ingredient or ingredients in the intestinal fluid.
Impregnated cigarette	A small roll of finely cut substance enclosed in a wrapper of thin paper, injected or impregnated with a medicinal substance for administration by inhalation.
Infusion	Infusions are sterile; they are usually made isotonic with blood. They are principally intended for administration in large volume.
Inhalation	Administered by non-aerosol inhalers.
Injection	Injections are sterile, suitable for parenteral use.
Irrigation	A sterile aqueous large volume preparation intended to be used for irrigation of body cavities, wounds and surfaces, for example during surgical procedures.
Irrigation solution	Sterile, aqueous large-volume preparation intended for irrigation of body cavities, wounds and surfaces, for example during surgical procedures. Irrigation solutions are either solutions of (an) active substance(s), electrolytes or osmotically active substances in water for injections or they consist of water for injections as such.
Modified-release	A special process designed to modify the rate or the place at which the active ingredient(s) are released.
Muco-adhesive	Tablet to be applied on mucous surfaces
Nebuliser	Liquid preparations to be converted into aerosols by continuously operating nebulisers or metered-dose nebulisers.
Ophthalmic insert	A sterile, solid or semi-solid preparations of suitable size and shape, designed to be inserted in the conjunctival sac, to produce an ocular effect. It generally consists of a reservoir of active substance embedded in a matrix or bounded by a rate-controlling membrane. The active substance, which is more or less soluble in physiological fluids, is released over a determined period of time.

Ophthalmic strip	Ophthalmic Strips are impregnated with an active substance intended for local application. They are usually individually wrapped and sterile.
Orodispersible	Disperses rapidly in contact with mucous membrane.
Paint	They are intended for application to the skin or, in some cases, mucous membranes. For throat paints and other paints for application to mucous surfaces, these are usually formulated in a liquid of high viscosity such as glycerol to hold the drug at the site of application.
Powder for gastrointestinal liquid	A powder or granules that can be reconstituted to produce a liquid that is administered via the enteral route either to provide sole nutrition or to supplement other food intake. The term covers emulsions, suspensions, and solutions provided for this use case.
Shampoo	Intended for application and subsequent washing away with water. Upon rubbing with water they usually form foam. It includes emulsions, suspensions or solutions.
Spray	For spraying into body cavities or canals. The preparation is supplied in containers with atomising devices or in pressurised containers fitted with a suitable adapter and with or without a metering dose valve. Sprays are usually supplied in multi-dose containers fitted with an appropriate applicator.
Wash	A preparation intended to cleanse the skin or certain mucosal membranes or body cavities or canals.

Table– Routes of administration and definitions (see Appendix VI for comprehensive list)

Routes of administration	Definition
Auricular	Administration of a medicinal product to the ear.
Cutaneous	Administration of a medicinal product to the skin and/or cutaneous wounds and/or nails and/or hair in order to obtain a local effect.
Dental	Administration of a medicinal product to and in the teeth.
Endocervical	Administration of a medicinal product to the cervix uteri.
Endosinusial use	Administration of a medicinal product to the sinuses to obtain a local or systemic effect.
Endotracheopulmonary	Administration of a medicinal product to the trachea and/or bronchiae by instillation (preparations for inhalation are excluded; see inhalation use).
Epidural	Injection of a medicinal product into the epidural space.
Extra-amniotic	Injection of a medicinal product between chorion and amnion.
Gastroenteral	Administration of a medicinal product to the stomach or duodenum by means of an appropriate device.
Gingival	Administration of a medicinal product to the gingivae.
Haemofiltration	Filtering of electrolytes with a concentration similar to that of plasma.
Haemodialysis	Clearance of the blood by means of a semipermeable membrane.
Hair	Application of a product to the hair of the scalp or other part of the body
Inhalation	Administration of a medicinal product to the respiratory system by inhalation to obtain a local effect in the lower respiratory tract. Nasal use and endo-tracheopulmonary use are excluded.
Intraamniotic	Injection of a medicinal product into the amniotic cavity.

Intraarterial	Injection of a medicinal product into an artery.
Intraarticular	Injection of a medicinal product into an articular cavity.
Intrabursal	Injection of a medicinal product into bursae and tendons.
Intracardiac	Injection of a medicinal product into the cardiac muscle and/or cardiac cavity.
Intracavernous	Injection of a medicinal product into the corpus cavernosum.
Intracerebroventricular	Injection of a medicinal product into the ventricular system of the brain.
Intracervical	Injection of a medicinal product into the cervix uteri.
Intracoronary	Injection of a medicinal product into the coronary artery.
Intradermal	Injection of a medicinal product into the dermis.
Intradiscal	Injection of a medicinal product into the nucleous pulposus of an intervertebral disc.
Intraepidermal	Administration of a medicinal product into the epidermis
Intralesional	Administration by injection or any other means of a medicinal product directly to a lesion.
Intralymphatic	Injection of a medicinal product into a lymphatic vessel.
Intramuscular	Injection of a medicinal product into muscular tissue.
Intramuscular-deep	Injection of a medicinal product into deep muscular tissue such as the gluteal muscle.
Intraocular	Injection of a medicinal product into the eye (ocular use and subconjunctival use are excluded).
Intraperitoneal	Injection of a medicinal product into the peritoneal cavity.
Intrapleural	Injection of a medicinal product into the pleural cavity.
Intrasternal	Injection of a medicinal product into the bone marrow of the sternum.
Intrathecal	Injection of a medicinal product through the dura to the subarachnoid cavity.
Intrauterine	Administration of a medicinal product to the cavity of the uterus.
Intravenous	Injection of a medicinal product into a vein.
Intravesical	Administration of a medicinal product to the urinary bladder.
Nasal	Administration of a medicinal product to the nose to obtain a systemic or local effect. Inhalation therapy intended for the lower respiratory tract is excluded; see inhalation use.
Ophthalmic	Administration of a medicinal product upon the eyeball and/or conjunctiva.
Oral	Taking a medicinal product by means of swallowing.
Oromucosal	Administration of a medicinal product to the oral cavity to obtain a local or systemic effect. Oral use is excluded.
Periarticular	Injection of a medicinal product around a joint.
Perineural	Injection of a medicinal product into the direct surroundings of one or more nerves.
Peritoneal	Injection of a medicinal product into the peritoneal cavity.
Rectal	Administration of a medicinal product to the rectum in order to obtain a local or systemic effect.

Regional perfusion	Perfusion of a specific region of the body or organ with a drug by addition of the drug to the isolated blood circulation of the body part or organ.
Route of administration not applicable	Applies to medicinal products not directly coming into contact with the body of the patient, or administration to various or non-specified anatomical sites.
Scalp	Application of a product to the scalp.
Subconjunctival	Injection of a medicinal product underneath the conjunctiva.
Subcutaneous	Injection of a medicinal product directly underneath the skin.
Sublingual	Administration under the tongue
Submucosal rectal	Injection of a medicinal product into the layer of connective tissue situated beneath the mucous membrane that supports the mucosa of the rectum.
Transdermal	Administration of a medicinal product to the skin in order to obtain a local or systemic effect after passing through the skin barrier.
Urethral	Administration of a medicinal product to the urethra.
Vaginal	Administration of a medicinal product to the vaginal.

Appendix V

List C – Virtual Medicinal Product Form

Editorial Policy: VMP form will consist of European Directorate for the Quality of Medicines & HealthCare (EDQM) Standard Terms as amended below. The amendments reduce unnecessary multiplicity of terms and exclude terms where the pharmaceutical form does not reflect the prescribed form, e.g. powder for oral solution will be represented by oral solution.

Note: some forms that feature in Part 3 of SmPCs and used in dm+d may not at the time of authoring feature in EDQM. These are therefore not defined until the time-lag for their inclusion into EDQM has passed. Also if no EDQM form exists, then Health and Social Care Information Centre staff will contact the MHRA to request a new form or term.

Use of concentrate / concentrated terms

The aforementioned terms only feature in the VMP name where they represent part of an Official Name e.g. Anise water concentrated, or in the title of a Generic name VMP e.g. Generic Ceanal Concentrate shampoo.

For VMPs with one of these official names, the coded dose form is always populated as 'not applicable'. Where 'Concentrate' is part of a licensed name of a product, this will be represented in the AMP description only e.g. Dexdor 1mg/10ml concentrate for solution for infusion vials. Sometimes a VMP e.g. Vancomycin 1g powder for solution for infusion vials, has a selection of AMPs attached that differ in whether the licensed names refer to concentrate or not.

Whilst there are an increasing number of EDQM combined terms that use the word 'concentrate' in the name, there is no consistent definition to date of when they would be applied. Until such a time as 'concentrate' is formally defined and approved by the appropriate authorities, the VMP will not use this term other than in the scenarios above.

NHS dm+d Terms (EDQM Terms)	NHS dm+d Definitions	Source of Definitions	Examples (Not inclusive)
Aerosol generator	This is a system that delivers radiolabel led products to the lungs by inhalation for the study of lung functionality. It is a generator powered by compressed gas that delivers aerosols, it does not contain any propellants nor does it contain medicated products.	Adapted	
Bath additive	This covers liquid, solid and semi-solid preparations that are added to the bath water for protective, therapeutic or prophylactic purposes (e.g. for moisturising and cleansing).	Adapted from various sources.	
Bladder irrigation	Sterile, aqueous large volume solutions for bladder irrigation prepared by dissolving one or more substances, electrolytes or osmotically	EDQM Term (based on PhEur	

	active substances in water complying with the requirements for <i>Water for injections</i> .	Monograph No 1116)	
Buccal film	Single or multilayer sheet of suitable material(s) to be applied to the buccal cavity (pouch) to obtain a systematic effect.	EDQM Term	
Buccal tablet	Tablet to be applied to the buccal cavity or to be sucked.	EDQM Term	
Cachet	Solid disc-shaped dosage form made of wafer enclosing a unit-dose for oral use	EDQM Term	
Capsule	A solid preparation with hard or soft shells of various shapes and capacities, usually containing a single dose of active ingredient(s). The capsule shells are made of gelatin or other substance. The contents of capsules may be solid, liquid or of a paste-like consistency. For oral administration, the digestive fluids attack the shell and the contents are released. Capsules can also be formulated for use via a variety of administration routes (e.g. oromucosal, rectal, vaginal) to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes.	EP	Capsules, hard; Capsules, soft; oromucosal capsules; rectal capsules; vaginal capsules
Cement	It is a grout / putty-like substance that penetrates into the interstitial space and achieves mechanical bonding rather than chemical bonding. It does not work like glue as it has no adhesive properties. It is prepared from two separate components one liquid and the other a powder, which have to be mixed into a paste just prior to being applied to the bone surface. The cement may be impregnated with a therapeutic substance	Adapted	Bone cement, Dental cement.
Chewable capsule	Solid single-dose preparation contained in a soft shell. The soft capsule is intended to be chewed to release its contents into the mouth. The contents of the soft shell may be a semi-solid or liquid preparation intended for local action or systemic delivery after absorption through the oral mucosa or, when swallowed, in the gastrointestinal tract.	EDQM Term	
Chewable tablet	An oral preparation designed to be broken down rapidly in the buccal cavity by the action of teeth.	Pharm Codex	
Collodion	Liquid usually containing pyroxylin in a mixture of ether and ethanol. Forms a flexible film at	EDQM Term	

	the site of application.		
Cream	A multiphase preparation consisting of lipophilic phase and an aqueous phase. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes.	Adapted from BP & Pharm Codex. Amended EDQM Term	Cutaneous cream, ear cream, eye cream, nasal cream, rectal cream, vaginal cream
Cutaneous emulsion	Liquid multidose preparation consisting of an emulsion intended for cutaneous use.	EDQM Term	
Cutaneous patch	Flexible single-dose preparation intended to be applied to the unbroken skin to obtain a local effect by penetration of the active substance(s) into the skin.	EDQM Term	
Cutaneous solution	liquid multidose preparation consisting of a solution of the active substance in a vehicle intended for cutaneous use.	EDQM Term	
Cutaneous sponge	Sponge impregnated with an active substance intended for cutaneous use.	EDQM Term	
Dental gel	Semi-solid multidose preparation consisting of a hydrophilic gel intended for administration on teeth and gums by rubbing.	EDQM Term	
Dental insert	Medicated insert to be placed between the gingiva and the tooth (within the tooth socket / periodontal membrane).	Former EDQM Term	Deprecated by the EDQM. See Periodontal insert.
Dental suspension	Liquid, usually multidose preparation consisting of a suspension intended for administration on teeth and gums.	EDQM Term	
Dispersible tablet	Dispersible tablets are uncoated or film-coated tablets intended to be dispersed in water before administration giving a homogeneous dispersion.	EP	
Dispersion for injection	Liquid sterile preparation consisting of two or more phases of which at least one is dispersed in the liquid phase, intended for administration by injection. To be used only when emulsion for injection is not appropriate. Solid suspension preparations are excluded.	EDQM Term	

Drops (Under review)	<p><i>Restricted use e.g. where a product has multiple routes e.g. betamethasone eye/ear/nose drops):</i></p> <p>A solution, emulsion or suspension administered in small volumes such as drops by means of a suitable device. It may contain one or more active substances.</p> <p>The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.</p>	Adapted from BP & Pharm Codex. EDQM Term	For use just where a product has multiple routes
Ear drops	Liquid single-dose or multidose preparation consisting of an aqueous or oily solution, suspension or emulsion intended for application to the external auditory meatus. Multidose containers may be dropper containers or containers provided with a dropper applicator, or the dropper may be supplied separately.	EDQM Term	
Ear/eye/nose drops solution	This term is only to be used in cases where there is not a single predominant route of administration for the medicinal product.	EDQM	
Eye drops	Liquid single-dose or multidose preparation consisting of a sterile aqueous or oily solution, suspension (or emulsion) intended for ocular use. Multidose preparations are presented in containers that allow successive drops to be administered.	Adapted from EDQM	
Nasal drops	Liquid single-dose or multidose preparation consisting of a solution, suspension or emulsion intended for nasal use by means of a suitable applicator.	EDQM Term	
Effervescent granules	Effervescent granules are uncoated granules generally containing acid substances and carbonates or hydrogen carbonates which react rapidly in the presence of water to release carbon dioxide. They are intended to be dissolved or dispersed in water before administration.	EP	
Effervescent powder	Effervescent powders are presented as single-dose or multidose powders and generally contain acid substances and carbonates or hydrogen carbonates which react rapidly in the presence of water to release carbon dioxide. They are intended to be dissolved or dispersed in water before administration.	EP	

Effervescent tablet	Effervescent tablets are uncoated tablets generally containing acid substances and carbonates or hydrogen carbonates which react rapidly in the presence of water to release carbon dioxide. They are intended to be dissolved or dispersed in water before administration.	EP	
Effervescent vaginal tablet	A solid preparation intended for vaginal use. Upon insertion, the active ingredient(s) is released by an effervescent-like reaction between the product and the vaginal fluids.	Adapted from various sources.	
Enema	The term "enema" is used to cover liquid preparations (solutions, emulsions and suspensions) intended for rectal use in order to obtain a systemic or local effect, or for diagnostic purposes. The enema is usually supplied in single-dose containers and contains one or more active substances dissolved or dispersed in water, glycerol or macrogols or other suitable solvents. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.	EP	Rectal solution, Rectal suspension, Rectal emulsion
Ear drops	See under 'drops' above		
Eye drops	See under 'drops' above		
Eye lotion	A sterile aqueous solution intended for use in washing or bathing the eye or for impregnating eye dressings. The term also covers solid and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use.	EP	
Eye ointment	Semi-solid single-dose or multidose preparation consisting of a sterile ointment intended for ocular use. Eye ointments may be presented in collapsible tubes fitted with a cannula and having a content of not more than 5 g of the preparation. Eye ointment may also be presented in suitable designed single-dose containers. The containers or nozzles of tubes are of such a shape to facilitate administration without contamination.	EDQM	
Foam	A foam consists of large volumes of gas dispersed in a liquid and generally contains one or more active substances. It is usually formed at the time of administration from a liquid	Adapted from BP & Pharm Codex. Modified	Cutaneous foam, vaginal foam.

	preparation in a pressurised container. The container is equipped with a device consisting of a valve and a push button suitable for the delivery of the foam.	EDQM Term	
Gargle	An aqueous solution used for gargling. The process of gargling is intended to bring the liquid into intimate contact with membranous lining of the throat. Gargle is different from a <i>Mouthwash</i> in that the latter is used on the mucous membranes of the oral cavity rather than in the throat. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.	Adapted from various sources.	
Gastroenteral liquid	A liquid administered via the enteral route (oral, nasogastric, PEG, jejunostomy etc.) used either to provide sole nutrition or to supplement other food intake. The term covers emulsions, suspensions, and solutions provided for this use case.	EDQM Term	
Gastro-resistant capsule	Gastro-resistant capsules are modified release capsules that are intended to resist the gastric fluid and to release their active ingredient or ingredients in the intestinal fluid. They are prepared by providing hard or soft capsules with a gastro-resistant shell (enteric capsules) or by filling capsules with granules or with particles covered with a gastro-resistant coating.	EP	Gastro-resistant capsule, hard; Gastro-resistant, soft
Gastro-resistant granules	Gastro-resistant granules are delayed-release granules that are intended to resist the gastric fluid and to release the active substance(s) in the intestinal fluid. These properties are achieved by covering the granules with a gastro-resistant material (enteric-coated granules) or by other suitable means.	EP	
Gastro-resistant tablet	Gastro-resistant tablets are delayed-release tablets that are intended to resist the gastric fluid and to release their active substance(s) in the intestinal fluid. Usually they are prepared from granules or particles already covered with a gastro-resistant coating or in certain cases by covering tablets with a gastro-resistant coating (enteric-coated tablets).	EP	

Gel	A semi-solid preparation consisting of liquids gelled by means of suitable gelling agents. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes. The term “gel” can also be used to describe some viscous preparations (e.g. suspensions) for oral use such as aluminium hydroxide gel.	Adapted from BP & Pharm Codex. Modified EDQM Term	Cutaneous gel ear gel, eye gel, nasal gel, oral gel, rectal gel, vaginal gel
Granules	Granules are preparations consisting of solid, dry aggregates of powder particles sufficiently resistant to withstand handling. They are usually intended for oral administration. Some are swallowed as such, some are chewed and some are dissolved or dispersed in water or another suitable liquid before administration. Granules are presented as single-dose or multidose preparations. For administration routes other than oral, granules also provide a convenient dosage form that can be reconstituted to a liquid preparation prior to use (e.g. injections, rectal liquid preparations).	EP	
Herbal material	Solid preparation consisting of whole, broken or fragmented plants or parts of plants. Note: this excludes herbal teas, instant herbal teas as well as preparations that are formulated into capsules, granules or powders which will use the appropriate pharmaceutical dose form.	dm+d Content Committee	
Herbal tea	Herbal teas consist exclusively of one or more herbal drugs intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use. Herbal teas are usually supplied in bulk form or in sachets.	EP	
Homeopathic forms — see towards end of table			
Implant	Implants are sterile, solid preparations of a size and shape suitable for parenteral implantation and release the active substance(s) over an extended period of time. Each dose is provided in a sterile container.	EP	
Implantation suspension	Suspension to be implanted in the body.	EDQM Term	

Impregnated cigarette	A small roll of finely cut substance enclosed in a wrapper of thin paper, injected or impregnated with a medicinal substance for administration by inhalation.	Adapted from various sources.	
Impregnated dressing	A piece or strip of gauze or other suitable fabric, impregnated with a liquid or a semi-solid preparation.	EDQM Term	
Inhalation gas	A compressed, liquefied or dissolved gas with medical use(s)	Adapted from EP and Pharm Codex.	
Inhalation powder	Powders for inhalation are presented as single-dose powders or multidose powders. To facilitate their use, active substances may be combined with a suitable carrier. They are generally administered by dry-powder inhalers. In pre-metered systems, the inhaler is loaded with powders pre-dispensed in capsules or other suitable pharmaceutical forms. For devices using a powder reservoir, the dose is created by a metering mechanism within the inhaler. The delivered dose is the dose delivered from the inhaler. For some preparations, the dose has been established as a metered dose or as a predispensed dose.	EP	Inhalation powder, hard capsule; Inhalation powder, pre-dispensed
Inhalation solution	Liquid, usually multidose preparation consisting of a solution intended for inhalation use. The preparation is presented in a non-pressurised container fitted with a metering dose mechanism 'Nebuliser solution' and 'Pressurised inhalation, solution' are excluded.	EDQM Term	
Inhalation vapour	Preparations intended to be converted into vapour are solutions, dispersions or solid preparations. They are usually added to hot water and the vapour generated is inhaled, but may include products that are available as a vapour ready for inhalation e.g. inhalation anaesthetics.	EP	Inhalation vapour, solution; Inhalation vapour, tablet; Inhalation vapour, ointment; Inhalation vapour, liquid; Inhalation vapour, powder; Inhalation vapour,

			capsule.
Injection forms — see towards end of table			
Instant herbal tea	Instant herbal teas consist of powder or granules of one or more herbal drug preparation(s) intended for the preparation of an oral solution immediately before use.	EP	
Intestinal gel	Semi-solid preparation consisting of a gel intended for intestinal use	EDQM	
Intrauterine device	A device designed to be inserted into the uterus. It may contain an active medicament that is slowly released over a period of time.	EDQM Term	
Intravesical solution	Aqueous solution intended for intravesical use by means of a suitable applicator. Bladder irrigation is excluded. This term replaces 'Solution for intravesical use'.	EDQM Term	
Irrigation (Under review as use of the EDQM term irrigation solution is more widely adopted)	<i>Restricted use</i> A sterile aqueous preparation intended to be used for irrigation of body cavities, wounds and surfaces, for example during surgical procedures. Preparations for irrigation are either solutions prepared by dissolving one or more active substances, electrolytes or osmotically active substances in water or they consist of water alone. Irrigation solutions are usually adjusted to be isotonic with blood. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.	BP	

