NHS
Business Services Authority

Department of Health & Social Care

PART IX OF THE DRUG TARIFF APPLICATION GUIDANCE JULY 2025 VERSION 2.3

Record of changes to Part IX of the Drug Tariff Application Guidance

Version	Paragraph	Amendment	Date change made
V2.3	Table 14 page 40	No known plans for blood glucose strips to be discontinued~~/ or the meter has already been discontinued~~ To ensure that service user is able to obtain the blood glucose strips ~~and continue to use existing meter~~	14/01/26
V2.3	Paragraph 37	**Added:** To note, although we welcome Net Zero Commitment Statements from all suppliers, in line with NHS England procurement guidance, companies with annual Part IX dispensing of less than the value of £135,018 are exempt from supplying a Net Zero Statement if they choose. This means the supplier does not have to submit a carbon reduction plan or a net zero commitment.	14/01/26
V2.2	Table 17, page 40	Removed row 'Is this a safety pen needle'	24/10/2025
V2.1	60	The benchmark price is set against the lowest proposed price of a product in the cluster, that supplies at least 5% of the cluster prescription volumes of products ~~and~~, once prescriptions volumes have been standardised against the cluster UOM. The benchmark must also have passed on quality at the time of renewal. The benchmark price is based on the prices submitted at renewal. The cluster is the comparable group of products, the lowest level on the categorisation. If there is no product with 5% of prescription volumes, the product with the highest prescription volumes will be considered as the benchmark. ~~If there was a case where 2 products had the same volumes, the product with the lowest price of the two would be selected.~~	04/09/2025
V2.1	61	NHS Prescription Services will group products that are clinically comparable. This means it is appropriate to substitute one product for another in a clinical setting. For example, a pack of 20 syringes is clinically comparable to a pack of 10 syringes. NHS Prescription Services will compare the prices and prescriptions of products in a	04/09/2025

		cluster by setting a Unit of Measurement (UOM) that considers how products are interchangeable. For example, a pack of 20 syringes is twice as large as a pack of 10, so the price per syringe will be considered when comparing prices. Similarly, when confirming which product sets the benchmark price with 5% of volumes of prescriptions, the total number of syringes prescribed will be considered. These principles provide BSA with a consistent but flexible approach to comparing products, ensuring products in every cluster will be compared according to their clinical comparability.	

Produced by the Department of Health and Social Care in conjunction with NHS Prescription Services and the Part IX Drug Tariff Industry Forum

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INTRODUCTION

This guidance relates and refers to Part IX of the Drug Tariff. 'The Drug Tariff – National Health Service England and Wales' [from hereon – the Drug Tariff] is a monthly publication issued by NHS Prescription Services of the NHS Business Services Authority (NHSBSA) on behalf of the Secretary of State for Health and Social Care. Part IX contains the appliances and chemical reagents, which can be prescribed by prescribing practitioners in primary care operating under NHS General Medical Services.

Manufacturers and distributors wishing to supply an appliance or chemical reagent for NHS prescribing must first seek approval from NHS Prescription Services for inclusion of that product in Part IX of the Drug Tariff. This guidance aims to assist manufacturers submitting products for inclusion into Part IX of the Drug Tariff. The Department of Health and Social Care (DHSC) compiled this guidance for manufacturers and suppliers of medical devices in conjunction with NHS Prescription Services and the Part IX Drug Tariff Industry Forum.

Given the number of medical devices now available and the increasing demand for them, DHSC has worked closely with NHS Prescription Services team to update how listings on Part IX will be assessed. This has included updating the categorisation on Part IX and updating the assessment to the 'enhanced assessment framework'.

Existing listings on Part IX will be gradually undergoing a renewal process after which the new categorisation will be reflected in the published Drug Tariff.

This version (2.0) of the guidance applies to listings due to be renewed and to new applications that are in the same category as listings being renewed. Therefore, if applying for a listing on Part IX, it is important firstly to identify if you should apply under the enhanced assessment framework or under the original guidance (v1.7). Indicative timings can be found on the NHSBSA website. If unsure, please email partixrenewals@nhsbsa.nhs.uk

This application guidance should be read alongside the enhanced assessment framework, to support completion of the application forms, when applying for the Drug Tariff or applying to renew a listing and to support general queries.

Temporary listings are a new feature of the updated listings process and are covered in paragraph 12 and 23-26.

The addition of clinical, expert and patient input from Independent Advisory Panels is a new addition to the process.

DESCRIPTION OF PART IX OF THE DRUG TARIFF

1. Regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 provides that the Secretary of State must compile and publish a statement, referred to as the Drug Tariff; which must include, among other things, the list of appliances and chemical reagents dispensed, or expected to be dispensed, in accordance with NHS prescriptions. NHS Prescription Services deals with applications on behalf of the Secretary of State. Part IX of the Drug Tariff contains the appliances and chemical reagents, which can be prescribed by prescribing practitioners at NHS expense.