Irrigation solution	Sterile, aqueous large-volume preparation intended for irrigation of body cavities, wounds and surfaces, for example during surgical procedures. Irrigation solutions are either solutions of (an) active substance(s), electrolytes or osmotically active substances in water for injections or they consist of water for injections as such.	EDQM Term	
Kit for radiopharmaceutical preparation	A preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration. The word radiopharmaceutical may be omitted if there is no ambiguity on the radiopharmaceutical nature of the product. Combinations with other standard terms are not recommended.	EDQM Term	
Liquid	Liquid preparations are usually solutions, emulsions or suspensions containing one or more active substances in a suitable vehicle. They may, however, consist of liquid active substances used as such. They are formulated for use via a variety of administration routes (e.g. cutaneous, oromucosal, rectal, vaginal). The term also includes concentrates which have to be diluted with a suitable liquid before use. Oral emulsions, oral solutions and oral suspensions are not included. Emulsions, solutions and suspensions that are to be given by the oral route are only termed as a liquid if they have additional routes of administration e.g. Barium enemas are suspensions that may be given both orally and rectally — in this scenario the form of liquid will be used.	Adapted from BP and various sources	Cutaneous liquid, Rectal liquid, Vaginal liquid
Living tissue equivalent	Cultured, living tissue used for the reconstitution of parts of the body. The tissue may consist of ex vivo expanded cells with an extracellular matrix. Where appropriate, the tissue of origin, such as epidermis, dermis, cartilage or muscle, will need to be stated elsewhere in the product information.	EDQM Term	
Lozenge	Hard candy to be sucked to obtain a local effect. It can contain one or more active ingredients.	EDQM Term	
Medicated chewing-gum	A solid, single-dose preparation with a base consisting mainly of gum that is intended to be chewed but not swallowed. They contain one	EDQM / EP Term	

	or more active ingredients which are released by chewing over an extended period of time.		
Medicated nail lacquer	Medicated liquid preparations of a variety of viscosities intended to be applied to the nails in order to obtain a local action.	Adapted from various sources	
Medicated plaster	Medicated plasters are flexible preparations containing one or more active substances. They are intended to be applied to the skin. They are designed to maintain the active substance(s) in close contact with the skin such that these may be absorbed slowly or act as protective or keratolytic agents.	EDQM / EP Term	
Modified-release capsule	Modified-release capsules are hard or soft capsules in which the contents or the shell or both contain special excipients or are prepared by a special process designed to modify the rate or the place at which the active ingredient(s) are released.	EP	Modified-release capsule, hard; Modified-release capsule, soft
Modified-released drops	A drop preparation where the rate of release of the active substance(s) is different from that of a conventional release drop preparation administered by the same route. This deliberate modification is achieved by a special formulation design and/or manufacturing method.	Adapted from BP & Pharm Codex. Amended EDQM Term	
Modified-release granules	Modified-release granules are coated or uncoated granules designed to modify the rate, the place or the time at which the active substance or substances are released. Modified-release granules include prolonged-release granules and delayed-release granules.	EP	
Modified-release tablet	Modified-release tablets are coated or uncoated tablets designed to modify the rate, the place or the time at which the active substance(s) are released. Modified-release tablets include prolonged-release tablets, delayed-release tablets, pulsatile-release tablets and accelerated-release tablets.	EP	
Mouthwash	An aqueous solution intended for use in contact with mucous membranes of the oral cavity, usually after dilution with warm water. It can contain one or more active ingredients. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or	EDQM / EP Term	

	diluted using a suitable liquid diluent before use.		
Muco-adhesive buccal tablet	Tablet to be applied on mucous surfaces in the buccal cavity.	EDQM Term	
Nasal drops	See under 'drops' above		
Nasal gel	Semi-solid single-dose or multidose preparation consisting of usually a hydrophilic gel, intended for nasal use to obtain a local effect. Nasal gels are usually presented in tubes fitted with a nasal applicator.	EDQM Term	
Nasal ointment	Semi-solid single-dose or multidose preparation consisting of an ointment, intended for nasal use to obtain a local effect. Nasal ointments are usually presented in tubes fitted with a nasal applicator.	EDQM Term	
Nebuliser liquid	Liquid preparations for inhalation intended to be converted into aerosols by continuously operating nebulisers or metered-dose nebulisers are solutions, suspensions or emulsions. Liquid preparations for nebulisation in concentrated form for use in continuously operating nebulisers are diluted to be prescribed volume with the prescribed liquid before use. Liquids for nebulisation may also be prepared from powders or other forms of solids.	EP	Nebuliser solution, Nebuliser suspension; Nebuliser emulsion
Ointment	A semi-solid preparation consisting of a single-phase basis in which solids or liquids may be dispensed. It is intended to be applied to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes.	Adapted from BP & Pharm Codex. Modified EDQM Term	Cutaneous ointment, Ear ointment, Eye ointment, Nasal ointment, Rectal ointment, Vaginal ointment,
Ophthalmic insert	A sterile, solid or semi-solid preparations of suitable size and shape, designed to be inserted in the conjunctival sac, to produce an ocular effect. It generally consists of a reservoir of active substance embedded in a matrix or bounded by a rate-controlling membrane. The active substance, which is more or less soluble in physiological fluids, is released over a determined period of time.	EP	

Ophthalmic strip	Ophthalmic Strips are impregnated with an active substance intended for local application. They are usually individually wrapped and sterile.	Adapted	
Oral dispersion	A system consisting of 2 or more phases. To be used only when suspension or emulsion are not appropriate.		
Oral drops	Liquid multidose preparation intended for oral use.	EDQM Term	
Oral emulsion	This is a stabilised oil-in-water dispersion, either or both phases of which may contain dissolved solids. Solids may also be suspended in oral emulsions. It can contain one or more active ingredients.	BP	
Oral gel	Semi-solid single-dose or multidose preparation intended for oral use. It consists of a gel, usually hydrophilic, to be swallowed after administration to the oral cavity.	EDQM Term	
Oral gum	Semi-solid preparation with a basis of gum and sugar which is to be sucked or chewed before swallowing. Medicated chewing gum is excluded.	EDQM	
Oral solution	An oral liquid containing one or more active ingredients dissolved in a suitable vehicle. The term also covers powders, granules and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use.	BP	
Oral suspension	An oral liquid containing one or more active ingredients suspended in a suitable vehicle. Suspended solids may slowly separate on standing but are easily redispersed. The term also covers powders, granules and liquid preparations which have to be reconstituted or diluted using a suitable liquid diluent before use.	BP	
Oral lyophilisate	Freeze dried, fast releasing preparation to be placed on the tongue, or alternatively to be dissolved in water before administration.	EDQM Term	
Orodispersible film	Single or multilayer sheet of suitable material(s) to be placed in the mouth where it disperses rapidly before being swallowed	EDQM	
Orodispersible tablet	Tablet to be placed in the mouth where it disperses rapidly before swallowing.	EDQM Term	

Oromucosal gel	Semi-solid single-dose or multidose preparation consisting of a hydrophilic gel intended for oromucosal use. It is applied to the oral cavity or onto a specific part of the oral cavity, to obtain a local effect. Gingival gel is excluded.	EDQM Term	
Oromucosal solution	Liquid multidose preparation consisting of a solution intended for oromucosal use.	EDQM Term	
Paint	Solutions or dispersions of one or more active ingredients. They are intended for application to the skin or, in some cases, mucous membranes. For throat paints and other paints for application to mucous surfaces, these are usually formulated in a liquid of high viscosity such as glycerol to hold the drug at the site of application.	Adapted from BP and Pharm Codex Not a EDQM Term	
Paste	A semi-solid preparation that is much stiffer than ointments. It usually consists of finely ground insoluble powders (at concentrations of 20% to 60%) dispersed in hydrocarbon or water-miscible bases. It can contain one or more active ingredients and is intended to be used for protective, therapeutic or prophylactic purposes.	Adapted from Pharm Codex. Modified EDQM Term	Oral paste, Toothpaste
Pastille	A medicinal preparation containing gelatine and glycerine, usually coated with sugar. It is intended to be dissolved in the mouth so that the medication is applied to the mouth or throat. It can contain one or more active substances.	Adapted from various sources. Not a EDQM Term	
Periodontal insert	Solid single-dose preparation consisting of a medicated insert to be placed within the tooth socket/periodontal membrane. The biodegradable insert is a sheet which slowly releases active substance(s).	EDQM Term	
Pessary	Moulded pessary. Pessaries are solid, single-dose preparations. They have various shapes, usually ovoid, with a volume and consistency suitable for insertion into the vagina. They contain one or more active substances dispersed or dissolved in a suitable basis that may be soluble or dispersible in water or may melt at body temperature. They can be used to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes.	EP	

Poultice	A hydrophilic, heat-retentive basis in which solid or liquid active substances are dispersed. It is usually spread thickly on a suitable dressing and heated before application to the skin.	EP	
Powder	A preparation consisting of solid, loose, dry particles of varying degrees of fineness. It can contain one or more active ingredients and is intended to be used for protective, therapeutic or prophylactic purposes. The term “powders” can be used to describe a solid dosage form (e.g. oral powders or dusting powders) or as a convenient dosage form which can be reconstituted to be a liquid preparation prior to use (e.g. rectal liquid preparations).	Adapted from various sources. Modified EDQM Term	Ear powder, Cutaneous powder
Powder and gel for gel	Powder and gel intended for the preparation of a gel (for cutaneous use) by mixing the powder in the gel.	EDQM Term	
Note that for powder forms that relate to either infusions or injections please see under the ‘Infusion Forms’ and the ‘Injection Forms’ sections.			
Powder and solvent for intravesical solution	Powder (including freeze-dried powder) and solvent intended for the preparation of an intravesical solution by dissolving the powder in the solvent.	EDQM Term	
Powder and solvent for nebuliser solution	Powder and solvent that when combined are intended for inhalation use.	EDQM Term	
Powder and solvent for solution for instillation	See the note before the start of the table		
Powder and solvent for solution for intraocular irrigation	See the note before the start of the table		
Powder and solvent for suspension for instillation	See the note before the start of the table		
Powder for gastroenteral liquid	A powder or granules that can be reconstituted to produce a liquid that is administered via the enteral route either to provide sole nutrition or to supplement other food intake. The term covers emulsions, suspensions, and solutions provided for this use case.		
Powder for intravesical solution	Solid preparation consisting of one or more powders, including freeze-dried powders, intended to be dissolved in the specified liquid to obtain an	EDQM Term	

	intravesical solution.		
Powder for nebuliser solution	Solid preparation intended for administration as an aerosol (dispersion of solid or liquid particles in a gas) to the lung to obtain a local or systemic effect. The powder may contain one or more active substance to be dissolved or dispersed in a suitable vehicle.	EDQM Term based on PhEur Monograph No 671	
Powder for oral solution	Conforms to the PhEur Monograph on Oral powders. They may contain excipients in particular to facilitate dispersion or dissolution and to prevent cracking. After dissolution or suspension, they comply with the requirements for oral solutions.	EDQM Term based on PhEur Monograph No 672	
Powder for solution for iontophoresis	Solid preparation consisting of a powder intended to be dissolved in the specified liquid to create a solution for iontophoresis. Freeze-dried powders are included.	EDQM Term	
Powder for reconstitution for instillation	A sterile or non-sterile solid (powder or granules) that is reconstituted with a solvent or diluent to produce a solution, suspension, dispersion or emulsion for instillation into a body cavity. This is different from an irrigation in that the resulting 'solution' is left in situ for a given period of time.	Adapted	
Pressurised inhalation	Pressurised metered-dose preparations for are solutions, suspensions or emulsions supplied in special containers equipped with a metering valve and which are held under pressure with suitable propellants or suitable mixtures of liquefied propellants, which can also act as solvents. The delivered dose is the dose delivered from the inhaler to the patient. For some preparations, the dose has been established as a metered dose.	EP	Pressurised inhalation, solution; Pressurised inhalation, suspension; Pressurised inhalation, emulsion
Radionuclide generator	This is a system incorporating a fixed parent radionuclide from which is produced a daughter nuclide which is removed by elution and suitable for injection or preparation of radio-labelled products.	BP	
Rectal foam	See definition of foam and also PhEur Monograph No: 1145	EDQM Term	
Rectal ointment	Semi-solid preparation consisting of an ointment usually presented in a single-dose container provided with a suitable applicator. Rectal ointments are intended for rectal use to obtain a local effect.	EDQM Term	

Shampoo	This covers liquid or, occasionally semi-solid preparations intended for application to the scalp and subsequent washing away with water. Upon rubbing with water they usually form a foam. It includes emulsions, suspensions or solutions.	EP	
Soluble tablet	Soluble tablets are uncoated or film-coated tablets. They are intended to be dissolved in water before administration. The solution produced may be slightly opalescent due to the added excipients used in the manufacture of the tablets.	EP	
Solution for blood fraction modification	Liquid sterile preparation consisting of a solution intended for use in extracorporeal modification of a blood fraction that is returned to the patient following modification.	EDQM Term	
Solution for cardioplegia	Sterile preparation consisting of an aqueous solution intended to be used for inducing cardiac arrest during heart surgery. Some preparations may require mixing with other preparations prior to administration, for example to adjust the pH.	EDQM Term	
Solution for haemofiltration	Sterile aqueous solution intended for parenteral use. The solution contains electrolytes with a concentration close to the electrolytic composition of plasma. Glucose may be included.	EDQM Term	
Solution for iontophoresis	Solid preparation consisting of a powder intended to be dissolved in the specified liquid to create a solution for iontophoresis. Freeze-dried powders are included.	EDQM Term	
Solution for peritoneal dialysis	Sterile aqueous solution intended for intraperitoneal use. The solution contains electrolytes with a concentration close to the electrolytic composition of plasma and glucose in varying concentrations or other suitable osmotic agents.	EDQM Term	
Solution for sealant	Solution more or less viscous preparation intended for use as tissue glue.	EDQM Term	
Solution for skin prick test	Allergen product for cutaneous and transdermal diagnostic use.	EDQM Term	
Solvent for BCG Vaccine AJV	Solvent for <i>AJV</i> Vaccines Bacillus Calmette-Guerin (BCG) Vaccine	SmPC	
Spray	Solutions, emulsions or suspensions of one or more active substances in liquids intended for spraying into body cavities or canals. The preparation is supplied in containers with atomising devices or in pressurised containers	EP	Ear spray, solution; Ear spray, suspension; Ear spray,

	fitted with a suitable adapter and with or without a metering dose valve. Sprays are usually supplied in multi-dose containers fitted with an appropriate applicator.		emulsion
Sterile solution	<i>Restricted use:</i> A sterile apyrogenic solution suitable for injection but not injected directly into the patient. The solutions are used for in vitro mixing with other sterile substance prior to injection and are used in the preparation of Radiopharmaceuticals	Adapted	
Stick	Sticks for medical uses are solid preparations intended for local application. They are rod-shaped or conical preparations consisting of one or more active substances alone or which are dissolved or dispersed in a suitable basis which may dissolve or melt at body temperature. Urethral sticks and sticks for insertion into wounds are sterile.	Adapted from EP. Modified EDQM Term	Dental stick
Sublingual spray	Solution to be sprayed under the tongue.	EDQM Term	
Sublingual tablet	Tablet intended to be held under the tongue	Pharm. Codex	
Suppository	A solid, single-dose preparation with a shape, volume and consistency suitable for rectal administration. It contains one or more active substances dispersed or dissolved in a suitable basis which may be soluble or dispersible in water or may melt at body temperature. It can be used to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes.	EP	
Tablet	Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volume of particles. For oral administration, this term is used to cover both uncoated and coated tablets as well as film-coated tablets. The excipients used are not specifically intended to modify the release of the active substance in the digestive fluids. Tablets can also be formulated for use via other administration routes (e.g. vaginal) to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes.	EP	Coated tablet, film-coated tablet
Tablet for cutaneous solution	Tablet to be made into a solution for cutaneous use only		

Tampon	A solid dosage form intended to be used to plug a cavity or canal in order to absorb blood or secretions or to deliver active substance(s) to obtain a systemic or local effect for protective, therapeutic or prophylactic purposes. Medicated tampons are intended to be inserted for a limited time and usually consist of a suitable material such as cellulose, collagen or silicone impregnated with one or more active substances.	Adapted from various sources. Modified EDQM Term	Ear tampon, rectal tampon, medicated vaginal tampon.
Transdermal patch	Transdermal patches are flexible pharmaceutical preparations of varying sizes, containing one or more active substances. They are intended to be applied to the unbroken skin in order to deliver the active substance(s) to the systemic circulation after passing through the skin barrier.	EP	
Transdermal system	Assembly of components intended for transdermal delivery driven by external forces (e.g. electric current, chemical reaction). Transdermal patch is excluded.	EDQM Term	
Vaginal delivery system	Drug delivery system intended to be inserted in the vagina where it releases its contents over an extended period of time. Note: vaginal sponge and medicated vaginal tampon are excluded.	EDQM Term	
Vaginal device	Vaginal insert intended to release its content over extended period of time.	EDQM Term	
Vaginal gel	Semi-solid preparation consisting of a gel usually presented in a single-dose container provided with a suitable applicator. Vaginal gels are intended for vaginal use to obtain a local effect.	EDQM Term	
Vaginal sponge	Sponge impregnated with an active substance intended for vaginal use.	EDQM Term	
Wash	A preparation intended to cleanse the skin or certain mucosal membranes or body cavities or canals. It is usually an aqueous solution with a pH within physiological limits. The term also covers solid and liquid preparations which have to be dissolved or reconstituted or diluted using a suitable liquid diluent before use.	EP	Ear wash, solution; Ear wash, emulsion
Not applicable	Applies to products where it is not possible to assign a form in particular combination products where there is a mixture of forms e.g. tablets and capsules or cream and pessaries.		
HOMEOPATHIC FORMS:			
Homeopathic Cream	A preparation for application to the skin consisting		

	of a lipophilic phase and an aqueous phase in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. The concentration of homeopathic ingredient is not defined by a pharmacopoeia and may vary by manufacturer and/or prescriber.		
Homeopathic Crystals	Solid preparations composed of sucrose, resembling granulated sugar and intended for oral or sublingual use. Coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies and usually administered by measuring the prescribed amount of crystals as a dose. Sometimes dispensed in a single dose sachet, similar to homeopathic oral powder.		
Homeopathic Drops	Liquid dosage form, composed of a low strength alcohol solution (typically 15-30%) in purified water combined with the high strength alcohol preparation of one or more homeopathic potencies. Intended for oral use, directly or in water, via a dropper mechanism contained within the bottle. Also sometimes termed 'homeopathic liquid potency'.		
Homeopathic Elixir	A viscous liquid preparation, composed of a honey or syrup base in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. Intended for oral use in the treatment of coughs and acute throat pain. Sometimes termed 'homeopathic linctus'.		Homeopathic Elixir, Homeopathic Linctus
Homeopathic Eye Drops	A sterile solution containing a homeopathic dilution intended to be applied to the eye by means of a suitable dropper mechanism.		
Homeopathic Gel	A semi-solid preparation for application to the skin consisting of liquids gelled by means of a suitable gelling agent in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. The concentration of homeopathic ingredient is not defined by a pharmacopoeia and may vary by manufacturer and/or prescriber.		
Homeopathic Granules	Very small solid spherical preparations composed of sucrose, lactose or a compound of the two		

	intended for oral or sublingual use. Coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies and usually administered by measuring the prescribed amount of granules as a dose. Size and composition are not defined by a pharmacopoeia and may vary by manufacturer. Sometimes dispensed in a single dose sachet, similar to homeopathic oral powder.		
Homeopathic Injection	A sterile solution, presented in an ampoule, containing a homeopathic dilution or appropriately prepared aqueous plant extract intended for parenteral use.		
Homeopathic Liniment	An oil based preparation for application to the skin in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. The concentration of homeopathic ingredient is not defined by a pharmacopoeia and may vary by manufacturer and/or prescriber.		
Homeopathic Liquid Potency	Liquid dosage form, composed of a low strength alcohol solution (typically 15-30%) in purified water combined with the high strength alcohol preparation of one or more homeopathic potencies. Intended for oral use, directly or in water. When used via a dropper mechanism contained within the bottle termed 'homeopathic drops'.		
Homeopathic Lotion	An aqueous preparation for application to the skin in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. The concentration of homeopathic ingredient is not defined by a pharmacopoeia and may vary by manufacturer and/or prescriber.		
Homeopathic Mother Tincture	Alcoholic primary plant extract, where applicable prepared to the standards of a national homeopathic pharmacopoeia. Forms the basis for preparation of subsequent potencies of a homeopathic remedy by the process of potentisation. The mother tincture may also be a medicinal product in its own right to be used as an external application to the skin. Diluted in water, a mother tincture may also be used for direct oral		

	administration or as a gargle/mouthwash.		
Homeopathic Ointment	A semi-solid single-phase preparation for application to the skin in which may be dispersed one or more homeopathic mother tinctures or high strength alcohol preparations of a homeopathic potency to the required concentration. The concentration of homeopathic ingredient is not defined by a pharmacopoeia and may vary by manufacturer and/or prescriber.		
Homeopathic Oral Powder	A solid preparation composed of lactose and intended for oral (directly or dissolved in water) or sublingual use. The appropriate amount of powder is coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies and enclosed in a paper sachet to form a single dose unit.		
Homeopathic Oral Solution	Liquid dosage form, composed of a low strength alcohol solution (typically 10%) in purified water combined with the high strength alcohol preparation of one or more homeopathic potencies intended for direct oral use.		
Homeopathic Pillules	Sometimes termed 'pills' or 'globules', these are spherical solid dose unit preparations composed of sucrose, lactose or a compound of the two intended for oral or sublingual use. Coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies. Size and composition are not defined by a pharmacopoeia and may vary by manufacturer.		
Homeopathic Soft Tablets	Solid dosage form preparations, composed of a loose aggregate of lactose, intended to dissolve readily when administered by the oral or sublingual routes. Coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies. Size and composition are not defined by a pharmacopoeia and may vary by manufacturer.		
Homeopathic Tablets	Solid dose unit preparations, typically white and biconvex in nature, composed of lactose or a compound of lactose/sucrose intended for oral or sublingual use. Usually prepared by compression of a uniform volume of the excipients and then coated ('medicated') with a high strength alcohol preparation of one or more homeopathic potencies, although an alternative method of		

	preparation exists whereby homeopathic granules are medicated and then compressed to form the tablets. Size and composition are not defined by a pharmacopoeia and may vary by manufacturer.		
Homeopathic Medicating Potency	Liquid form of a remedy, composed of a high strength alcohol solution (typically 70-96%) in purified water, used to prepare the final dosage form of a homeopathic medicine by the process of 'medicating'. Not for administration as a medicine.		
INFUSION FORMS			
Emulsion for infusion	An emulsion for infusion is a sterile emulsion suitable for parenteral use.	EDQM Term	
Infusion	A sterile solution, suspension or emulsion intended for infusion.	EDQM Term	
Powder and solvent for solution for infusion	A powder and solvent for solution for injection is a solid, sterile substance distributed in its final container with a specified volume of a specific sterile liquid or solvent. When shaken together it rapidly forms a clear solution. After dissolution it complies with the requirements for infusions. Freeze-dried products for parenteral use are considered as powder and solvent for solution for infusion.	EDQM Term	
Powder and solvent for suspension for infusion	See the note before the start of the table		
Powder for dispersion for infusion	Solid sterile preparation consisting of one or more powders, including freeze-dried powders, intended to be dispersed in the specified liquid to obtain a dispersion for infusion.	EDQM Term	
Powder for solution for infusion	A powder for solution for infusion is a solid, sterile substance distributed in its final container and which, when shaken with the prescribed volume of a prescribed sterile liquid rapidly forms a clear solution. After dissolution it complies with the requirements for infusions. Freeze-dried products for parenteral use are considered as powders for solution for infusion.	EDQM Term	
Powder for suspension for infusion	Similar to 'Powder for solution for infusion' except this is a suspension	Adapted	
Solution for infusion	A solution for infusion is a sterile solution suitable for parenteral use.	EDQM Term	

Suspension for infusion	Similar to 'Solution for infusion' except this is a suspension	EDQM combined term	
Obsolete – Intravenous infusion	This form has now been superseded by the injection forms above		
INJECTION FORMS*			
Concentrate and solvent for solution for injection	Sterile concentrate and sterile solvent intended for the preparation of a solution for injection by diluting the concentrate with the solvent.	EDQM Term	
Emulsion for injection	An emulsion for injection is a sterile emulsion suitable for parenteral use.	EDQM Term	
Gel for injection	Sterile single-dose preparation consisting of a hydrophilic gel intended for injection into a specific tissue or organ.	EDQM Term	
Powder and solvent for dispersion for injection	A powder and solvent for dispersion for injection is a solid, sterile substance distributed in its final container with a specified volume of a specific sterile liquid or solvent. When shaken together it rapidly forms dispersion. A dispersion is a system consisting of two or more phases, and is used only when suspension and emulsion are not appropriate.	Adapted from EDQM	
Powder and solvent for prolonged-release suspension for injection	Sterile powder (including freeze-dried powder) and sterile solvent intended for the preparation of a prolonged-release suspension for injection by dispersing the powder in the solvent.	EDQM Term	
Powder and solvent for solution for injection	A powder and solvent for solution for injection is a solid, sterile substance distributed in its final container with a specified volume of a specific sterile liquid or solvent. When shaken together it rapidly forms a clear solution. After dissolution it complies with the requirements for injections. Freeze-dried products for parenteral use are considered as powder and solvent for solution for injection	EDQM Term	
Powder and solvent for suspension for injection	A powder and solvent for suspension for injection is a solid, sterile substance distributed in its final container with a specified volume of a specific sterile liquid or solvent. When shaken together it rapidly forms a suspension. After dissolution it complies with the requirements for injections. Freeze-dried products for parenteral use are considered as powder and solvent for suspension for injection	EDQM Term	

Powder and suspension for suspension for injection	A powder and suspension, plus see the definition for suspension for injection below.	EDQM combined term	
Powder for injection	<i>Restricted use:</i> The EDQM Short term of powder for injection is to be used only when the powder may be reconstituted to produce a solution or a suspension depending upon the volume of solvent added. Example Zinacef injection where you produce a suspension for IM use or a solution for IV use by adding a different volume of solvent.	EDQM Term	
Powder for solution for injection	A powder for solution for injection is a solid, sterile substance distributed in its final container and which, when shaken with the prescribed volume of a prescribed sterile liquid rapidly forms a clear solution. After dissolution it complies with the requirements for injections. Freeze-dried products for parenteral use are considered as powders for solution for injection.	EDQM Term	
Powder for suspension for injection	A powder for suspension for injection is a solid, sterile substance distributed in its final container and which, when shaken with the prescribed volume of a prescribed sterile liquid rapidly forms a uniform suspension. After suspension it conforms to the requirements for injections. Freeze-dried products for parenteral use are considered as powders for suspension for injection.	EDQM Term	
Prolonged-release solution for injection	Liquid sterile preparation consisting of a solution intended for administration by injection; the active substance(s) are released over an extended period of time.	EDQM Term	
Prolonged-release suspension for injection	Liquid sterile preparation consisting of a suspension intended for administration by injection; the active substance(s) are released over an extended period of time.	EDQM Term	
Solution for dispersion for injection	A solution for dispersion for injection is a sterile solution that when shaken rapidly forms a dispersion suitable for injection or infusion. A dispersion is a system consisting of two or more phases, and is used only when suspension and emulsion are not appropriate.	Adapted	
Solution for injection	A solution for injection is a sterile solution suitable for parenteral use.	EDQM Term	

Suspension and emulsion for injection	Combination of appropriate 'suspension' and 'emulsion' type terms within this 'injection' section.	Combined EDQM term	
Suspension for injection	A suspension for injection is a sterile suspension suitable for parenteral use.	EDQM Term	
Obsolete - Injection	This form has now been superseded by the injection forms above		

Clarification of forms

Preparations by EDQM Routes	EDQM Standard Terms for Forms	Route	Proposed dm+d Forms
Oral Preparations	Powder for syrup	Oral	Oral solution or oral suspension (product specific)
Oral Preparations	Granules for syrup	Oral	Oral solution or oral suspension (product specific)
Oral Preparations	Powder for oral solution*	Oral	Oral solution
Oral Preparations	Powder for oral suspension	Oral	Oral suspension
Oral Preparations	Granules for oral solution	Oral	Oral solution
Oral Preparations	Granules for oral suspension	Oral	Oral suspension
Oral Preparations	Powder and solvent for oral solution	Oral	Oral solution
Oral Preparations	Powder and solvent for oral suspension	Oral	Oral suspension
Oromucosal and gingival preparations	Concentrate for gargle	Oromucosal, gingival, dental	Gargle
Oromucosal and gingival preparations	Gargle, powder for solution	Oromucosal, gingival, dental	Gargle
Oromucosal and gingival preparations	Gargle, tablet for solution	Oromucosal, gingival, dental	Gargle
Oromucosal and gingival preparations	Mouth wash, tablet for solution	Oromucosal	Mouthwash
Cutaneous & transdermal preparations	Concentrate for cutaneous solution	Cutaneous	Liquid
Eye preparations	Eye lotion, solvent for reconstitution	Ocular	Eye lotion
Eye preparations	Eye drops, powder and solvent for solution	Ocular	Drops

Eye preparations	Eye drops, powder and solvent for suspension	Ocular	Drops
Eye preparations	Eye drops, solvent for reconstitution	Ocular	Drops
Rectal preparations	Concentrate for rectal solution	Rectal	Liquid
Rectal preparations	Powder for rectal solution	Rectal	Liquid
Rectal preparations	Powder for rectal suspension	Rectal	Liquid
Rectal preparations	Tablet for rectal solution	Rectal	Liquid
Rectal preparations	Tablet for rectal suspension	Rectal	Liquid
Preparations for inhalation	Powder for nebuliser suspension	Inhalation	Nebuliser liquid
Preparations for inhalation	Powder for nebuliser solution	Inhalation	Nebuliser liquid
* It is intended that the medicine be reconstituted prior to use by the patient.			

Appendix VI

List D – Virtual Medicinal Product Route

Editorial Policy: VMP route will consist of EDQM Standard Terms as amended below.

Routes of administration	Definition
Auricular	Administration of a medicinal product to the ear.
Body cavity use	Administration of a medicinal product to non-specified anatomical sites. This route is primarily intended for use with contrast media.
Buccal REPLACED Oromucosal Buccal summer 2015	Administration of a medicinal product to the buccal cavity (pouch located between the cheek and the gum) to obtain a systemic effect.
Cutaneous	Administration of a medicinal product to the skin and/or cutaneous wounds and/or nails and/or hair in order to obtain a local effect.
Dental	Administration of a medicinal product to and in the teeth.
Endocervical	Administration of a medicinal product to the cervix uteri.
Endosinusial	Administration of a medicinal product to the sinuses to obtain a local or systemic effect.
Endotracheopulmonary	Administration of a medicinal product to the trachea and/or bronchiae by instillation (preparations for inhalation are excluded; see inhalation use).
Epidural	Injection of a medicinal product into the epidural space.
Epileisional	Administration of a medicinal product into a lesion.
Extra-amniotic	Injection of a medicinal product between chorion and amnion.
Gastroenteral	Administration of a medicinal product to the stomach or duodenum by means of an appropriate device.
Gingival	Administration of a medicinal product to the gingivae.
Haemodialysis	Clearance of the blood by means of a semipermeable membrane.
Haemofiltration	Clearance of the blood by the use of a positive hydrostatic pressure across a semi-permeable membrane and the use of replacement fluid.
Inhalation	Administration of a medicinal product to the respiratory system by inhalation to obtain a local or a systemic effect in the lower respiratory tract. Nasal use and endo-tracheopulmonary use are excluded.
Intestinal	Administration of a medicinal product to the intestine (duodenum, jejunum, ileum and colon) by means of an appropriate device. Gastrointestinal use is excluded.
Intraamniotic	Injection of a medicinal product into the amniotic cavity.
Intraarterial	Injection of a medicinal product into an artery.
Intraarticular	Injection of a medicinal product into an articular cavity.
Intrabursal	Injection of a medicinal product into bursae and tendons.
Intracameral	Administration of a medicinal product directly into the anterior chamber of

	the eye
Intracardiac	Injection of a medicinal product into the cardiac muscle and/or cardiac cavity.
Intracavernous	Injection of a medicinal product into the corpus cavernosum.
Intracerebroventricular	Injection of a medicinal product into the ventricular system of the brain.
Intracervical	Injection of a medicinal product into the cervix uteri.
Intracoronary	Injection of a medicinal product into the coronary artery.
Intradermal	Injection of a medicinal product into the dermis.
Intradiscal	Injection of a medicinal product into the nucleous pulposus of an intervertebral disc.
Intraductal	Injection or instillation of a medicinal product into a duct.
Intraepidermal	Administration of a medicinal product into the epidermis.
Intraglandular	Administration of a medicinal product directly into a gland, usually by injection. Only to be used where more specific terms such as 'Intraprostatic use' and 'Intramammary use' do not apply.
Intralesional	Administration by injection or any other means of a medicinal product directly to a lesion.
Intralymphatic	Injection of a medicinal product into a lymphatic vessel.
Intramuscular	Injection of a medicinal product into muscular tissue.
Intraocular	Injection of a medicinal product into the eye (ocular use and subconjunctival use are excluded).
Intraosseous	Administration of a medicinal product into the bone
Intraperitoneal	Injection of a medicinal product into the peritoneal cavity.
Intrapleural	Injection of a medicinal product into the pleural cavity.
Intrasternal	Injection of a medicinal product into the bone marrow of the sternum.
Intrathecal	Injection of a medicinal product through the dura to the subarachnoid cavity.
Intratumoral	Injection of a medicinal product into a tumor.
Intrauterine	Administration of a medicinal product to the cavity of the uterus.
Intravenous	Injection of a medicinal product into a vein.
Intraventricular cardiac	Injection of a medicinal product into a cardiac ventricle.
Intravesical	Administration of a medicinal product to the urinary bladder.
Intravitreal	Administration of a medicinal product into the rear chamber of the eye.
Iontophoresis	Introduction of (an) ionised active substance(s) through the intact skin by application of a direct electric current
Nasal	Administration of a medicinal product to the nose to obtain a systemic or local effect. Inhalation therapy intended for the lower respiratory tract is excluded; see inhalation use.

Ocular	Administration of a medicinal product upon the eyeball and/or conjunctiva.
Oral	Taking a medicinal product by means of swallowing.
Oromucosal	Administration of a medicinal product to the oral cavity to obtain either a systemic or a local effect. The term oromucosal is only for use when a more specific term (e.g. buccal, gingival, sublingual...) does not apply. Oral use is excluded.
Oromucosal Buccal Was REPLACED summer 2015 by Buccal	Administration of a medicinal product to the buccal cavity to obtain a local or systemic effect. Oral use is excluded.
Oromucosal Sublingual Was REPLACED summer 2015 by Sublingual	Administration of a medicinal product under the tongue to obtain a local or systemic effect. Oral use is excluded.
Oromucosal Other Was REPLACED summer 2015 by Oromucosal	Administration of a medicinal product to the oral cavity to obtain a local or systemic effect. Sublingual use and buccal use are excluded. Oral use is also excluded.
Periarticular	Injection of a medicinal product around a joint.
Perineural	Injection of a medicinal product into the direct surroundings of one or more nerves.
Rectal	Administration of a medicinal product to the rectum in order to obtain a local or systemic effect.
Regional perfusion	Perfusion of a specific region of the body or organ with a drug by addition of the drug to the isolated blood circulation of the body part or organ.
Route of administration not applicable	Applies to medicinal products not directly coming into contact with the body of the patient, or administration to various or non-specified anatomical sites.
Subconjunctival	Injection of a medicinal product underneath the conjunctiva.
Subcutaneous	Injection of a medicinal product directly underneath the skin
Sublingual REPLACED Oromucosal Sublingual summer 2015	Administration of a medicinal product under the tongue to obtain a systemic effect.
Submucosal rectal	Injection of a medicinal product into the layer of connective tissue situated beneath the mucous membrane that supports the mucosa of the rectum.
Transdermal	Administration of a medicinal product to the skin in order to obtain a local or systemic effect after passing through the skin barrier.
Urethral	Administration of a medicinal product to the urethra.
Vaginal	Administration of a medicinal product to the vaginal.
Obsolete - Intraventricular	Superseded route replaced by more specific routes

Appendix VII

List E – Units of Measure

Editorial Policy: Units Of Measure are used in several places within the Drug Dictionary. They are used to quantify the value of the strength of active ingredient and excipient (if necessary) at VMP and AMP level respectively and at VMPP and AMPP level to indicate the amount of VMP within a container e.g. Quantity = 28, Unit of Measure = Tablet.

SI units will be used where appropriate at VMP and AMP level, descriptive terms as listed below will be used at VMPP and AMPP level. As far as is practicable the descriptive terms will be a subset of the form terms.

Unit of measure	Definition
Application	application
cm	centimetre
elastomeric device/ml	
GBq	gigabecquerel
GBq/ml	gigabecquerel/millilitre
g/actuation	gram/actuation
g/application	gram/application
g/dose	gram/dose
g/l	gram/litre
g/ml	gram/millilitre
gram	gram
gram/gram	
HEP	Histamine Equivalent in Prick testing
hour	
iu	international units
iu/g	international units/gram
iu/mg	international units/milligram
iu/ml	international units/millilitre
Kallikrein inactivator unit	
Kallikrein inactivator units/ml	
kBq	kilobecquerel
kBq/ml	kilobecquerel/millilitre
Kg	kilogram
kg/l	kilogram/litre
Litre	
M	metre

MBq	megabecquerel
MBq/ml	megabecquerel/millilitre
mega unit	mega units
mega unit/ml	mega units/millilitre
mg	milligram
mg/16 hours	milligram/16hours
mg/24 hours	milligram/24hours
mg/72 hours	milligram/72hours
mg/actuation	milligram/actuation
mg/application	milligram/application
mg/dose	milligram/dose
mg/g	milligram/gram
mg/kg	milligram/kilogram
mg/l	milligram/litre
mg/mg	milligram/milligram
mg/ml	milligram/millilitre
mg/square cm	milligram/square centimetre
microgram	
micrograms/24 hours	
micrograms/72 hours	
micrograms/actuation	microgram/actuation
micrograms/dose	
micrograms/g	microgram/gram
micrograms/hour	
micrograms/ml	microgram/millilitre
micrograms/square cm	
microlitre	
110icromole110/g	110icromole110/gram
110icromole110/ml	
Micromole	
110icromole/ml	
million plaque forming units/ml	
ml	millilitre
ml/gram	
ml/kg	millilitre/kilogram
ml/l	millilitre/litre

ml/ml	millilitre/millilitre
mm	millimetre
mmol	millimole
mmol/litre	millimole/litre, millimolar, mM
mmol/ml	millimole/millilitre
mol/l	mole/litre
molar	
nanogram	
nanograms/ml	nanogram/millilitre
nanolitre	
nanolitre/ml	
pack	applied to combination products with different component dose forms
%v/w	percentage volume in weight
%w/v	percentage weight in volume
%w/w	Percentage weight in weight
ppm	parts per million
SQ-T	Standardised Quality units Tablet
square cm	
teragenome copies/ml	
tuberculin unit	
tuberculin units/ml	
unit	units
unit/actuation	
unit dose	units
unit/drop	
unit/gram	
unit/mg	
unit/ml	unit/millilitre
unit/square cm	
vector genome/ml	
v/v	volume/volume
Obsolete – mM	

Unit of measure	
actuation	multipack
ampoule	nebule
applicator	million plaque forming units
bag	needle
baguette	no value
bandage	pack
bar	pad
blister	pastille
bottle	patch
can	pessary
capsule	piece
carton	pillule
cartridge	pizza base
catheter	plaster
cell	pot
cigarette	pouch
component	pre-filled disposable injection device
container	roll
cup	sachet
cycle	scoop
cylinder	spoonful
device	stocking
disc	straw
dose	strip
dose step	suppository
dressing	suture
dual dose sachet	swab
enema	syringe
elastomeric device	system
film	tablet
generator	teragenome copies
glove	truss
kit	tube
lancet	unit dose
larva	vector genome
loaf	vial
lozenge	week supply

month supply	

Appendix VIII

List F 1 – Actual Medicinal Product Manufacturer

Editorial Policy: the list of manufacturers / suppliers will be as inclusive as possible to meet the range of products included in the dictionary. The inclusivity of the list will be maintained only if the manufacturers / suppliers regularly provide data to the dictionary maintainer. SNOMED codes will be used as identifiers and where possible SNOMED Clinical Terms (CT) will be utilised.

Appendix IX

List G – Actual Medicinal Product Flavours

Editorial Policy: The list of flavours used to populate the dictionary will be derived from product descriptions provided by the manufacturer / supplier.