2. Part IX has historically had four sections:

    A. Dressings, bandages and certain other appliances;

    B. Incontinence appliances;

    C. Stoma appliances;

    R. Chemical reagents.

3. Part IX is transitioning over time towards eight top level (level one) categories:

    1. Wound and Skin Care;
    2. Gastrointestinal and Urological Care;
    3. Respiratory and Airway Management;
    4. Lymphoedema, Support and Therapeutics;
    5. Sexual, Reproductive and Pelvic Health;
    6. Point of Care Testing and Hypodermic Equipment;
    7. Oral, Dental, Ear, Eye and Nasal Care;
    8. General Clinical Use.

4. The Drug Tariff is published monthly and is available electronically from NHS Prescription Services' website.

5. Manufacturers wishing to supply appliances and chemical reagents for the primary care market must seek approval from NHS Prescription Services (on behalf of the DHSC) for inclusion of a product in Part IX. Regulation 89 (see paragraph 1) sets out that the Drug Tariff must state the prices at which the dispenser's reimbursement for appliances is to be calculated.

Geographical basis and devolution

6. DHSC's responsibilities in relation to Part IX of the Drug Tariff extend only to England. Wales operates a common policy with the DHSC in England and therefore the Drug Tariff currently covers both England and Wales. Scotland and Northern Ireland maintain and publish separate Drug Tariffs, and manufacturers are advised to check their individual arrangements.

7. Further information on inclusion in the Northern Ireland and Scottish Drug Tariffs can be obtained from their websites:

   Public Health Scotland:
   Prescribing practice and dispensing pharmacy open data - October to December 2024 - Prescribing practice and dispensing pharmacy open data - Publications - Public Health Scotland

   Business Services Organisation, Northern Ireland:
   https://bso.hscni.net/directorates/operations/family-practitioner-services/pharmacy/

Appropriate practitioners and supplementary prescribing

8. A listing in Part IX enables products to be prescribed on the NHS by GPs, dentists (if they are also listed in the Dental Formulary), appropriate practitioner prescribers (provided this is done within their competency), supplementary prescribers (where this is part of an agreed clinical management plan), and community practitioners where appropriate.

9. Referenced above, an appropriate practitioner is a non-medical prescriber and includes a range of professions including doctors, nurses, pharmacists and a number of Allied Health Professionals (AHPs). More information on which AHPs can prescribe is available here. Some qualified supplementary prescribers can also prescribe under agreed Clinical Management Plans. Dentists can prescribe medical devices on the NHS if they are listed in the Dental Formulary. Similarly, Community Practitioner Nurse Prescribers can prescribe any medical devices on the NHS if they are listed in the Nurse Prescribers' Formulary (all Part IX devices are included in the formulary).

TRANSITION INTO NEW ENHANCED ASSESSMENT FRAMEWORK

10. A new categorisation of Part IX and an enhanced assessment framework for listings on Part IX is being introduced from July 2025. Changes will be gradually implemented, with indicative waves and timings outlined on the NHSBSA website. Following the first wave of renewals, DHSC will undertake a review of the process and outcomes to ensure intended outcomes are being delivered. DHSC will make any adjustments needed as well as adjust subsequent wave categories and renewal dates where necessary.

11. Until each category has undergone its first renewal, assessments for new listings will be in line with the existing guidance v1.7.

12. Temporary listings (see paragraphs 23-26) will be considered for all applicants as appropriate from July 2025. These will be assessed under the enhanced assessment framework if it is the renewal period for that category or if the category has already been renewed.

13. For both temporary and standard listings, if a supplier applies ahead of their category's renewal period, applications are considered in line with the original process as set out in the guidance v1.7. Two months into the notice of renewal is the last opportunity to apply outside of the enhanced assessment framework.

14. If a supplier applies for a new listing at the time of that category's renewal, the application will be assessed against the enhanced assessment framework.

15. Applications received after a category has been renewed will be assessed against the enhanced assessment framework.

16. DHSC reserves the right to review the policy throughout, in particular, after the first round of renewals and make any necessary policy changes as required. If required, it will be done in conjunction with partners.

17. Listings in Part IXA technical specifications will be exempt from the process. Following feedback from the Expert Reference Groups, the only other products to be exempted from the renewals process are neonatal and paediatric stoma bags. The need for renewal applies to all other products on Part IX of the Drug Tariff. DHSC reserves the right to exclude additional products from categorisation on a case by case basis, which may include products that are bespoke or highly personalised.

Categorisation

18. The listings on Part IX have been recategorised into eight level one categories to roughly guide clinical areas (see paragraph 3). Level two onwards guides prescribers and suppliers to product areas resulting in a cluster. Clusters are the comparable group of products or unique single product clusters, and the lowest level on the categorisation.