Flavour	
All day scramble	Lemon & lime
Almond	Lemon menthol
Aniseed	Mango
Apple	Mango & passion fruit
Apple & blackcurrant	Melon
Apple and pear	Menthol
Apricot	Minestrone
Apricot-peach	Mint
Asparagus	Mixed berries
Balsamic herb	Mixed fruit
Banana	Mocha
Beef & tomato	Mushroom
Berries	Natural
Berry burst	Neutral
Berry fruit	Nut
Biscuit	Onion
Blackcurrant	Onion & chive
Blackcurrant & apple	Orange
Butterscotch	Orange crème
Cabbage and bacon	Orange honey
Cappuccino	Orange & lemon
Caramel	Orange & pineapple
Cheese	Pea & mint
Cheese & onion	Peach
Cherry	Peach & orange
Cherry & vanilla	Pear & cherry
Chicken	Pineapple
Chicken and mushroom	Plain
Chip shop curry	Plum
Chocolate	Praline
Chocolate-caramel	Raspberry
Chocolate & cranberry	Raspberry & blackcurrant
Chocolate mint	Raspberry ripple
Citrus	Ready salted
Citrus berry	Rogan style curry
Citrus cola	Rosemary & onion

Coffee	Salt & vinegar
Cool red fruits	Sausage
Cola	Savoury tomato
Cranberry	Sour cream & onion
Cranberry & blackcurrant	Strawberry
Creamy chicken	Strawberry biscuit
Creamy tomato	Strawberry & raspberry
Creamy vanilla	Sundried tomato & pesto
Egg nogg	Summer fruits
Eucalyptus	Sweetcorn
Forest fruits	Toffee
Fruit	Tomato, olive & oregano
Fruit(s) of the Forest	Tropical fruits
Garden vegetable	Tutti Frutti
Ginger	Unflavoured
Grapefruit	Vanilla
Honey & ginger	Vegetable cream
Jackfruit	White tea
Jalapeno	Wild berry
Leek & potato	Wild raspberry
Lemon	

This list is not comprehensive. New flavours will be added as and when required.

Appendix X

List H – Actual Medicinal Product Excipients

Editorial Policy: A specified list of ‘interesting’ excipients (those that may have a biological action) will be included in the dictionary providing the excipient is declared on the SmPC. If the excipient substance identification field is not populated then this merely infers that the excipient was not stated on the SmPC, or the SmPC data was not available. If the prescriber considers that it is essential to confirm the absence of an excipient then this should be done with the manufacturer.

The specified list of ‘interesting’ excipients will comprise those included in the introduction to BNF 42, those included at the beginning of BNF Chapter 13, preservatives commonly used in eye drops, plus lactose and phenylalanine.

Excipient	E number / synonym / additional information
Arachis oil	Ground-nut oil, Peanut oil, Arachidis oleum, <i>Aextreff CT</i> , earthnut oil, katchung oil, <i>Lipex 101</i> , nut oil
Aspartame	E951, Aspartamum, 3-Amino-N-(α -carboxyphenethyl)succinamic acid N-methyl ester, 3-Amino-N-(α -methoxycarbonylphenethyl) succinamic acid, APM, aspartyl phenylamine methyl ester, <i>Canderel, Equal</i> , methyl N- α -L-aspartyl-L-phenylalaninate, <i>NutraSweet, Sanecta</i> , SC-18862, <i>Tri-Sweet</i>
Beeswax	E901, White Beeswax, Cera alba, white wax, bleached wax, Yellow Beeswax, Cera flava, yellow wax, refined wax, <i>Apifil</i>
Benzalkonium chloride	Benzalkonii chloridum, Alkylbenzyltrimethylammonium chloride, alkyl dimethyl benzyl ammonium chloride, BKC, <i>Hyamine 3500, Pentonium, Zephiran</i>
Benzododecinium bromide	Lauralkonium bromide, Lauryldimethylbenzylammonium bromide, Benzyl-dodecyl-dimethylammonium bromide
Benzethonium chloride	Benzethonii chloridum, BZT, <i>Hyamine 1622</i> , diisobutylphenoxy-ethoxyethyl dimethyl benzyl ammonium chloride, Benzyl-dimethyl-[2-[2- <i>p</i> -1,1,3,3-tetramethylbutylphenoxy)ethoxy]ethyl]ammonium chloride,
Benzyl alcohol	Alcohol benzylicus, α -Hydroxytoluene, phenylcarbinol, phenylmethanol, α -toluenol, Benzenemethanol
Butylated hydroxyanisole	E320, Butylhydroxyanisolum, BHA, <i>tert</i> -butyl-4-methoxyphenol, 1,1-dimethylethyl-4-methoxyphenol, <i>Nipanax BHA, Nipantiox 1-F, Tenox BHA</i>
Butylated hydroxytoluene	E321, Butylhydroxytoluenum, <i>Agidol</i> , BHT, 2,6-bis(1,1-dimethylethyl)-4-methylphenol, butylhydroxytoluene, <i>Dalpac</i> , dibutylated hydroxytoluene, 2,6-di- <i>tert</i> -butyl- <i>p</i> -cresol, 3,5-di- <i>tert</i> -butyl-4-hydroxytoluene, <i>Embanox BHT, Impruvol, Ionol CP, Nipanax BHT, OHS28890, Sustane, Tenox BHT, Topanol, Vianol</i>
Cetostearyl alcohol	Alcohol cetylicus et stearylicus, Cetearyl alcohol, <i>Crodacol CS90, Lanette O, Tego Alkanol 1618, Tego Alkanol 6855</i>
Cetrimide	Cetrimidium, <i>Bromat, Cetab, Cetavlon, Cetraol, Lissolamine V, Micol, Morpan CHSA, Morphans, Quammonium, Sucticide</i>
Cetyl alcohol	Cetanol, Alcohol cetylicus, <i>Avol, Cachalot, Crodacol C70, Crodacol C90, Crodacol C95</i> , ethal, ethol, 1-hexadecanol, <i>n</i> -hexadecyl alcohol, <i>Hyfatol 16-95, Hyfatol 16-98, Kessco CA, Lanette 16, Lipocol C</i> , palmityl alcohol, <i>Rita CA</i> ,

	<i>Tego Alkanol 16</i> , Hexadecan-1-ol
Chlorhexidine acetate	Chlorhexidini diacetat
Chlorocresol	Chlorocresolom, 4-chloro- <i>m</i> -cresol, <i>p</i> -chloro- <i>m</i> -cresol, 2-chloro-5-hydroxytoluene, 6-chloro-3-hydroxytoluene, 3-methyl-4-chlorophenol, <i>Nipacide PC</i> , parachlorometacresol, PCMC
Disodium edetate	disodium edathamil, disodium ethylenediamine-tetraacetate, edathamil disodium, edetate disodium, edetic acid disodium salt, EDTA disodium, and 'hydrated' forms
Edetic acid	EDTA, ethylenediaminetetra-acetic acid, Acidum edeticum, <i>Dissolvine</i> , edathamil, (ethylenedinitrilo) tetraacetic acid, <i>Questric acid 5286</i> , <i>Sequestrene AA</i> , tetracemic acid, <i>Versene Acid</i>
Ethylenediamine	Edamine, Edamina, Ethylendiaminum
Fragrances	
Gluten	
Hydroxybenzoates (parabens)	Benzyl Hydroxybenzoate,
	Butyl Hydroxybenzoate, Butyl parahydroxybenzoate, Butylis parahydroxybenzoas, Butylparaben, 4-hydroxybenzoic acid butyl ester, <i>Lexgard B</i> , <i>Nipabutyl</i> , <i>Tegosept B</i> , <i>Trisept B</i> , <i>Uniphen P-23</i> , <i>Unisept B</i>
	E214, Ethyl Hydroxybenzoate, Ethyl parahydroxybenzoate, Ethylis parahydroxybenzoas, Ethyl paraben, ethyl- <i>p</i> -hydroxybenzoate, <i>Ethyl parasept</i> , 4-hydroxybenzoic acid ethyl ester, <i>Solbrol A</i> , <i>Tegosept E</i>
	E218, Methyl Hydroxybenzoate, Methyl parahydroxybenzoate, Methylparaben, Methylis parahydroxybenzoas, 4-hydroxybenzoic acid methyl ester, methyl <i>p</i> -hydroxybenzoate, <i>Nipagin M</i> , <i>Uniphen P-23</i> , Methyl-4-hydroxybenzoate
	E216, Propyl Hydroxybenzoate, Propyl parahydroxybenzoate, Propylis parahydroxybenzoas, Propylparaben, 4-hydroxybenzoic acid propyl ester, <i>Nipasol M</i> , propagin, propyl <i>p</i> -hydroxybenzoate, <i>Propyl parasept</i> , <i>Solbrol P</i> , <i>Uniphen P-23</i>
	Sodium Butyl Hydroxybenzoate, Butylparaben sodium, butyl-4-hydroxybenzoate sodium salt
	E219, Sodium Methyl Hydroxybenzoate, Methylparaben sodium, methyl 4-hydroxybenzoate sodium salt, soluble methyl hydroxybenzoate
	E217, Sodium Propyl Hydroxybenzoate, Propylparaben sodium, Propyl 4-hydroxybenzoate sodium salt, soluble propyl hydroxybenzoate
Imidurea	<i>Biopore 100</i> , <i>Germall 115</i> , <i>Tri-Stat IU</i> , imidazolidinyl urea, methane-bis[N,N'(5-ureido-2-4-diketotetrahydroimidazole)-N,N-dimethylol], 1,1'-methylenebis{3-{3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl}urea}
Isopropyl palmitate	Isopropylis palmitas, <i>Crodamol IPP</i> , <i>Emerest 2316</i> , hexadecanoic acid isopropyl ester, isopropyl hexadecanoate, <i>Kessco IPP</i> , <i>Lexol IPP-NF</i> , <i>Liponate IPP</i> , palmitic acid isopropyl ester, <i>Protachem IPP</i> , <i>Rita IPP</i> , <i>Stepan IPP</i> , <i>Tegosoft P</i> , <i>Unimate IPP</i> , <i>Waglinol 6016</i> , <i>Wickenol 111</i> , 1-methylethyl hexadecanoate
Lactose	will cover lactose monohydrate, anhydrous lactose, spray dried lactose etc. <i>Lactosum monohydricum</i> , <i>Aero Flo 20</i> , <i>Aero Flo 65</i> , <i>Aero Flo 95</i> , <i>Anhydrox</i> ,

	<i>CapsuLac, Fast-Flo, 4-(β-D-galactosido)-D-glucose, FlowLac, GranuLac, InhaLac, HMS, Lactochem, Lactohale, Lactopress, Microfine, Microtose, milk sugar, Pharmatose, PrismaLac, Respitose, saccharum lactis, SacheLac, SorboLac, Super-Tab, Tablettose, Wyndale, Zeparox</i>
N-(3-Chloroallyl)hexaminium chloride	Quaternium 15
Phenylalanine	α-aminohydrocinnamic acid, Fenilalanina, Phenylalaninum, L-2-amino-3-phenylpropionic acid
Phenylmercuric acetate	PMA, (Acetato-O)phenylmercury, acetoxyphenylmercury, <i>Gallotox, Liquiphene</i> , phenylmercury acetate
Polyoxyl castor oil	Polyethoxylated castor oil, Hydrogenated polyoxyl castor oil, Macrogoglyceroli ricinoleas, Macrogoglyceroli hydroxystearas, <i>Cremophor, Arlatone, Cremothon, Mapeg, Marlowet, Simulsol</i>
	Polyoxyl 5 castor oil, <i>Acconon CA-5</i> , PEG-5 castor oil, polyoxyethylene 5 castor oil
	Polyoxyl 9 castor oil, <i>Acconon CA-9</i> , castor oil POE-9, PEG-9 castor oil, polyoxyethylene 9 castor oil, <i>Protachem CA-9</i>
	Polyoxyl 15 castor oil, <i>Acconon CA-15</i> , castor oil POE-15, PEG-15 castor oil, polyoxyethylene 15 castor oil, <i>Protachem CA-15</i>
	Polyoxyl 35 castor oil, <i>Cremophor EL, Cremophor ELP, Etocas 35</i> , glycerol polyethyleneglycol ricinoleate, polyethoxylated castor oil, polyoxyethylene 35 castor oil
	Polyoxyl 40 castor oil, Castor oil POE-40, <i>Croduret 40, Eumulgin RO, Nonionic GR-40</i> , PEG-40 castor oil, polyoxyethylene 40 castor oil, <i>Protachem CA-40</i>
	Polyoxyl 40 hydrogenated castor oil, <i>Cremophor RH 40, Eumuligin HRE 40</i> , glycerol polyethyleneglycol oxystearate, hydrogenated castor oil POE-40, PEG-40 hydrogenated castor oil, polyethoxylated hydrogenated castor oil, polyoxyethylene 40 hydrogenated castor oil, <i>Lipocol HCO-40, Lipocol LAV HCO 40, Nikkol HCO 40, Nonionic GRH-40, Protachem CAH-40</i>
Polyoxyl 60 hydrogenated castor oil, <i>Eumuligin HRE 60</i> , hydrogenated castor oil POE-60, PEG-60 hydrogenated castor oil, polyoxyethylene 60 hydrogenated castor oil, <i>Lipocol HCO-60, Nikkol HCO 60, Protachem CAH-60</i>	
Polysorbate	Includes Polysorbate 20, 40, 60, 80, Polysorbatum 20, 60, 80 E432; E433; E434; E435; E436 <i>For additional synonyms see table below</i>
Propylene glycol	E1520, Propane-1,2-diol, Propyleneglycolum, 1,2-Dihydroxypropane, 2-hydroxypropanol, methyl ethylene glycol, methyl glycol,
Sesame oil	Sesami oleum raffinatum, Benne oil, gingelly oil, gingili oil, jinjili oil, <i>Lipovol SES</i> , teel oil
Sodium metabisulfite	E223, Sodium metabisulfite, Natrii metabisulfis, Disodium disulfite, disodium pyrosulfite, disulfurous acid disodium salt, Natrii disulfis, sodium acid sulfite, sodium pyrosulfite

Sorbic acid	E200, Acidum sorbicum, (2-butenylidene) acetic acid, crotylidene acetic acid, hexadienic acid, hexadienoic acid, 2,4-hexadienoic acid, 1,3-pentadiene-1-carboxylic acid, 2-propenylacrylic acid, (<i>E,E</i>)-sorbic acid, <i>Sorbistat K</i> , (<i>E,E</i>)-Hexa-2,4-dienoic acid
Stearyl alcohol	Alcohol stearylicus, <i>Cachalot</i> , <i>Crodacol S95</i> , <i>Hyfatol 18-95</i> , <i>Hyfatol 18-98</i> , <i>Lanette 18</i> , <i>Lipocol S</i> , <i>Lipocol S-DEO</i> , <i>n</i> -octadecanol, octadecyl alcohol, <i>Rita SA</i> , stanol, <i>Tego Alkanol 18</i>
Tartrazine	E102, 4,5-dihydro-5-oxo1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1 <i>H</i> -pyrazole-3-carboxylic acid trisodium salt, FD&C yellow #5, hydrazine yellow
Thiomersal	Sodium(2-carboxy-phenylthio)ethylmercury, Thimerosal, Mercurothiolate, Thiomersalum, [(<i>o</i> -Carboxyphenyl)thio]ethylmercury sodium salt, ethyl (2-mercaptobenzoato- <i>S</i>)-mercury sodium salt, ethyl (sodium <i>o</i> -mercaptobenzoato)mercury, sodium ethylmercurithiosalicylate, <i>Thimerosal Sigmaultra</i> , Thiomersalate
Wool fat	Includes related substances including lanolin:
	Purified lanolin, <i>Adeps lanae</i> , <i>Cera lanae</i> , <i>Corona</i> , lanolina, lanolin anhydrous, <i>Protalan anhydrous</i> , refined wool fat,
	Hydrous wool fat, Hydrous lanolin, <i>Adeps lanae cum aqua</i> , <i>Lipolan</i> ,
	Wool alcohols, <i>Alcoholes adipis lanae</i> , <i>Lanolin alcohols</i> , <i>Alcoholia lanae</i> , <i>alcolanum</i> , <i>Argowax</i> , <i>Hartolan</i> , <i>lanalcolum</i> , <i>Ritawax</i> , wool wax alcohols

Table of synonyms of selected polysorbates

Polysorbate 20	<i>Armotan PML 20; Capmul POE-L; Campul POE-L Low PV; Crillet 1; Drewmulse; E432; Durfax 20; Eumulgin SML; Glycosperse L-20; Hodag PSML-20; Lamesorb SML-20; Liposorb L-20; Liposorb L-20K; Montanox 20; Nissan Nonion LT-221; Norfox Sorbo T-20; POE-SML; Ritabate 20; Sorbax PML-20; sorbitan monododecanoate; Sorgen TW-20; T-Maz 20 T-Maz 20K; poly(oxy-1 ,2-ethanediyl) derivatives; polyoxyethylene 20 laurate; Protasorb L-20; Tego SML 20; Tween 20</i>
Polysorbate 21	<i>Crillet 11; Hodag PSML-4; Protasorb L-5; Tween 21</i>
Polysorbate 40	<i>Crillet 2; E434; Eumulgin SMP; Glycosperse S-20; Hodag PSMP-20; Lamesorb SMP-20; Liposorb P-20; Lonzest SMP-20; Montanox 40; poly(oxy-1 ,2-ethanediyl) derivatives; Protasorb P-20; Ritabate 40; sorbitan monohexadecanoate; Sorbax PMP-20; Tween 40</i>
Polysorbate 60	<i>Atlas 70K; Atlas Armotan PMS 20; Capmul POE-S; Cremophor PS 60; Crillet 3; Drewpone 60K; Durfax 60; Durfax 60K; E435; Emrite 6125; Eumulgin SMS; Glycosperse S-20; Glycosperse S-20FG; Glycosperse S-20FKG; Hodag PSMS-20; Hodag SVS-18; Lamsorb SMS-20; Liposorb S-20; Liposorb S-20K; Lonzest SMS-20; Nikkol TS-10; Norfox SorboT-60 Montanox 60; Polycon T 60 K; polyoxyethylene 20 stearate; Ritabate 60; Protasorb S-20; Sorbax PMS-20; sorbitan monoctadecanoate poly(oxy-1 ,2-ethanediyl) derivatives; T-Maz 60; T-Max 60KHS; Tween 60; Tween 60K; Tween 60 VS</i>
Polysorbate 61	<i>Crillet 31; Hodag PSMS-4; Liposorb S-4; Protasorb S-4; Tween 61</i>
Polysorbate 65	<i>Alkamuls PSTS-20; Crillet 35; E436; Glycosperse TS-20; Glycosperse TS-20 FG; Glycosperse TS-20 KFG; Hodag PSTS-20; Lamesorb STS-20; Lanzet STS-20; Liposorb TS-20; Liposorb TS-20A; Liposorb TS-20K; Montanox 65; Protasorb STS-20; Sorbax PTS-20; sorbitan trioctadecanoate poly(oxy-1 ,2-ethanediyl) derivatives; T-Maz 65K; Tween 65; Tween 65K; Tween 65V</i>
Polysorbate 80	<i>Atlas E; Armotan PMO 20; Capmul POE-O; Cremophor PS 80; Crillet 4; Crillet 50; Drewmulse POE-SMO; Drewpone 80K; Durfax 80; Durfax 80K; E433; Emrite 6120; Eumulgin SMO; Glycosperse O-20; Hodag PSMO-20; Liposorb O-20; Liposorb O-20K; Montanox 80; polyoxyethylene 20 oleate; Protasorb O-20; Ritabate 80; (Z)- sorbitan mono-9-octadecenoate poly(oxy1,2-ethanediyl) derivatives; Tego SMO 80; Tego SMO 80V; Tween 80</i>
Polysorbate 81	<i>Crillet 41; Hetsorb O-5; Hodag PSMO-5; Protasorb O-5; Sorbax PMO-5; sorbitan mono-9-octadecenoate poly(oxy-1,2-</i>
Polysorbate 85	<i>ethanediyl) derivatives; T-Maz 81; Tego SMO 81; Tween 81</i>
Polysorbate 120	<i>Alkamuls PSTO-20; Crillet 45; Glycosperse TO-20; Hodag PSTO-20; Lonzest STO-20; Liposorb TO-20; Montanox 85; Protasorb TO-20; Sorbax PTO-20; sorbitan tri-9-octadecenoate poly(oxy 1 ,2-ethanediyl) derivatives; Tego STO 85; Tween 85</i> <i>Crillet 6</i>

Appendix XI

List I – Abbreviated name (for label name only) at VMP & AMP level

Editorial Policy (history): The abbreviated name at VMP and AMP level is to satisfy the use case requirement from Pharmacy system suppliers for a label name of no more than 60 characters. The ethos was and remains that a pragmatic ‘clinically intuitive’ approach will be taken in the abbreviating of a product name. However, the convention, rules, and style for abbreviating names has been an evolving area in the evolution of dm+d.

Updated guidance in the autumns of 2008 and 2009

Further to National Patient Safety Agency (NPSA) guidance on labelling of medicinal products, the dm+d Editorial Group sought recommendations from a small group of interested parties on improving the method for abbreviating VMP and AMP names where necessary. The recommendations were presented to the Programme Board which decided to adopt the abbreviation guidance as agreed with the NPSA as the policy for constructing abbreviated names in dm+d. These guidelines will supersede all previous authoring guidelines on abbreviated names in dm+d, and are as follows:

1. Length of abbreviated name

The NPSA guidance specifies a maximum of 70 characters to be allocated for the product name on the label. The dm+d abbreviated name (or label name) is a maximum of 60 characters. It was agreed to retain this length for the term string since the extra 10 characters would allow for the total quantity dispensed to be specified.

2. Use Case

It should be clearly understood and stated in the Editorial Policy and any implementation guidance (including CUI guidance) that these abbreviations are only to be utilised to create a label name. *The name is intended solely for the purpose of creating dispensing labels.*

3. Scope

Scope of abbreviations should be expanded to include:-

- VMPs included in Schedule 1 of the NHS (General Medical Services Contracts — Prescription of Drugs etc.) Regulations 2004 and their associated AMPs
- Component only combination pack components and their associated AMPs.
- Enteral feeds and appliance/medical device concepts where instructions for usage may be required as a label and their associated AMPs i.e. not to be applied to catheters, stoma bags, hosiery but would be applied to products that move from medicine to device status (and new devices that share similar features to some conventional medicines) e.g. irrigation fluids, synovial fluid injections, skin preparations, enteral feeds.

4. Communication

- Where it is not possible to create a suitable label name that is considered safe it should be stated as an identified **exception**. This will be communicated to dm+d license holders via the NHS Digital Technology Reference Data Update Distribution Service (TRUD) as appropriate.
- Where new product comes to market, and using the currently agreed abbreviations it is not possible to create a label name of suitable brevity, proposals for a suitable abbreviated name should be sent for discussion with interested parties including experts in the field for which this product is intended to be used. If it is not possible to create a label name prior to product launch then this field should not be populated until such time as agreement is reached. Should it not be possible for interested parties to reach agreement subsequently then the product will become a stated **exception**.

5. Rules for application of abbreviations

The redefined rules to be applied step-wise to the full term until a name of 60 Characters or less is achieved are shown below under the 'Rules for application of abbreviations' heading.

6. Permitted Abbreviations

- No abbreviation of 'with' or 'and' since the + and & can be misread.
- The existing list of abbreviations published in the Editorial Policy has been amended to remove any of the abbreviations that are not currently used in dm+d (see the table of permitted abbreviations below).
- It was decided that for all injectable dose forms the abbreviated form of injection would be "inj".
Note: for AMPs and VMPs where the name includes the word infusion, this will be abbreviated to 'inf'.

Permitted Abbreviations

Full Name	Abbreviation
acellular	acell
acetate	acet
additive	add
adsorbed	ads
alcohol	alc
alginate	algin
ammonium	ammon
ampoule(s)	amp
application	applic
Australia	AU (i.e. the ISO 3166 code)
Bacillus Calmette-Guerin	BCG
bath additive	bath add
bicarbonate	bicarb

biphasic	biphas
blister(s)	blist
bottle(s)	btl
breath-actuated	BA
bromide	brom
calcium	calc
caproate	capro
capsule(s)	caps
carbonate	carb
cartridge(s)	cart
catheter maintenance solution	cath maint soln
cetylpyridinium	cetylpyr
chewable	chew
chloride	chlor
chlorofluorocarbon	CFC
citrate	cit
concentrate and solvent for solution for infusion	concentrate and solvent for inf
concentrate for solution for infusion	concentrate for inf
concentrate for solution for injection	concentrate for inj
concentrate for suspension for infusion	concentrate for inf
conjugated, conjugate	conj
country name	use ISO 3166 code
cream	crm
crystalline	cryst
device(s)	dev
diluent	dil
Diphtheria (adsorbed), Tetanus and (whole-cell) Pertussis	DTwP
Diphtheria (adsorbed), Tetanus and Pertussis (acellular component)	DTaP
Diphtheria / Tetanus (adsorbed) vaccine	DT/Vac/Ads(Child)
Diphtheria / Tetanus (adsorbed) vaccine for adults and adolescents	DT/Vac/Ads(Adult)
Diphtheria (low dose) / Tetanus / Pertussis (acellular component) / Poliomyelitis (inactivated) vaccine (adsorbed)	dTAP/IPV
Diphtheria / Tetanus / Pertussis (acellular component) / Poliomyelitis (inactivated) vaccine (adsorbed)	DTaP/IPV
dipropionate	diprop
disodium	disod
disposable	dispos

drops	dps
effervescent	efferv
eicosapentaenoic	eicosapent
emollient	emol
emulsion	emulsn
emulsion for infusion	inf
emulsion for injection	inj
oral emulsion	emulsn
ethinylestradiol	ethinylest
ether	eth
extract	ext
fluorescein	fluoresc
gastro-resistant	gast res
gluconate	glucon
glucose	gluc
gluten free	GF
glycerophosphate	glycerophos
granules	gran
Haemophilus Influenzae type b	Hib
Hepatitis A	Hep A
Hepatitis B	Hep B
hexanoate	hexan
human	hum
hydrobromide	hydrobrom
hydrochloride	hydrochlor
hydroxyquinolone	hydroxyquin
implantation suspension	imp
inactivated	inact
Industrial methylated spirit	IMS
Influenza Vaccine (Inactivated Split Virion)	Flu/Vac/Split
Influenza Vaccine (Inactivated Surface Antigen)	Flu/Vac/SA
infusion	inf
concentrate and solvent for solution for infusion	concentrate and solvent for inf
concentrate for solution for infusion	concentrate for inf
concentrate for suspension for infusion	concentrate for inf
emulsion for infusion	inf
powder and solvent for concentrate for solution for infusion	pdr and solvent for concentrate for inf

powder and solvent for solution for infusion	inf
powder and solvent for suspension for infusion	inf
powder for concentrate and solvent for solution for infusion	pdr for concentrate and solvent for inf
powder for concentrate for solution for infusion	pdr for concentrate for inf
powder for solution for infusion	inf
powder for suspension for infusion	inf
solution for infusion	inf
suspension for infusion	inf
inhaler	inh
injection	inj
concentrate for solution for injection	concentrate for inj
emulsion for injection	inj
powder and solvent for dispersion for injection	inj
powder and solvent for prolonged-release suspension for injection	inj
powder and solvent for solution for injection	inj
powder and solvent for suspension for injection	inj
powder and suspension for suspension for injection	inj
powder for injection	inj
powder for solution for injection	inj
powder for suspension for injection	inj
prolonged-release suspension for injection	inj
solution for dispersion for injection	inj
solution for injection	inj
suspension for emulsion for emulsion for injection	inj
suspension for injection	inj
intravesical solution	Intravesical soln
iotroxate	iotrox
ipecacuanha	ipecac
irrigation	irrig
irrigation solution	irrig soln
powder and solvent for solution for intraocular irrigation	irrig
lactate	lact
liquid	liq
litre(s)	L
lozenge(s)	Loz
magnesium	mag

Measles, Mumps and Rubella	MMR
medicated chewing gum	chewing gum
medium	med
meglumine amidotrizoate	meg amido
methylprednisolone	methylpred
microgram(s)	microg
microlitre to microL	microlitre to microL
mixture	mixt
modified	modfd
modified-release	MR
monofluorophosphate	monofluorophos
monopotassium	monopot
nasal	nsI
nasal spray	nsI spy
nebuliser	neb
nebuliser liquid	neb liq
nebuliser solution	neb soln
norethisterone	norethist
Nurse Prescribers' Formulary	NPF
ointment	oint
oral emulsion	emulsn
emulsion	emulsn
oral gum	gum
oral lyophilisate	lyophilisate
oral solution	soln
solution	soln
oral suspension	susp
suspension	susp
suspension for injection	inj
Papua New Guinea	PG (i.e. the ISO 3166 code)
pastille(s)	pstI
patch(es)	ptch
pessary, pessaries	pess
phosphate	phos
pivalate	pival
plastic	plstc
Poliomyelitis Vaccine, Inactivated	Pol/Vac (Inact)
Poliomyelitis Vaccine, Live (Oral)	Pol/Vac (Oral)

polyethylene (only abbreviate if part of the form description, not if part of the drug name e.g. methoxy polyethylene products)	polyeth
polysaccharide	polysacch
porcine	porc
potassium	pot
potassium chloride	KCL
powder	pdr
powder and gel for gel	gel
powder and solvent for instillation	instil
powder and solvent for solution for infusion	inf
powder for solution for infusion	inf
powder and solvent for dispersion for injection	inj
powder and solvent for nebuliser solution	neb soln
powder and solvent for prolonged-release suspension for injection	inj
powder and solvent for solution for injection	inj
powder and solvent for solution for instillation	instill
powder and solvent for solution for intraocular irrigation	irrig
powder and solvent for suspension for infusion	inf
powder and solvent for suspension for injection	inj
powder and suspension for infusion	inf
powder and suspension for suspension for injection	inj
powder for injection	inj
powder for reconstitution for instillation	instil
powder for solution for injection	inj
powder for suspension for infusion	inf
powder for suspension for injection	inj
pre-filled	pf
pre-filled disposable device	pf dispos dev
pre-filled syringe(s)	pfs
preservative free	preserv free
purified protein derivative	PPD
recombinant	rcmb
sachet(s)	sach
self aspirating	self asp
shampoo	shmp
sodium	sod
sodium amidotrizoate	sod amido

sod chlor	NaCl
solution (Note: more options are under 'infusion' or 'injection')	soln
oral solution	soln
solution for dispersion for injection	inj
solution for haemofiltration	soln
solution for infusion	inf
solution for injection	inj
solution for instillation	soln
solution for peritoneal dialysis	soln
solution for skin prick test	soln
spray	spy
square centimetre	sq cm
sublingual	SL
succinate	succin
sugar free	SF
sulfate	sulf
suppository, suppositories	suppos
suspension (Note: more options are under 'infusion' or 'injection')	susp
implantation suspension	imp
oral suspension	susp
prolonged-release suspension for injection	inj
suspension for emulsion for emulsion for injection	inj
suspension for infusion	inf
suspension for injection	inj
tablet(s)	tab
tartrate	tart
tripotassium	tripot
Tetanus Adsorbed Vaccine	Tet/Vac/Ads
unit dose	ud
unit dose vial	ud vial
units	u
vaccine	vacc
von Willebrand factor	vWf
wheat free	WF
White soft paraffin	WSP
Yellow soft paraffin	YSP

Notes on table:

- 1) Vaccines names will be abbreviated following the style used in the Department of Health 'green book' resource: 'Immunisation against infectious disease'.
- 2) Country names are to be abbreviated with the ISO 3166 short code.
- 3) For information, some terms are duplicated in the table to help the reader e.g. powder forms associated with injections are repeated under both the powder and injection entries.

Rules for application of abbreviations (refer to the table of permitted abbreviations above)

In order to support implementation of the following rules, tables indicating the names that can be abbreviated at each rule step are included in the relevant quality management system module used by the authoring team.

When applying a rule, ALL the actions possible at that rule step should be applied to the name to be abbreviated unless where the rule step indicates otherwise with language such as 'in the following order of priority'.

In the autumns of 2008 and 2009, the NHS dm+d Editorial Group approved these rules and principles. Where appropriate, examples are given at some of the rules steps as a guide to supporting implementation of the rules for application of abbreviations.

1. The form should be abbreviated (and where more than one form exists in a name e.g. Coal tar solution 12% / salicylic acid 3% in clobetasone 0.05% ointment, all forms should be abbreviated). (Note: EDQM form terms consist of both form and route information but this rule refers to the 'true' form exclusive of any route information).
2. Form modifications to be abbreviated (This includes release characteristics and site of usage information).
3. Unit dose *forms* to be abbreviated **except** vials.
4. Freeness types to be abbreviated. (Note: Chlorofluorocarbon free is always expressed as CFC free even in the full term).
5. Microgram(s) to be abbreviated to microg.
6. For combination products where the strength unit of measure is expressed as mg/ml or micrograms/actuation the unit of measure for the first component will be omitted, e.g.:

<u>Example</u> 1		<u>Length</u>
Full Name	Fluticasone 50micrograms/dose / Salmeterol 25micrograms/dose inhaler CFC free	77
Step 3	Fluticasone 50micrograms/dose / Salmeterol 25micrograms/dose inh CFC free	73
Step 5	Fluticasone 50microg/dose / Salmeterol 25microg/dose inh CFC free	65
Step 6	Fluticasone 50microg / Salmeterol 25microg/dose inh CFC free	60

7. To remove the space in CFC free to CFCfree.

8. To eliminate spaces either side of slashes where there is no numeric either side.
9. Abbreviate the drug salt.
10. Abbreviate the drug name.
11. Abbreviate litre(s) to L and microlitres to microL.
12. Remove unit dose *form*. (Note: with e.g. dressings do not remove dimensions).
13. Where strength is dual expressed remove the bracketed strength except for potassium chloride containing infusions or injections where the mmol/ unit dose of potassium should be the retained strength. Where both drugs are dual represented then remove dual representation for both drugs.

<u>Example</u>		<u>Length</u>
<u>2</u>		
Full Name	Potassium chloride 0.3% (potassium 20mmol/500ml) / Glucose 4% / Sodium chloride 0.18% solution for injection 500ml bags	119
Step 1	Potassium chloride 0.3% (potassium 20mmol/500ml) / Glucose 4% / Sodium chloride 0.18% inj 500ml bags	100
Step 8	Potassium chloride 0.3% (potassium 20mmol/500ml)/Glucose 4%/Sodium chloride 0.18% inj 500ml bags	96
Step 9	Potassium chlor 0.3% (potassium 20mmol/500ml)/Glucose 4%/Sodium chlor 0.18% inj 500ml bags	90
Step 10	Pot chlor 0.3% (pot 20mmol/500ml)/Glucose 4%/Sod chlor 0.18% inj 500ml bags	75
Step 12	Pot chlor 0.3% (pot 20mmol/500ml)/Glucose 4%/Sod chlor 0.18% inj 500ml	71
Step 13	Pot chlor 20mmol/500ml/Glucose 4%/Sod chlor 0.18% inj 500ml	59

14. If sufficient characters add the abbreviated unit dose form back in at this stage to remove the problem of duplication. Note: Taking the following example where addition of the unit dose form 'pfs' in two places takes the text string length back to over 60 characters, (Rebif 22microg/0.5ml inj pfs and Rebif 8.8microg/0.2ml inj pfs), just add this back in at the end of the name.
15. Remove any flavours and colours (e.g. natural, porcelain, and blackcurrant).
16. Remove any branded dose form text (e.g. Macoflex, Meltdown Combi, One A Day or OAD, Steripod, Viaflex).
17. Remove any outstanding route information e.g.
 - dental
 - inhalation
 - periodontal
 - topical
 - transdermal
18. Remove any information indicating freeness (e.g. CFC Free, preservative free, sugar free etc.).
19. Remove the form 'applicators' completely.
20. Remove the following dose form modifications completely
 - with luer connector
 - with spike connector
21. Abbreviate these names in the following order of priority:
 - glucose to **gluc**

- sod chlor to **NaCl**
 - alcohol to **alc**
 - ether to **eth**
 - purified protein derivative to **PPD**
 - monopotassium to **monopot**
 - monofluorophosphate to **monofluorophos**
 - disodium to **disod**
 - tripotassium to **tripot**
 - ipecacuanha to **ipecac**
22. Where the AMP name includes reference to the suppliers name then it can be removed (e.g. Boots, Seven Seas, Lloydspharmacy).
23. If a name contains a country name then abbreviate as per ISO 3166 short codes for country names e.g.
- Australia to **AU**
 - Papua New Guinea to **PG**
24. Remove pack size e.g. 500ml. (Note: with e.g. dressings do not remove dimensions).
25. Remove reference to a description of a process used in product formulation (e.g. demineralised, impregnated).
26. Remove hydration information completely (e.g. dihydrate, dodecahydrate, hexahydrate, hydrate, monohydrate).
27. Where the dose form is duplicated in a combination product only, the first instance of the dose form can be removed, e.g.
- Interferon beta-1a 6million units/0.5ml inj and Interferon beta-1a 2.4million units/0.2ml inj, to:
 - Interferon beta-1a 6million units/0.5ml and Interferon beta-1a 2.4million units/0.2ml inj
28. Where the drug name is repeated in a combination product, the second instance of the drug name only can be removed e.g.
- Interferon beta-1a 6million units/0.5ml and Interferon beta-1a 2.4million units/0.2ml inj, to:
 - Interferon beta-1a 6million units/0.5ml and 2.4million units/0.2ml inj
29. Completely remove any remaining form or abbreviated form.
30. Abbreviate potassium chloride to **KCl**.
31. Abbreviate units to **u**.
32. Remove all secondary information in brackets e.g. (Timothy Grass).

Stated Exceptions

It has not been possible to create an abbreviated or label name that is safe to use and applicable in all potential scenarios for the following concepts. These **exceptions** are:

Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 1.25cm x 100cm
Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 1.25cm x 200cm
Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 1.25cm x 300cm
Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 2.5cm x 100cm
Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 2.5cm x 200cm
Bismuth subnitrate 20% / Iodoform 40% paste impregnated gauze dressing 2.5cm x 300cm
Celvapan (H1N1) vaccine (whole virion, Vero cell derived, inactivated) suspension for injection

Coal tar 5% / Salicylic acid 2% in Betamethasone valerate 0.025% ointment
Coal tar solution 5% / Salicylic acid 3% in Clobetasone 0.05% ointment
Coal tar solution 5% / Salicylic acid 5% in Betamethasone valerate 0.025% ointment
Coal tar solution 5% / Salicylic acid 10% in Betamethasone valerate 0.025% ointment
Coal tar solution 10% / Salicylic acid 2% in Betamethasone valerate 0.1% ointment
Dithranol 0.4% / Salicylic acid 2% / Emulsifying wax 25% in liquid paraffin to 100% ointment
Human papillomavirus (type 6, 11, 16, 18, 31, 33, 45, 52, 58) vaccine (adsorbed) suspension for injection 0.5ml pre-filled syringes
Hydrocortisone 1% / Tretinoin 0.025% / Hydroquinone 4% in Aqueous cream
Hydrocortisone 1% / Tretinoin 0.025% / Hydroquinone 4% in Generic Unguentum M cream
Hydrocortisone 1% / Tretinoin 0.025% / Hydroquinone 4% in Unguentum M cream
Lemsip Cough for Mucus Cough Sugar & Colour Free 100mg/2.5mg/5ml oral solution
Nurofen for Children Cold, Pain and Fever Orange Flavour 100mg/5ml oral suspension
Nurofen for Children Cold, Pain and Fever Strawberry Flavour 100mg/5ml oral suspension
Plegridy 63micrograms/0.5ml and 94micrograms/0.5ml solution for injection pre-filled pens treatment initiation pack
Urea 40% / Starch 7.2% / Zinc oxide 7.2% / Salicylic acid 0.6% in White soft paraffin

Appendix XII

Homeopathic Preparations

Editorial Policy:

Formulation definitions: Forms are defined in Appendix V

Ingredients: Ingredients will not be populated because of the complexities inherent in describing homeopathic 'ingredients'.

Strength: The expression of potency will be based upon the common, accepted expressions of dilution used in the homeopathic community:

- **Decimal**

Definition: diluted 1 to 9 at each dilution stage ($=10^{-1}$ dilution)

1 dilution is 1x, 2 dilutions 2x etc.

Abbreviation: x

- **Centesimal**

Definition: diluted 1 to 99 at each dilution stage

($=10^{-2}$ dilution)

1 dilution is 1c, 2 dilutions 2c etc.

Abbreviation: c

Note: 1M = 1000c where M refers to the Millesimal scale

- **Fifty Millesimal**

Definition: diluted 1 to 50, 000 at each stage

Abbreviation: LM

Where continental manufacturers express dilution in terms of 'd' and 'ch' these will be expressed on the dictionary as 'x' and 'c' respectively.

Appendix XIII

Unlicensed Products

The population of VMPs of unlicensed products will fall into one of four categories, or types. Two of these follow the established methods; the remaining two differ in the amount of detail in the VMP description. Only products of type A will be prescribable as VMPs, products of type B, C, & D will be assigned 'never valid to prescribe as a VMP' status. Ingredients will not be included for product types C & D, except for those products where there is a use case, or where the data is ambiguous.

Type A: Treat as Licensed Medicines (Name, Strength & Form)

This is the simplest of the four methods of populating unlicensed products as they are populated in the same manner as licensed medicines. Only single or double ingredient preparations will be populated in this manner, those that contain three or more ingredients will be entered as per type B. Examples of this type are;

- Melatonin 2mg tablet
- Melatonin 2mg modified-release tablet
- Melatonin 3mg capsule
- Gamolenic Acid 40mg capsule

Type B: Generic XXXX

This will apply to multi-ingredient preparations that do not fit any other Type for unlicensed product population. They will be populated using the established "Generic XXXX" convention, and therefore can only be prescribed at AMP. An example of this type is;

- Generic Osteoflex tablets

Where standardised ingredients and units of strength or potency can be confirmed these will be populated. In cases where non-standardised ingredients or strengths are used or where there is ambiguity these fields will not be populated. As per current Editorial Policy an ingredient may be populated with no strength.

Type C: Strength Omitted (Name & Form)

This group of products will have a VMP similar to that for licensed medicines but with the omission of strength. Products of type C will be prescribable at AMP level only.

E.g.

- Acidophilus capsules
- Acidophilus tablets
- Acidophilus and Bifidus capsules
- Brewers Yeast tablets
- Echinacea capsules
- Echinacea liquid
- Echinacea tablets
- Garlic capsules
- Ginkgo Biloba capsules

Ginkgo Biloba tablets
 St. Johns Wort capsules
 St. Johns Wort liquid
 St. Johns Wort tablets

This type applies to products generally of organic origin. The active constituents of plants and products of this nature cannot easily be identified. Unlike licensed medicinal products that have identifiable single chemical entities plants can have a multiplicity of chemical constituents.

At VMP level strength of ingredients will not usually be included due to the lack of standardisation and either because there are different measures of potency and/or quantity, or circumstances where these measures are absent (for example, Acidophilus capsules). Any claimed strength and units of strength used, whether standard units of measurement or not, would be stated at AMP as part of the AMP description. Where applicable ingredients will be populated to assist decision support.

Prescribers would not be able to prescribe at VMP level with the VMP prescribing status indicator set at "Never valid to prescribe as a VMP".

Exception:

Cod-liver oil preparations although of organic origin will be treated as type A.

Type D: Non-Specific General VMP (non-specific name and form)

This group will be populated using a general non-specific VMP name that will encompass a large number of infrequently used AMPs. A VMP is an abstract concept representing the template of properties which constitute one or more actual medicinal products. Type D products will represent a more abstract concept than traditional licensed medicines. Products of type D will be prescribed at AMP level only. Examples of proposed VMP and some further examples of attached AMP are given below.

VMP	AMP
Multivitamin and Mineral capsules	
Multivitamin and Mineral liquid	
Multivitamin and Mineral tablets	<i>Multivitamin and Iron tablets (Lloyds)</i>
Multivitamin capsules	<i>Multivitamin capsules (Boots)</i>
Multivitamin liquid	<i>Adeks Oral Drops</i>
Multimineral capsules	
Multimineral liquid	<i>Nutrisorb Trace Minerals liquid (Biocare)</i>
Multimineral tablets	
Multinutrient capsules	<i>Cod Liver Oil and Multivitamin capsules (Seven Seas)</i> <i>Co-Enzyme Q10 and Vitamin E capsules (Natrahealth)</i>
Multinutrient liquid	
Multinutrient tablets	<i>VM-2000 Multinutrient tablets (Solgar)</i> <i>VM-75 Multinutrient tablets (Solgar)</i>
Herbal capsules	

Herbal cream	<i>Chickweed Cream (Avicenna)</i>
Herbal liquid	<i>Juniper Berry Organic Tincture(Avicenna)</i> <i>Marshmallow Root Organic Tincture (Avicenna)</i> <i>Sweet Violet Herbal Organic Tincture (Avicenna)</i> <i>Vegetable Cough Remover (Potters)</i>
Herbal tablets	
Herbal tea	
Toiletries lotion	<i>Allergenics Soothing Body Lotion</i> <i>E45 Skin Confidence Body Lotion</i> <i>Infaderm Baby Lotion</i> <i>T-Gel Anti dandruff shampoo</i>
Toiletries shampoo	
Toiletries cream	
Toiletries ointment (including balms)	<i>Weleda Foot Balm</i> <i>Weleda Massage Balm</i>
Toiletries wash (including soap substitutes, scrubs, etc.).	<i>Veil Cleansing cream</i>

Ingredients will not usually be included for type D products. Type D products will not be prescribable at VMP level.

A summary table detailing how products of type A, B, C & D will be populated follows:

Table Detailing Population at Various Indicator (where a field is empty the general principle is that the information is the same as that in the field immediately to the left)

Proposed Population Type	A	B	C	D
VMP: Field Description				
Name	rINN, BAN etc. where available, otherwise most prominent name as stated on product packaging (label or leaflet) or information from supplier.	Generic XXXX	As type A	Non-specific general title taken from limited list
Abbreviated Name	Current editorial policy			
Form	Current editorial policy where applicable			
Ontology Form & Route				
Prescribing Status	Valid as a prescribable product	Never valid to prescribe as a VMP	Never valid to prescribe as a VMP	Never valid to prescribe as a VMP
Absence Flag	Not applicable			
Combination Product Indicator	Current editorial policy, Rarely applicable			
Controlled Drug Presc. Information	No controlled drug status			
Unit Dose Form	Current editorial policy			

Information				
Availability Indicator	As applicable			
VMPP: Field Description				
Drug Tariff Category & Price	Not applicable			
AMP: Field Description				
Name	Current editorial policy.		A strength & form will be added if not already apparent.	
Abbreviated Name	Current editorial policy			
Manufacturer/ Supplier Name	Most prominent on packaging if not already apparent			
Licensing Authority	Not applicable			
Flavour	Current editorial policy where information can be determined			
Licensed Route	Not applicable			
Excipient details	Not applicable			
Restrictions on Availability	"None", or rarely "Imported"			
Status Change Reason	Current editorial policy			
AMPP: Field Description				
Legal Category	Not applicable			
Sub-pack Information	Current editorial policy, only when available data			

	is reliable			
Schedule 1 (Previously Schedule 10)	Current editorial policy, frequently applicable			
Schedule 2 (Previously Schedule 11)	Not currently applicable to any products			
Hospital Only Pack	Not currently applicable to any products			
ACBS	Not applicable			
EMA Monitoring	Current editorial policy			
Nurse, Extended Nurse, & Dental Practitioners Formulary	Not applicable			
Component Pack	Current editorial policy, rarely applicable		Present if not subject to frequent variation	
Prescription Charges/ Dispensing Fees	Current editorial policy			
Broken Bulk	Current editorial policy			
Limited Stability	Not applicable and the attribute is no longer populated in dm+d			
Discount Not Deducted	Some specifically included in list, other preparations may be covered by more general terms, indicate accordingly			
Price				

<i>Ingredient Substance Information</i>	When ingredients can be identified these will be entered	When ingredients can be identified these will be entered	No ingredients listed apart from those identified for decision support use case	No ingredients listed apart from those identified for decision support use case
Identification	Use SNOMED code if available, otherwise code will be allocated	Use SNOMED code if available, otherwise code will be allocated	Not applicable	Not applicable
Name	As per VMP; rINN, BAN etc.	As per VMP; rINN, BAN etc.	Not applicable	Not applicable
Quantity, UOM	Usually present	Present only if expressed in standard terms	Not applicable	Not applicable

Appendix XIV

Injections and Infusions

The default method for expressing the strength of liquid parenterals is to express the total quantity of drug in the total volume as per the Medicines and Healthcare products Regulatory Agency (MHRA) guidance on labelling and the National Patient Safety Agency (NPSA) recommendations. This method will be used in every instance except where a predefined **exception** has been stated.

Examples:

Furosemide 20mg/2ml solution for injection ampoules

Haloperidol 5mg/1ml solution for injection ampoules

Enoxaparin 12,000unit/0.8ml solution for injection pre filled syringes

There will be a possibility of using one of three further methods for the predefined **exceptions** where a clinical use case demonstrates the requirement.

Alt method 1

The first of these allowable **exceptions** 'alt. method 1' being to quote the unit strength i.e. mg/ml. This method will be used for insulins and other identified multidose injections where the intention is that only a proportion of the total quantity will be administered at any one time.

Example:

Human soluble insulin 100units/ml solution for injection 10ml vials

Alt Method 2

The second **exception** 'alt method 2' will be to allow for dual representation of the strength which will be represented as unit strength in both instances. This will be used for preparations such as **lidocaines, adrenalines**, and other preparations where the strength is quoted as biological activity, in units, or as ratios/percentages as well as in milligrams or micrograms. This method would also be used where standard pharmaceutical references recommend dual representation of strength on patient safety grounds.

Examples:

Adrenaline (base) 500micrograms/0.5ml (1 in 1,000) solution for injection ampoules

Lidocaine 400mg/20ml (2%) solution for injection ampoules

Mannitol 100g/500ml (20%) infusion bags

Trichloroacetic acid 15% (150mg/1ml) solution

The convention is to quote the strength in SI units followed by the second representation in parentheses.

Contrastmedia / radiopharmaceuticals where the quantity of base element needs to be represented. In these cases the defining chemical i.e. iodine etc. will be written out in full and not abbreviated to the chemical symbol.

Example:

Iodixanol 625mg/ml (Iodine 320mg/ml) solution for injection 20ml vials

Alt method 3

A third **exception** 'alt method 3' is proposed for large volume infusion fluids, electrolyte solutions and other specified injections (Dextrans, oily phenol etc.) whereby these are quoted as a %.

Examples:

All sodium chloride parenterals (0.9%, 1.8% and 30%)
Sodium chloride 0.9% solution for infusion 1litre bags

All glucose parenterals (5%, 10%, 50%, 70%)
Glucose 5% solution for injection 10ml ampoules

Combinations of above
Glucose 4% / Sodium Chloride 0.18% solution for infusion 500ml bags

All sodium bicarbonate parenterals
Sodium bicarbonate 8.4% solution for injection 10ml pre filled syringes

All calcium and magnesium sulfate parenterals
Calcium chloride 13.4% solution for injection 10ml ampoules
Calcium gluconate 10% solution for injection 10ml ampoules
Magnesium sulfate 50% solution for injection 5ml ampoules

Dextrans
Dextran '70' 6% in sodium chloride 7.5% solution for infusion 250ml bags.
Albumin e.g. Human Albumin 20% solution for infusion 50ml vials
Gelatin e.g. Succinylated gelatin 4% solution for infusion 500ml bags

Etherified starches
Hexastarch 6% in sodium chloride 0.9% solution for infusion 500ml bags

Oily Phenol
Oily Phenol 5% solution for injection 5ml ampoule

For potassium containing solutions. The concentration of potassium salt being quoted as a % and also in parenthesis, immediately following, the total mmol of potassium per unit dose.

Potassium chloride 15% (Potassium 20mmol/10ml) solution for injection ampoules

In addition for large volume parenterals containing potassium the potassium will be quoted as the first ingredient.

Potassium chloride 0.15% (Potassium 20mmol/1litre) / Glucose 4% / Sodium chloride 0.18% solution for infusion 1litre bags

Definitive list of exceptions to the default method

Alt method 1

Insulin parenterals

Alt method 2

Adrenaline parenterals

Lidocaine parenterals

Tuberculin PPD

Contrast media parenterals

Radiopharmaceutical parenterals

Trichloroacetic acid solutions

Alt method 3

Sodium chloride parenterals

Glucose parenterals

Glucose and Sodium chloride parenterals

Potassium containing parenterals (in addition the number of mmol of potassium will be included)

Sodium bicarbonate parenterals

Calcium chloride parenterals

Calcium gluconate parenterals

Magnesium sulfate parenterals

Dextran parenterals

Albumin parenterals

Gelatin parenterals

Etherified starch parenterals

Oily phenol parenterals

Ethanolamine oleate parenterals

Sodium tetradecyl sulfate parenterals

Parenteral lipids

Appendix XV

Appendix XV (a) - 'Specials'

Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.

Specials may be:

- manufactured under a specials licence
- sourced under an importers licence issued by the MHRA,
- or prepared by a dispensing contractor or third party under the manufacturing part of the Section 10 exemption from the Medicines Act 1968.

In order to facilitate the population of 'specials', the following criteria will be followed.

1) Drug Tariff Special Order products

All packs of the Drug Tariff Special Order products held in Part VIII B will be populated on dm+d. Indicative prices will be held at AMPP level only.

At AMP level, there will be a single supplier named Drug Tariff Special Order.

The Drug Tariff Special Order product description will represent an umbrella term to encompass Standard formulation including standard flavours (STD) as well as all the following formulations where indicated in the Drug Tariff:

- SF Sugar free
- AF Alcohol free
- CF Colour free
- FF Flavour free
- LF Lactose free
- PF Preservative free
- NSF Non standard flavours

The strength of the active ingredient will be included in the VMP and AMP names and the ingredient details will be populated accordingly.

2) All other Special Order products

For 'specials' products that are NOT included in the Drug Tariff Part VIII B, these will have a single supplier named Special Order at AMP level.

A single VMPP and AMPP will be created based on the unit of measure i.e. 1ml etc.

The strength of the active ingredient will be included in the VMP and AMP names and the ingredient details will be populated accordingly. Note: indicative prices are not populated.

3) Collaboration with the NHS Pro-File Information Resource

In 2007 the NHS dm+d Editorial Committee (former Content Committee) agreed to include in dm+d real pack sizes for 'Specials' that are identified on the Pro-File database to enable the population of Global Trade Item Numbers (GTINs) for these Special Order products.

Appendix XV (b) – Rawmaterials

For 'raw materials' the suppliers from where the product is sourced is populated.

The form of the product will be specifically included within the name e.g. Almond oil liquid, Acacia powder, Kaolin light powder, Acetone liquid

Appendix XVI

Authoring of bandages

Following the Editorial Group meeting in September 2005, bandages have been reauthored to include the length of each individual bandage at VMP level. At VMPP level the pack will be expressed in terms of entities e.g. 1 bandage:

VMP:

- Cohesive bandage 10cm x 2.5m
- Cohesive bandage 10cm x 6m
- Cohesive bandage 10cm x 6.5m
- Crepe bandage BP 1988 15cm x 4.5m

VMPP:

- Cohesive bandage 10cm x 2.5m x 1 bandage
- Cohesive bandage 10cm x 6m x 1 bandage
- Cohesive bandage 10cm x 6.5m x 1 bandage
- Crepe bandage BP 1988 15cm x 4.5m x 1 bandage

Absorbent cotton, gauzes and stockinette are still regarded as 'continuous substances' and are described at pack level in terms of length:

VMP:

- Absorbent cotton BP 1988
- Absorbent cotton gauze type 13 light BP 1988
- Cotton stockinette bleached BP 1988 heavyweight 10cm

VMPP:

- Absorbent cotton BP 1988 x 25g
- Absorbent cotton BP 1988 x 50g
- Absorbent cotton gauze type 13 light BP 1988 x 25m
- Cotton stockinette bleached BP 1988 heavyweight 10cm x 6m

Appendix XVII

Investigational Medicinal Products

The following are specific to the population of Investigational Medicinal Products (IMPs) in dm+d

Virtual Medicinal Product

- Virtual Medicinal Product Prescribing status will be set at 'never valid to prescribe'

- Non-availability Indicator will be absent. The VMP shall be considered to have corresponding actual products (although these may not be generally prescribable in primary care)

Actual Medicinal Product

- Current Licensing Authority will be set to 'none'.
 - Restrictions on availability will be set to 'clinical trial'.

 - Actual product excipients will not be populated for IMPs. The fact that the excipient substance identification and pharmaceutical strength fields are not populated merely infers that the SmPC data was not available. If the prescriber considers that it is essential to confirm the absence of an excipient then this should be done with the clinical trial sponsor.

Virtual Medicinal Product Pack

- Drug Tariff payment category, price, price date and previous price will not be populated for IMPs.

Actual Medicinal Product Pack

- Where the legal category has been defined for the IMP then current editorial policy will be followed. If the legal category of the IMP cannot be determined then the value of 'not applicable' will be input.

- Personally administered, FP10MDA prescription, nurse formulary, nurse extended formulary and dental formulary indicators will not be populated for IMP

- Reimbursement Information and medicinal product price will not be populated for IMPs.

Appendix XVIII

Global Trade Item Numbers

Global Trade Item Numbers (GTINs) are populated at AMPP level for medicines and medical devices/appliances. The GTIN is a globally unique number used to identify trade items, products, or services.

Field Population:

- A string (13 or 14 digits)
- A date

The GTIN is a maximum of 14 digits but 13-digit and 8-digit numbers are also in use. A 14-digit GTIN is achieved by adding a preceding leading zero to a 13-digit GTIN. The Global Standards 1 (GS1) [UK website](#) gives more detail on how the GTIN is derived.

Additional Information:

The Brand Owner, the organisation that owns the specifications of the trade item regardless of where and by whom it is manufactured, is responsible for the allocation of the GTIN. The Brand Owner is responsible for the accurate transmission of the GTIN for population in dm+d.

A live GTIN in dm+d will have a single relationship to one AMPP at any point in time (i.e. a GTIN *cannot* have one to many valid live AMPP relationships).

There are rare circumstances in which an AMPP may have a one to many GTIN relationships e.g. Drug Tariff Special Order product packs.

GTINs are populated with a start date and an end date. The start date and the end date for when a GTIN is no longer current are the dates the Brand Owner notifies to the dm+d maintainers.

Pharmaceutical companies should *never* transfer a GTIN from one product pack to another one. On dm+d sometimes concepts need to be invalidated and reauthored and in this context a GTIN could be given an end date on one AMPP and then transferred to another AMPP.

Note: a record of GTINs transferred will be provided in a spreadsheet with the weekly dm+d TRUD extract files.

A GTIN will be populated on dm+d where provided by a supplier where appropriate. Exceptions include:

- GTINs which are provided for 'outer' packaging (as 'outers' are not authored in dm+d).
- Special Order products populated with a single VMPP and AMPP that have been created based on the unit of measure e.g. 1ml etc.
- Unflavoured AMPPs that have been authored for some food substances with a supplier of 'Flavour Not Specified'.

Special attention also needs to be given to the following:

- A GTIN will be populated for a component in a combination pack where the supplier has allocated a GTIN to each component. There may also be a GTIN populated that identifies the combination pack if it is an AMPP in its own right.
- Special order products included in the Pro-File database are populated with 'real' pack sizes. GTINs will be populated for the AMPPs. Where the GTIN distinguishes characteristics such as 'freeness' or flavours that are not represented in the AMPP, there will be many GTINs to one AMPP. Where there are a number of suppliers, there will be many GTINs to one AMPP.

Additional note:

The dm+d authors will only use information received from manufacturers / MA holders / brand owners to author GTINs. These are considered to be holders of the primary source of information, and the evidence provided will be retained for audit purposes. Validation is built into dm+d to check that no live duplicate GTINs are published, however accountability for accurate and up to date information relating to GTINs rests with providers of the primary information source.

Appendix XIX

Amino Acids

The representations of amino acids (VTMs, VMPs and ingredients) in the dm+d are authored in the following style:

- For a VTM/VMP where the amino acid has an approved name (e.g. rINN) and ONLY ONE stereoisomer is represented across all VMPs in dm+d, then the approved name will be used. (The approved name may make no reference to the stereoisomerism but it will be able to be determined from the actual INN list and will be also covered by the ingredient).
- For a VTM/VMP where the amino acid has an approved name but MORE THAN ONE stereoisomer is represented in dm+d AND the approved names cover ALL stereoisomers then the approved names will be used.
- For a VTM/VMP where the amino acid has an approved name but MORE THAN ONE stereoisomer is represented in dm+d AND there are NOT approved names for ALL the stereoisomers, the approved name will be modified to identify the specific stereoisomer.
- For a VTM/VMP where the amino acid does NOT have an approved name the stereoisomer will ALWAYS be indicated in the name even where only one stereoisomer is represented in dm+d.

For ingredients that are amino acids the name will always specify their stereoisomerism regardless of whether more than one stereoisomer is represented in dm+d at ingredient level. The only exception is where approved names exist to cover all three possibilities.

Appendix XX

VMP and AMP Strength Description Differences

Sometimes there is a difference in how the strength is described in a VMP description compared with its linking AMP description(s). At AMP, the representation of strength is based upon how the supplier or manufacturer states the strength. Representation of the strength of a product can vary depending on a number of factors including:

- whether the product is a drug, medical device/appliance, cosmetic, food, or toiletry
- if the product is a licensed medicinal product or not
- if the product contains two or more active ingredients
- the ingredient naming style used by manufacturers
- the pharmaceutical form of the product
- the unit of measure associated with the strength
- whether the strength is expressed by total amount, or amount of drug present in a unit dose volume

The following table is not comprehensive but details instances of where this occurs in dm+d.

VMP and AMP strength mismatch examples and reasons

Reason for difference	AMP name	VMP name
AMP where the strength is not stated	J.L. Bragg's Charcoal capsules	Activated charcoal 300mg capsules
	Arnica cream	Arnica montana 0.9% cream
AMP where the strength is not stated and the product contains multiple active ingredients	Triptafen tablets	Amitriptyline 25mg / Perphenazine 2mg tablets
	Care Haemorrhoid Relief ointment	Allantoin 0.5% / Lidocaine 0.5% ointment
	Care Haemorrhoid Relief suppositories	Allantoin 10.25mg / Lidocaine 10.25mg suppositories
	Redoxon Double Action Vitamin C and Zinc effervescent tablets orange	Ascorbic acid 1g / Zinc citrate 10mg effervescent tablets sugar free
	Pabrinex Intramuscular High Potency No.2 solution for injection 2ml ampoules	Ascorbic acid 500mg/2ml / Nicotinamide 160mg/2ml solution for injection ampoules
	Imazin XL forte tablets	Aspirin 150mg / Isosorbide mononitrate 60mg modified-release tablets
	MigraMax oral powder sachets	Aspirin 900mg / Metoclopramide 10mg oral powder sachets sugar free
	Mydracaine No2 solution for injection 0.3ml ampoules	Atropine 1mg/0.3ml / Adrenaline (base) 120micrograms/0.3ml / Procaine hydrochloride 6mg/0.3ml solution for injection ampoules
	Duovent Autohaler	Fenoterol 100micrograms/dose / Ipratropium bromide 40micrograms/dose breath actuated inhaler
	Kao-C junior diarrhoea oral suspension	Kaolin 500mg/5ml / Calcium carbonate 250mg/5ml oral suspension sugar free
	Predsol-N ear/eye drops	Prednisolone 0.5% / Neomycin 0.5% ear/eye drops
	Kay-Cee-L syrup	Potassium chloride 375mg/5ml (potassium 5mmol/5ml) oral solution sugar free
AMP where the strengths are not stated where the pack is a starter / titration pack	Celance tablets 14 day starter pack	Pergolide 250microgram tablets and Pergolide 50microgram tablets
	Hypovase tablets B.D. starter pack	Prazosin 1mg tablets and Prazosin 500microgram tablets
	Neurontin titration pack	Gabapentin 600mg tablets and Gabapentin 300mg tablets

AMP states a single strength that represents the combined strength of multiple active ingredients (combination products)	Adderall XR 20mg capsules	Amfetamine 10mg / Dexamfetamine 10mg modified-release capsules
	Triple Bromide 1.2g/5ml oral solution	Ammonium bromide 400mg/5ml / Potassium bromide 400mg/5ml / Sodium bromide 400mg/5ml oral solution
	Tuinal 100mg Pulvules	Amobarbital 50mg / Secobarbital sodium 50mg capsules
	Tazocin 4.5g powder for solution for injection vials	Piperacillin 4g / Tazobactam 500mg powder for solution for injection vials
AMP does not state unit of measure for strength	OroNAC 600 capsules	Acetylcysteine 600mg capsules
	Xanthomax 100 tablets	Allopurinol 100mg tablets
	Amnivent-225 SR tablets	Aminophylline 225mg modified-release tablets
	Liberim D 250 solution for injection vials	Anti-D (RHO) immunoglobulin 250unit solution for injection vials
	Nu-Seals 300 gastro-resistant tablets	Aspirin 300mg gastro-resistant tablets
	Alphavase 5 tablets	Prazosin 5mg tablets
	Amix 250 oral suspension	Amoxicillin 250mg/5ml oral suspension sugar free
AMP does not state unit of measure for strength and the AMP strength does not represent the strength of the multiple active ingredients present	Wilate 1000 powder and solvent for solution for infusion vials	Factor VIII 1,000unit / von Willebrand factor 1,000unit powder and solvent for solution for injection vials
VMPs for most oral liquids are expressed as 'strength per 5ml' even where this differs from the product name in the SmPC	Seroxat 20mg/10ml liquid	Paroxetine 10mg/5ml oral suspension sugar free
	Reminyl 4mg/ml oral solution	Galantamine 20mg/5ml oral solution sugar free
	Thamicarb 84mg/1ml oral solution	Sodium bicarbonate 420mg/5ml (1mmol/ml) oral solution sugar free
	Kaletra 80mg/20mg/1ml oral solution	Lopinavir 400mg/5ml / Ritonavir 100mg/5ml oral solution
dm+d VMP naming convention where no generic title exists involves ordering active substances by the greatest quantity / then strength followed by alphabetical order, unless clinically intuitive	Sirdupla 25micrograms/dose / 250micrograms/dose inhaler	Fluticasone 250micrograms/dose / Salmeterol 25micrograms/dose inhaler CFC free
	Nuromol 200mg/500mg tablets	Paracetamol 500mg / Ibuprofen 200mg tablets
	Invicorp 25micrograms/2mg/0.35ml solution for injection ampoules	Phentolamine 2mg/0.35ml / Aviptadil 25micrograms/0.35ml solution for injection ampoules
	Mafamoz 62.5mg/25mg tablets	Proguanil 25mg / Atovaquone 62.5mg tablets
	Reprapog 250mg/100mg tablets	Proguanil 100mg / Atovaquone 250mg tablets
dm+d VMP naming convention for numeric	Muse 1000microgram urethral sticks	Alprostadil 1mg urethral sticks

expressions commencing with a numeral other than 0 will be used in preference to non-decimal greater than or equal to 1,000	Vipdomet 12.5mg/1000mg tablets	Alogliptin 12.5mg / Metformin 1g tablets
	Ferinject 1000mg/20ml solution for injection vials	Ferric carboxymaltose 1g/20ml solution for injection vials
	Panadol OA 1000mg tablets	Paracetamol 1g tablets
Expressions of strength in the VMP name will normally avoid using numeric expressions starting with the numeral 0 leading to different units of measure	One-Alpha 0.5microgram capsules	Alfacalcidol 500nanogram capsules
	Gilenya 0.5mg capsules	Fingolimod 500microgram capsules
	Flixotide 0.5mg/2ml Nebules	Fluticasone 500micrograms/2ml nebuliser liquid unit dose vials
	Signifor 0.9mg/1ml solution for injection ampoules	Pasireotide 900micrograms/1ml solution for injection ampoules
	Sanomigran 0.25mg/5ml elixir	Pizotifen 250micrograms/5ml oral solution sugar free
	Mirapexin 0.18mg tablets	Pramipexole 180microgram tablets
	Mepivacaine 66mg/2.2ml solution for injection cartridges	Scandonest plain 3% solution for injection 2.2ml cartridges
For specific pharmaceutical forms e.g. 'spray' forms, the strength / amount of spray is usually expressed as a weight in the VMP name	Syntaris 0.025% nasal spray	Flunisolide 25micrograms/dose nasal spray
	Pirinase Hayfever 0.05% nasal spray	Fluticasone propionate 50micrograms/dose nasal spray
dm+d naming convention hierarchy is that the rINN is preferred	Duaklir 340micrograms/dose / 12micrograms/dose Genuair	Aclidinium bromide 396micrograms/dose / Formoterol 11.8micrograms/dose dry powder inhaler
	Eklira 322micrograms/dose Genuair	Aclidinium bromide 375micrograms/dose dry powder inhaler
	Anoro Ellipta 55micrograms/dose / 22micrograms/dose dry powder inhaler	Umeclidinium bromide 65micrograms/dose / Vilanterol 22micrograms/dose dry powder inhaler
	Seebri Breezhaler 44microgram inhalation powder capsules with device	Glycopyrronium bromide 55microgram inhalation powder capsules with device
VMP expression of salt where two or more salts exist that are not clinically equivalent	Nurofen Express 342mg caplets	Ibuprofen lysine 200mg tablets
	Nurofen Express 256mg tablets	Ibuprofen sodium dihydrate 200mg tablets
Expression of insulin (Editorial Policy page 61 and Appendix XIV)	NovoMix 30 Penfill 100units/ml suspension for injection 3ml cartridges	Insulin aspart biphasic 30/70 100units/ml suspension for injection 3ml cartridges
	Insuman Comb 24 100units/ml suspension for injection 3ml pre-filled Solostar pen	Insulin isophane biphasic human 25/75 100units/ml suspension for injection 3ml pre-filled disposable device

AMP presents the calcium element content but dm+d policy is to author the strength of calcium salt	Calcichew 500mg chewable tablets	Calcium carbonate 1.25mg chewable tablets sugar free
AMP presents the iron element content but dm+d policy is to author the strength of iron salt	Lamberts Iron 14mg tablets	Ferrous citrate 62mg tablets
AMP strength expressed per hour	Nitro-Dur 0.2mg/hour transdermal patches	Glyceryl trinitrate 5mg/24hours transdermal patches
dm+d Editorial Policy Appendix XIII for unlicensed products is to create VMPs that are grouper concepts rather than generic products and so do not have a strength	BIOmega 3 Kids 1000mg capsules	Fish oil capsules
	Lloydspharmacy High Strength Omega Fish Oil 1g capsules	Fish oil capsules
For eye products (e.g. drops), the concentration (strength) of the active substance has traditionally been expressed as % in dm+d. Current practice based on European guidelines is now to express the strength as quantity per unit volume (or weight), e.g. mg/ml or micrograms/ml. dm+d will follow Part 1 of the SmPC and so in the transition, differences in expression of strength will occur for some similar VMPs and AMPs for eye products.	Timoptol 0.25% eye drops	Timolol 0.25% eye drops
	Eysano 2.5mg/ml eye drops	Timolol 2.5mg/ml eye drops preservative free

Appendix XXI

British Pharmacopoeia ('BP') reference in a Virtual Medicinal Product (VMP) description

As part of the dm+d naming convention process a decision needs to be made about whether or not the suffix BP should be used in the VMP name. This appendix includes a decision algorithm, in the form of a decision tree that represents the principles of the decision making process for determining this. This also takes into account whether there is a licensed medicinal product available that is covered by a Summary of Product Characteristics (SmPC).

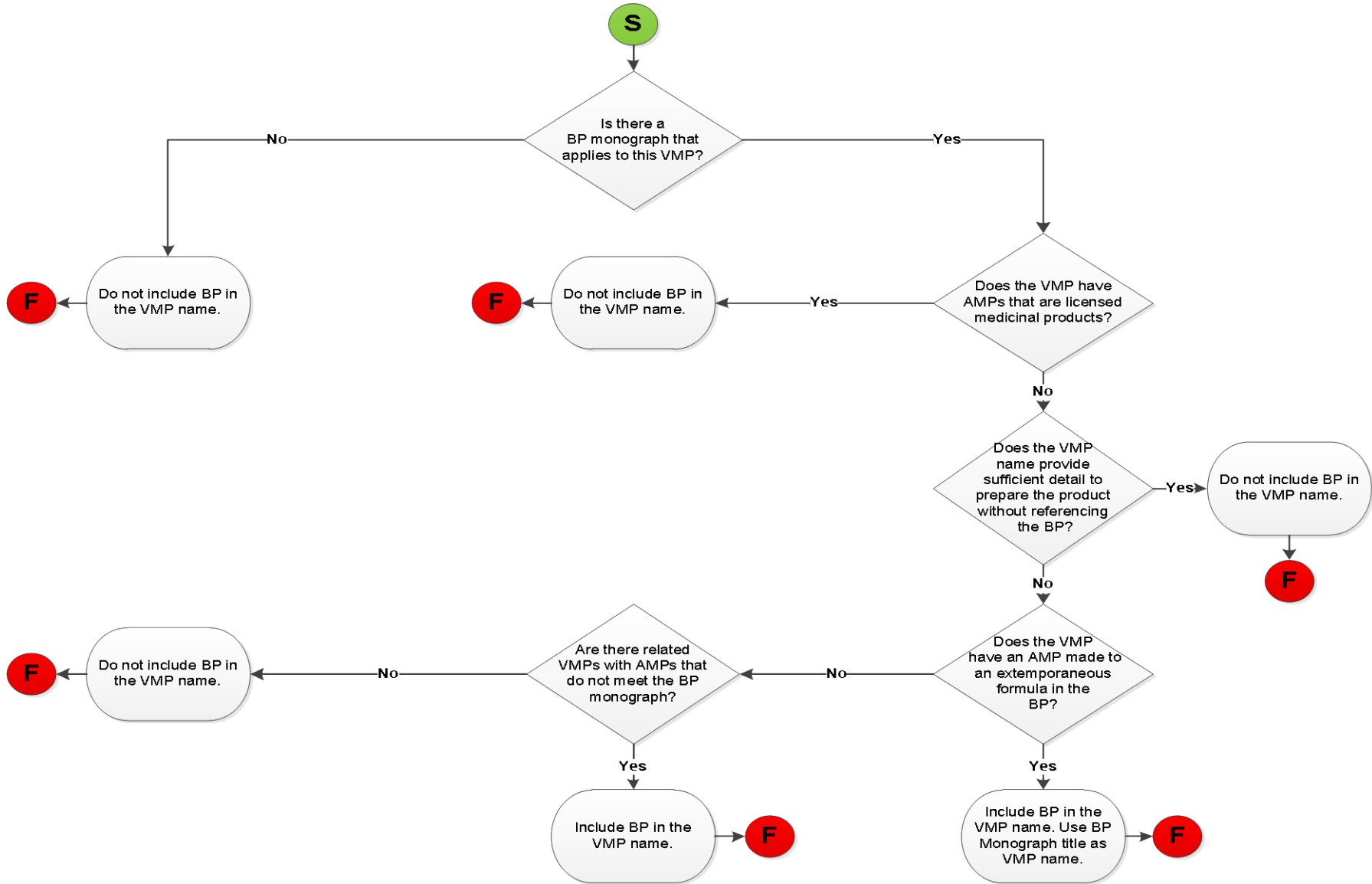
The VMP title normally follows the format of name + strength + form. The VMP name will then only distinguish whether there is a BP monograph that applies to the VMP when there are closely related VMPs that do not comply with the same monograph.

Closely related VMPs are defined as:

- VMPs with the same name and form but different strengths
- VMPs with the same name but different salts, same form and different strengths
- VMPs made to a specified formula (this may or may not be a BP formula) where there is a small difference in the formula (e.g. slightly different excipients such as flavours and colours, or slightly different strengths)

Note: BP won't be included in a VMP name where the strength of the active ingredient(s) is/are included in the VMP name and the base is specified.

Decision Tree for when the suffix 'BP' should be used in the VMP name



Appendix XXII

Medical Devices that may be prescribed in Secondary Care

The dm+d content committee meeting in June 2016 confirmed that the scope of medical devices/appliances for dm+d includes devices that are used in Secondary Care. This is to facilitate the recording of the administration or dispensing of Secondary Care Medical Devices using the same data entry system as is used for medicines and those devices available in primary care.

The original intention for the dictionary outlined by the UKCPRS programme was for it to be the single product to represent the Primary Care Drug Dictionary (PCDD), the Secondary Care Drug Dictionary (SCDD) and the Medical Devices Dictionary (MDD).

However it has to be noted that the scope of medical devices used in secondary care is large and to include all medical devices in the dm+d XML would potentially overwhelm the current content. The following therefore seeks to outline which items are in scope for inclusion in the native dm+d XML files noting that the full MDD will continue to be developed (by NHS Digital) to include the broader scope of medical devices and will be made available in an aligned, but separate download in the SNOMED CT UK Drug Extension.

dm+d will include medical devices that are in the Drug Tariff and those used in secondary care that are recorded in a patient's medical record. Range extensions to Drug Tariff-listed medical devices may also be added to support dispensing contractors in identifying products that will not be reimbursed through the NHS primary care pharmaceutical services in England and Wales.

To clarify the scope boundaries of which Secondary Care devices are considered to be within scope of dm+d XML release a list is provided below. The list should not be considered to be exhaustive and may be expanded if/when a use case for inclusion in the dm+d XML release is identified.

Dressings, multilayer bandages, venous ulcer compression systems, gauzes or bandages
To include those where the size is not listed in the Drug Tariff (England and Wales) or is indicated by the manufacturer to be only available to hospitals

To include those where the pack size is not listed in the Drug Tariff (England and Wales) or is indicated by the manufacturer to be a Hospital only pack.

Medical devices/appliances that are administered by injection for example

Substances for pleural adhesion

Dermal fillers

Sodium hyaluronate injections

Skin prick tests

Ophthalmic preparations for example

Eye drops

Eye sprays

Contact lens care preparations

CE marked devices/appliances that are applied to the skin or mucous membranes

Skin patch tests

Emollients

Lubricants

Douches

Irrigation Solutions

Bladder Instillations

Acne treatments

Dry mouth products

Ear wax softening medical devices

Inhalation Solutions

Nasal products – drops, powder, sprays

Oral film forming agents
Micro-enemas

Skin glues and sealants
Fibrin sealants
Cyanoacrylate glues intended for medical use

Bone cements

Haemofiltration solutions

Contraceptive devices

Condoms

Diaphragms – to include those that are not listed in the Drug Tariff (England and Wales)

Spermicides – to include those that are not listed in the Drug Tariff (England and Wales)

Test strips for near patient use

Blood test strips

Urine test strips

Appendix XXIII

Radiopharmaceuticals

Due to the requirements around safe handling and waste disposal, radiopharmaceuticals are not prescribed or administered in primary care. With the Falsified Medicines Directive (FMD) coming into effect February 2019, it has been decided to include information about radiopharmaceuticals in the Editorial Policy, however, the scope of radiopharmaceuticals for inclusion in dm+d at this time is limited to only those that are licensed medicines.

The inclusion of radiopharmaceuticals in dm+d requires a number of modifications to existing Editorial policy.

Expression of radiopharmaceutical activity in VMP and AMP terms

Radiopharmaceuticals have changing composition and radioactive strength over time, associated with the radioactive decay. For ready-for-use radiopharmaceuticals, the Summary of Product Characteristics (SmPC) quotes an Activity Reference Date — this is the date and/or time on which a specified amount of radioactivity is present. The amount of radioactivity present in the product when administered to the patient (is dependent on the date and time of usage) can be calculated used in conjunction with Activity Reference Schedules produced by the manufacturers.

Representing these products by using the strength on the reference date and time would mean that the concept would then be inaccurately described at any other time or date.

Therefore, the amount of radioactivity or 'strengths' for these products is not identified in the terminology. Instead, VMP and AMP concepts identify the active moiety, radioisotope and pharmaceutical form without reference to strength.

An example of such a concept would be:-

Sodium iodide [I-131] capsules

Active Ingredients

Active ingredient information for ready to use radiopharmaceuticals would be authored but no strength data. For kits, no active ingredient would be authored since these are combined with other components to create a final product and are not administered to the patient directly.

Expression of radioisotopes

For products containing a radioisotope the British Pharmacopoeia uses the convention of inserting a pair of square brackets immediately following the radioactive component of a salt. Within the square brackets the atomic number for the isotope is represented as superscript preceded by the chemical symbol for the isotope. For example: - Technetium [Tc^{99m}] Succimer

At this time it is unknown whether systems intending to implement SNOMED CT will be able to support the use of superscript. For these reasons dm+d will utilise the convention of identifying the radioisotope within square brackets as the chemical symbol for the element followed by the atomic number separated by a hyphen this would be preceded by the name of the radioactive part of the chemical entity.

Examples include:

Gallium [Ga-67] citrate

Chromium [Cr-51] edetate

Technetium [Tc-99m] exametazime

Dose forms for Radiopharmaceuticals

In the SNOMED CT, UK Drug Extension concepts are allocated dose forms in line with the dm+d Editorial policy. However, the dose forms currently in dm+d are not appropriate for all of the radiopharmaceutical products that would be included in the SNOMED CT UK Drug Extension.

The dm+d dose forms are derived from those included in the European Directorate for the Quality of Medicines and Healthcare (EDQM). In the Standard Terms document produced by this organisation there are a number of dose forms with definitions that are specific to Radiopharmaceuticals:-

- *Radiopharmaceutical precursor.* A radionuclide produced for the radio-labelling of another substance prior to administration.
- *Kit for Radiopharmaceutical preparation.* A preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.

These new dose forms will be used for the appropriate products. Where kits or precursors comprise a number of separate components (for example where two or more vials are to be combined in dm+d they are represented only as a single concept rather than each individual component being represented separately.

It should be noted that the majority of radiopharmaceutical products will be allocated a dose form from the concepts that already exist in dm+d.

Unit dose information

In dm+d Unit dose form e.g. ampoule, vial, pre-filled syringe etc. will be identified in the term at VMP and AMP level for radiopharmaceuticals. Where more than one size of unit dose is available they will be differentiated by the unit dose size being identified.

Precursors will have a unit dose form allocated as appropriate. Where this is for a single component this will be vial, ampoule or bottle as appropriate. Where it is a multicomponent the unit dose form will be kit.

Kits for radiopharmaceutical preparations will have a unit dose form allocated as appropriate. Where this is for a single component this will be vial, ampoule or bottle as appropriate.

Pack sizes

For ready- to-use radiopharmaceuticals, precursors and kits for radiopharmaceutical preparations, the pack sizes will be determined from product information provided by suppliers. This may be as product data sheets or product catalogues.

Routes of Administration

Ready to use radiopharmaceuticals will have an appropriate route of administration allocated where this can be determined from the product information supplied.

Precursors and kits for radiopharmaceutical preparations are not intended for direct patient use and so 'Route of Administration not applicable' will be allocated to these concepts.

Suppliers

Ready to use radiopharmaceuticals, precursors and kits for radiopharmaceutical preparations will have an appropriate supplier allocated as determined from the product information supplied.

Examples of radiopharmaceuticals

1. **VMP** Sodium iodide [I-131] capsules

AMP Sodium iodide (I-131) Diagnostic capsules (GE Healthcare Ltd)

AMP Capsion capsules (IBA UK Ltd)

AMP Sodium iodide [I-131] capsules (Tyco Healthcare UK Ltd)

AMP Theracap capsules (GE Healthcare Ltd)

It is important to note that because strength is not authored for VMP or AMP concepts, AMPs with different use cases and potentially very different strengths may be associated with the same VMP as per the example above.

2. **VMP** Radium [Ra-223] dichloride solution for injection vials

AMP Xofigo solution for injection vials (Bayer plc)

3. **VMP** Yttrium chloride [90Y] precursor solution vials

AMP Ytracis solution radiopharmaceutical precursor vials (IBA Molecular)

4. **VMP** Generic Osteocis kit for radiopharmaceutical preparation of Technetium [Tc-99m] oxidronate

AMP Osteocis kit for radiopharmaceutical preparation of Technetium [Tc-99m] oxidronate (IBA Molecular)

AMP Technescan HDP kit for radiopharmaceutical preparation of Technetium [Tc-99m] oxidronate (Mallinckrodt UK Commercial Ltd)

Appendix XXIV

Representation of diluents for Special Order cytotoxic infusions – SACT

NHS Trusts are measured in their compliance to the Systemic Anti-Cancer Therapies (SACT¹) dose bandings for adult anticancer therapies. The SACT dose bandings are an NHS initiative where chemotherapy doses are rounded, the infusion prepared in a standard volume and in many cases the diluent for the infusion is specified. In order to encourage NHS England commissioned providers of chemotherapy to move to prescribing a range of SACT drugs in accordance with the nationally approved dose bands Commissioning for Quality and Innovation (CQUIN). Payments will be made to Trusts based on their compliance Trusts will be set targets and the number of doses administered in line with the approved bandings measured against a target set for the Trust.

Where a Special Order product is being produced that is compliant with the SACT dose bandings (SACT dose bandings for many of the drugs require a specific diluent and infusion volume) it is added to dm+d with both the active drug and the diluent being identified in both the VMP and AMP terms.

Where no diluent is specified in the SACT bandings normal dm+d Editorial rules would apply and no diluent would be identified in the VMP and AMP terms.

Where SACT compliant products are licensed AMPs no diluent information is included in either the VMP or AMP terms (unless it is deemed to be part of the product name on the SmPC). Information about the diluent being used for licensed products is available in the SmPC if required by prescribers or dispensers.

1. ¹ 16/17 CQUIN Scheme CA2 Dose Banding for Adult Intravenous SACT Drug List
<https://www.england.nhs.uk/wp-content/uploads/2016/03/CA2-Drug-List-for-Dose-Banding-Adult-Intravenous-Systemic-Anticancer-Therapy-1.pdf>

Appendix XXV

Authoring of Systemic Anticancer Therapy (SACT) dose banded products

Biosimilar SACT Dose Banded Special Order products

The Nationally Standardised Dose Banded Tables for Adults Intravenous Systemic Anticancer Therapy (SACT) initiative has been developed by NHS England's Medicine Optimisation and Chemotherapy CRGs. This is aimed to deliver benefits for patients, Hospital Trusts and achieve improved value from our investment in chemotherapy services.

dm+d contains both licenced and unlicensed medicines and has undertaken to populate SACT compliant dose banded products into dm+d, this will support prescribing, dispensing and data collection within Hospital Trusts as per the previous dm+d Content Committee decision in 2016.

Some of the SACT compliant products are biosimilars and the Medicines and Healthcare Products Regulatory Agency (MHRA) recommends that "it is good practice to prescribe biosimilar products by brand name to ensure that inadvertent substitution does not occur when the medicine is dispensed by the pharmacist".

NHS England Dose banding product specification states clearly states the brand name of the brand leader and that of biosimilar products must be included on the label.

The dm+d Content Committee has agreed with the proposal that for Special Order biosimilars, the AMP names should therefore include Biosimilar brand name in brackets () after the biologic name e.g.

Rituximab (MabThera) 700mg/500ml in Sodium chloride 0.9% infusion bags (Special Order)
Rituximab (MabThera) 700mg/500ml in Sodium chloride 0.9% infusion bags (Special Order)
Rituximab (MabThera) 700mg/500ml in Sodium chloride 0.9% infusion bags (Special Order)

With the AMP examples above, there will be one parent VMP concept i.e.

Rituximab 700mg/500ml in Sodium chloride 0.9% infusion bags

SACT Dose Banded Special Order products with a strength equal to or over 1g/1000mg

The Nationally Standardised Dose Banded Tables for Adults Intravenous Systemic Anticancer Therapy (SACT) initiative has been developed by NHS England's Medicine Optimisation and Chemotherapy CRGs. This is aimed to deliver benefits for patients, Hospital Trusts and achieve improved value from investment in chemotherapy services.

dm+d contains both licensed and unlicensed medicines and has undertaken to populate SACT compliant dose banded products into dm+d This will support prescribing, dispensing and data collection within Hospital Trusts. Some of the special order SACT compliant products have strengths that are equal to or over 1g/1000mg. NHS England dose banding drug specifications and drug tables always express the strengths in mg. For example: 1000mg, 1200mg, 1800mg, 2000mg etc. Chemotherapy products are prescribed in *000mg and the dose for body weight/body surface area is calculated using mg. The dm+d Content Committee agreed that all SACT dose banded special order products \geq 1g/1000mg should be authored as *000mg at both VMP and AMP level e.g.

Fluorouracil 1000mg/40ml solution for injection pre-filled syringes
Gemcitabine 1254mg/250ml in Sodium chloride 0.9% infusion bags

Annex I

Document control prior to 2016

Date Issued	NHS dm+d	Change summary
21 April 2004	Release 2.0 Version 1.0	New Editorial Policy to match release 2.0 version 1.0 of NHS dm+d
22 July 2004	Release 2.0 Version 1.0	<p>Addition of agreed list of exceptions to default method for expressing strength of parenteral liquids – Appendix XIV</p> <p>Updated abbreviation list Appendix XI</p> <p>Inclusion of new route & Inclusion of new forms</p>
28 October 2004	Release 2.0 Version 1.0	<p>Addition of approach to and revisiting of issues added to introduction</p> <p>Inclusion of Appendix XV – Specials, Drug Tariff category E products</p> <p>Inclusion of the controlled drug category examples, prescription charge examples and appliance/medical device order number clarification transferred from the technical specification</p> <p>Lists updated</p>
28 June 2005	Release 2.0 Version 2.0	<p>Title amended to reflect extract release 2.0 version 2.0 – change of tag name from schedule 10 & 11 to schedule 1 & 2</p> <p>Addition of definition of Discontinued date at AMPP level</p> <p>Inclusion of new value Part VIII Category M at DT payment category, VMPP level</p> <p>References to NHS Information Authority amended to refer to NHS Connecting for Health (CfH)</p> <p>NPSA membership of Editorial Group added</p> <p>Lists updated – addition of new forms, new route, abbreviations, units of measure. Excipient list amended to include a range of synonyms from the Handbook of Pharmaceutical Excipients 4th Edition.</p> <p>Homeopathic form definitions moved from Appendix XII (Homeopathic preparations) to Appendix V (Virtual medicinal product form).</p> <p>VMP prescribing status addition of new product type for ‘never valid’, AMP generic product name clarification, two manufacturer clarification,</p>

28 November 2005	Release 2.0 Version 2.0	Inclusion of new authoring of bandages as Appendix XVI Updating of unit of measure list Addition of further examples to UDF information Addition of further examples to prescribing status Invalidity flag – further clarified Combination product further clarified Removal of list F2 following decision by EB not to currently provide an abbreviated description
20 January 2006	Release 2.0 Version 3.0	Title amended to reflect extract release 2.0 version 3.0 – inclusion of VTM previous identifier and date VTM – inclusion of previous VTM identifier and VTM identifier date Inclusion of further examples for Schedule 4 part I (Benz) controlled drugs
1 April 2006	Release 2.0 Version 3.0	All references to Prescription Pricing Authority (PPA) amended to NHS Business Services Authority (NHSBSA) Addition of further example of gel type to gel definition in Appendix V
28 July 2006	Release 2.0 Version 3.0	Addition of new routes Amending of route description to remove 'use'
20 December 2006	Release 2.0 Version 3.0	Revised definition of VMP Addition of new routes and forms Glossary of terms added Examples added to AMP definition
20 November 2007	Release 2.0 Version 3.0	Reference to CSM amended to CHM. Addition of new routes and forms. Addition of unit of measure and amendments for obsolete units of measure. Reference to the abbreviation 'Ins' for insulin removed from the abbreviation Appendix. Reference to change in terming of nutritional supplements at VMP to allow prescribing devoid of flavour.
28 April 2008	Release 2.0 Version 3.0	Addition of dm+d governance structure Addition of new form (see Solution for dispersion for injection)
16 September 2008	Release 2.0 Version 3.0	Combination products further clarified, with the addition of two new units of measure Addition to prescribing status and update to glossary to include Investigational Medicinal Products (i.e. clinical trials products) Addition of new forms and replacement of respiratory route with inhalation route Addition of units of measure

1 December 2008	Release 2.0 Version 3.0	<p>VMP prescribing status addition of 2 new product types for 'VMP not recommended to prescribe – brands not bioequivalent' and 'VMP not recommended to prescribe – patient training required', these are to replace 'Not Recommended To Prescribe As A VMP'.</p> <p>Updated Appendix XI on abbreviated names in-line with the recommendations of the 'Abbreviations Working Party' submitted to the Editorial Group.</p> <p>Addition of 'Gastroenteral liquid' and 'Powder for gastroenteral liquid' forms in-line with the 'Changes to attributes of enteral Nutritional feeds in dm+d' paper submitted to the Editorial Group.</p> <p>Addition of section on 'Identification of infusions' under the 'Liquid unit dose forms – injections and intravenous infusions' heading in-line with the 'Identification of infusions in dm+d' paper submitted to the Editorial Group.</p> <p>Updated list of forms.</p>
1 May 2009	Release 2.0 Version 3.0	<p>Addition of new forms.</p> <p>Update about price information for SCDD products which is now being logged if received.</p> <p>Notes added acknowledging that ACBS (and non-ACBS) liquid and powder food products will be populated with dose form and route information where available to support secondary care prescribing.</p> <p>Update and further clarification of Appendix XI, with respect to permitted abbreviations.</p>
1 April 2010	Release 2.0 Version 3.0	<p>Where reference is made to abbreviated names throughout, a note has been added that the scope was widened in 2008 (see Appendix XI for more details).</p> <p>Under Virtual Therapeutic Moiety and Virtual Medicinal Product introductions, reference to the Editorial Group having approved that the dm+d word order for VTM and VMP combination names should be in-line with the British National Formulary.</p> <p>Under Virtual Medicinal Product – Form and Route Information, reference to the Editorial Group having approved that products that move from medicine to device status and new devices that share similar features to medicines will be populated with dose form information.</p> <p>Under Semantic Normal Form Patterns used, Examples of SNF Patterns, Liquid unit dose forms, reference to the Editorial Group having approved that VMP and AMP names for liquid unit dose concepts should be described expressing the total strength based on the total volume (i.e. total dose) in-line with unit dose injectables and unit dose oral liquids. Details of exemptions are also provided.</p> <p>Addition of new route and form information to Appendix IV List B.</p> <p>Addition of new forms to Appendix V List C.</p>

		<p>Addition of new route information to Appendix VI List D.</p> <p>Addition of new units of measure to Appendix VII List E.</p> <p>Addition of new flavours to Appendix IX List G.</p> <p>Under Appendix XI, update of guidance, permitted abbreviations and rules for application of abbreviations.</p> <p>Under Glossary of Terms, addition of appliance and device terms.</p>
23 August 2010	Release 2.0 Version 3.0	<p>Virtual Therapeutic Moiety and Virtual Medicinal Product introductory sections: confirmation that the word order for combination names will follow the British National Formulary word order.</p> <p>VMP prescribing status: the textual description of value 002 'invalid as a prescribable product' is changed to 'invalid to prescribe in NHS primary care'</p> <p>Addition of new abbreviation and new stated exception to Appendix XI List I</p>
8 March 2012	Release 2.0 Version 3.0	<p>NHS dm+d Governance Structure, section updated.</p> <p>Virtual Therapeutic Moiety Name, Virtual Therapeutic Moiety Abbreviated Name, Additional Information. Further clarification provided.</p> <p>Virtual Medicinal Product Name, Additional Information. Clarification that the release time will not be included in the VMP name for modified release products unless there is a pharmacopoeia standard for duration of action.</p> <p>VMP prescribing status, clarification of the Yellow Fever Vaccine scenario</p> <p>VMP Ingredient, Basis of Strength Substance (BoSS), clarity of the move to populate noradrenaline concepts in an attempt to improve patient safety.</p> <p>AMP, Product Availability Information. AMP licensing authority options extended to include Traditional Herbal Medicines. Also the definitions for Medicines – MHRA and Devices – MHRA have been updated to more accurately reflect their statuses.</p> <p>AMP, Restrictions on Availability, Additional Information. Definitions of Imported products and Special products updated in-line with Drug Tariff.</p> <p>VMP Pack, Drug Tariff Category Information. Clarification that Category E is now obsolete. Note added clarifying that until a system change is made to dm+d, Part VIII here refers to section Part VIIIA.</p> <p>AMP Pack, Product Prescribing Information, ACBS Indicator, clarification that ACBS status does not apply to medical devices/appliances listed in Part IX of the Drug Tariff</p> <p>AMP Pack, Medicinal Product Price, Price Basis Flag, clarification of the risk sharing scheme price.</p> <p>Other Data, Semantic Normal Form Patterns used in NHS dm+d. Clarification that with combination products, the word order used in the BNF will be followed.</p> <p>Appendix V. Clarification added regarding current use of</p>

		<p>concentrate / concentrated terms. List C updated with forms added to dm+d.</p> <p>Appendix VI. List D updated with new route.</p> <p>Appendix IX. List G updated with new flavours.</p> <p>Appendix XI. Table of Permitted Abbreviations updated.</p> <p>Appendix XV. Updated to include how Special Order products are populated in dm+d following DH and Drug Tariff policy changes. Appendix separated into a) Specials and b) Raw materials.</p> <p>Reference also made to ongoing inclusion of real pack sizes for Specials in line with the Pro-File Information Resource as previously agreed by the Editorial Committee (former Content Committee).</p>
9 August 2013	Release 2.0 Version 3.0	<p>Representation of flavours – reference to VMP names reverting to ‘Generic xxxx’ in defined scenarios and authoring of unflavoured AMP concepts and use of ‘Flavour Not Specified’ supplier name.</p> <p>AMP level CHM Monitoring Indicator attribute name updated to EMA Additional Monitoring Indicator name</p> <p>AMPP level Limited Stability Indicator attribute will persist but will not be populated</p> <p>Calendar packs continue to be populated but no longer feature in the Drug Tariff</p> <p>Forms, Routes, Flavours updated</p> <p>‘Sulph’ to ‘sulf’ names changed where referenced</p> <p>Addition of Appendix XVIII Global Trade Item Numbers to reflect the changes approved by the Content Committee</p> <p>Additional abbreviations rules for the creation of abbreviated names</p>
May 2015	Release 2.0 Version 3.1	<p>dm+d — the NHS Standard and Governance Structure, reference made to the Information Standards Board standard and the more recent Standardisation Committee for Care Information.</p> <p>Updated text regarding the Approach to and the re-visiting of dm+d issues</p> <p>VMP Name section, examples given that are exceptions to authoring VMPs as ‘Generic XXXX’ where 3 active ingredients are present</p> <p>Addition of policy for the VMP prescribing status of medical devices</p> <p>Update to the VMP prescribing status of specific antiepileptic drugs in line with information published by the Commission on Human Medicines</p> <p>VMP Ingredient substance, an example of a combination inhaler provided where following Editorial Policy leads to a different expression of strength at VMP level compared with AMP level</p> <p>VMPP Drug Tariff Category Information updated in line with Part VIII now represented as Part VIIIA and Part VIIIB</p> <p>Minor modifications to EDQM Forms and Routes. Please note <i>Oromucosal Buccal</i>, <i>Oromucosal Sublingual</i> and <i>Oromucosal other</i> to be replaced by <i>Buccal</i>, <i>Sublingual</i> and <i>Oromucosal</i> respectively, summer 2015.</p>

		<p>List G of AMP flavours updated.</p> <p>Appendix XI update to table of exceptions where it has not been possible to create an abbreviated or label name.</p> <p>Addition of Appendix XIX describing how amino acid concepts are represented in dm+d.</p> <p>Annex I - Partition of document control with older information now located in Annex I towards the end of the document.</p>
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Glossary of terms

Term	Acronym	Description
Actual Medicinal Product	AMP	The AMP is a level within dm+d. It is a product that has been made available by a supplier. It is a physical entity that exists but is devoid of pack size information.
Actual Medicinal Product Pack	AMPP	The AMPP is a level within dm+d. It identifies the amount of a product that is in a pack that has been made available by a Supplier.
Appliance		In the dm+d this term is used synonymously with the term device. Only appliances / medical devices listed in Part IX of the Drug Tariff are allowed for supply against a primary care NHS prescription form FP10 order in England and Wales.
Basis of Pharmaceutical Strength	BoPS	This is an attribute at VMP level. It identifies if the strength of an ingredient present in a product is being expressed as the whole substance (ingredient substance) or any part of the complete substance (base substance).
Basis of Strength Substance	BoSS	A BoSS is an ingredient substance and is the part of the ingredient that the strength of a given product is based upon. For example Acebutolol 100mg capsules contain the ingredient substance Acebutolol hydrochloride, but the 100mg strength refers to the amount of Acebutolol that is present. In this example Acebutolol is the BoSS.
British Pharmacopoeia	BP	
Combination Product		A combination product is a product containing two or more components each of which is a VMP in its own right. It may consist of different forms e.g. cream + pessaries or the same form e.g. tablets + tablets. A combination product attribute can be found at both VMP and AMP level. Note: appliances/medical devices that are combination products will be populated in a similar way to a combination medicinal product pack.
Commissioning for Quality and Innovation	CQUIN	Commissioning for Quality and Innovation (CQUIN) framework supports improvements in the quality of services and the creation of new, improved patterns of care as part of the NHS Standard contract.
Component		This term is used to describe the separate products found in a combination product. Where the component can only be found within the combination product and is not available in its own right then this is known as a component only product.
Data Coordination Board		In 2017, the responsibility for the approval of Information Standards transferred from the Standardisation Committee for Care Information (SCCI) to the Data Coordination Board (DCB).
Device		In the dm+d this term is used synonymously with the term appliance. Only appliances / devices listed in Part IX of the Drug

		Tariff are allowed for supply against an NHS prescription form FP10 order in England and Wales.
Discontinued Flag & Date		These are attributes at AMPP level. They flag and identify the date from which the Supplier has stated that they will no longer supply the AMPP. This attribute only highlights that the pack has been discontinued, there may or may not be stock available within the supply chain.
Excipient		This is an attribute at AMP level. An excipient is an ingredient that is necessary for the finished pharmaceutical formulation of the product but is not the 'active ingredient'. List H of the Editorial Policy identifies those excipients that are deemed significant and when an excipient that is contained within the list is declared on a SMPC then it will be populated. This attribute positively confirms the presence of an excipient and a null value does not infer that it is absent.
Flavour		This is an attribute at AMP level. It describes the Manufacturers stated flavour of a product and is only populated where an AMP is available in more than one flavour.
GTIN		Global Trade Item Number. Where product packs contain a GS1 bar code that contains globally recognised identification keys to automatically identify a trade item.
Information Standards Board	ISB	The ISB was established by the NHS Information Authority (NHSIA) to govern information standards. In March 2014 the ISB was closed and its functions taken on by the Standardisation Committee for Care Information (SCCI)
Invalidity flag		This flag is found at VTM, VMP, VMPP, AMP and AMPP levels in addition to Supplier and Ingredient Substance. It identifies that the concept is invalid and should not be used. Editorial Policy dictates that invalid concepts are not removed from dm+d but are retained in case they have been used prior to their invalidation. Where a concept is to be made invalid, a communication explaining the reason for the invalidation (i.e. duplicate, outdated, ambiguous, erroneous, or reason not stated), and where possible notification of any replacement concept will be issued to all license holders in the run up to the weekly publication of the database affected by the change.
Medicines and Healthcare products Regulatory Agency	MHRA	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health
Non-Availability		This is an attribute at VMP level. It identifies when all linked AMPs are no longer available.
Prescribing Status		This is an attribute at VMP level. It identifies if the VMP is valid as a prescribable product or if the VMP is not valid as a prescribable product expands why - never valid, not recommended or invalid

		as a prescribable product.
Pro-File		Pro-File is a database of medicinal products produced by NHS manufacturing units under a Specials license. It is intended to allow NHS staff to identify and source products and is only accessible to NHS staff.
Restrictions on Availability		This is an attribute at AMP level. It is used to identify AMPs that are not readily available and identifies the particular restriction. Please note that this attribute does not identify AMPs that are temporarily out of stock but AMPs that are for example imported, drugs available on a named patient basis, specials etc.
SNOMED Identifier		Unique identifiers – SNOMED Clinical Term (CT) codes - allocated to the following concepts: VTM, VMP, AMP, AMPP, ingredient, form, route, unit of measure or supplier.
Standardisation Committee for Care Information (SCCI)	SCCI	Standardisation Committee for Care Information (SCCI) was responsible for the approval of information standards under the Health and Social Care Act 2012. In 2017, the responsibility for the approval of Information Standards transferred to the Data Coordination Board (DCB).
Systemic Anti-Cancer Therapies	SACT	The Systemic Anti-Cancer Therapy dataset is the national mandatory collection of systemic anti-cancer therapy activity from all NHS England chemotherapy providers.
Supplier		The supplier of a product is identified at AMP level and this may be the Manufacturer of the product, a Supplier whereby the product is manufactured by another organisation on behalf of the Supplier or a Distributor/Wholesaler of an AMP.
Terminology Reference Update Distribution site	TRUD	The web site used as the distribution mechanism for the publication of the dm+d data files https://isd.digital.nhs.uk/trud3/user/guest/group/0/home
Virtual Medicinal Product	VMP	The VMP is a level within dm+d. It describes the abstract or generic medicinal product.
Virtual Medicinal Product Pack	VMPP	The VMPP is a level within dm+d. It identifies the amount of a product that is available in a pack. This is expressed by mass, volume or the number of entities.
Virtual Therapeutic Moiety	VTM	The VTM is a level within dm+d. It is an abstract representation of the substance or material, without any reference to form or strength, intended by the prescriber to treat a patient