19. Suppliers are asked on the application form to indicate which "cluster" their product belongs to. Ahead of each wave the updated categorisation will be shared, which should provide a good indication of which cluster to apply to. Suppliers are able to apply to the cluster they think most appropriate, but the panels will make the final decision on which cluster products are listed in. Suppliers will be informed of their final cluster if it differs to the one applied for. At this point suppliers have the opportunity to appeal, suppliers have 5 working days to respond with the rationale where they disagree. A new cluster can be suggested but the supplier should provide justification for this, and the panel will make the final decision.

20. New categories and clusters can be created when different products come to market that are not comparable with existing listings. New clusters are not created for every distinguishing feature but may be created for those features which add value to the NHS.

21. NHS Prescriptions Services reserve the right to amend the categorisation further in future, both to act on feedback and cover any developments in clinical practice.

22. The General Clinical Use category (category 8) contains products that are used in a variety of clinical settings and are not specific to only one clinical setting. Therefore, the products listed within the General Clinical Use category will be renewed by the most appropriate panel, as part of the other waves, as set out in table 1 below. Category 8 will remain in the categorisation on the Drug Tariff, to facilitate navigation to these general use products.

Table 1 – Corresponding panel for each level 2 subcategory of General Clinical Use (category 8)

Level 2 subcategory	**Reviewing panel**
Gloves	No panel – (BSA only) *Wave 3*
General Use Lubricants	Gastrointestinal and Urological Care – *Wave 3*
Creams and ointments	Wound and Skin Care – *Wave 2*
Dressing protection	Wound and Skin Care – *Wave 2*
General use devices	Point of Care Testing and Hypodermic Equipment and Oral, Dental, Ear, Eye and Nasal Care – *Wave 1*

Temporary Listings

23. Companies considering a temporary listing should apply as usual to the Drug Tariff (in line with paragraphs 10-17). If the NHS Prescriptions Services team assess that it is an innovative product that meets an unmet clinical need but does not have sufficient evidence from the community then a temporary listing may be offered (in place of the application being rejected). As part of the consideration for temporary listing, a product specific evidence generation plan will be requested.

24. A temporary listing means that the product is listed on Part IX for a minimum period of two years assuming it complies with the terms of listing and no safety concerns emerge. At the end of the two years, a three-month review of the product takes place. It is expected that the relevant Independent Advisory Panel would input into this review.

25. It is likely that products granted temporary listings will require a new cluster and therefore will have no benchmark price. The Independent Advisory Panel and NHS Prescriptions Services will be guided by Annex A to determine if the proposed price is a “reasonable price”.

26. Following the review, the outcomes could be either removal from the Drug Tariff, an extension of the temporary listing whilst the supplier continues to gather more evidence, or a permanent listing. If it is determined that the product should not remain listed on Part IX, then a six month notice of removal from Part IX will be issued.

ENHANCED ASSESSMENT FRAMEWORK

27. **Table 2** - Overall scoring approach below summarises the overall scoring approach across the enhanced assessment framework. All products will receive an overall score as part of their renewal or listing process. The Overall Score calculation is Quality Score + Social score + Price Score = Overall Score. All evaluation criteria apply to all suppliers that own the Drug Tariff listing, including manufacturers and distributors.

28. For an applicant to pass, they must meet the minimum overall pass score of 55 and the minimum quality score of 20 and the minimum price score of zero. See the price evaluation section (paragraphs 59-70), for further details on price scoring.

29. If a supplier initially fails on price, suppliers will have the opportunity to lower prices to remain listed on the Drug Tariff, as long as they meet the minimum requirements for quality.

Table 2 - Overall scoring approach

Prequalification criteria		**Quality scoring**		**Social scoring**		**Price scoring**	
Question	*Pass/ Fail*	*Question*	*Points*	*Question*	*Points*	*Product Price*	*Points*
Regulatory	Pass	Value add	10	Circular economy	4	Benchmark	40
Appropriate for prescribing in primary and community care	Pass	Value add	10	Sustainable packaging	2	+8% higher price	30
Carbon Reduction plan	Pass	Value add	10	Resilient supply chains	4	+16% higher price	20
Modern Slavery	Pass	Minimum requirement	20			+24% higher price	10
						+32% higher price	0
						> 32% higher price	Fail
Pass/Fail		**Maximum Score**	**50**	**Maximum Score**	**10**	**Maximum Score**	**40**
Overall Pass Score:						**55/100**	

Prequalification criteria

30. Before products are evaluated, they must meet the prequalification criteria. If it is not clear to NHS Prescription Services team if the product is appropriate for prescribing, the Panel will be asked for advice. Criteria include:

    For product:

- Evidence meets the relevant medical device regulatory requirements;
- Appropriateness for prescription in primary and community care;
- Confirmation company is still supplying.

From the supplier:

- Completed Carbon Reduction Plan or Net Zero commitment;
- Statement of how supplier complies with preventing modern slavery.

Table 3 - Prequalification criteria at the product and supplier level

		Evidence requirement	Evidence supplied
Product	Regulatory	Evidence meets the relevant medical device regulatory requirements.	Supply of up-to-date CE and/or UKCA certificate MHRA registration number and date registered with MHRA*
	Appropriateness for prescription in primary and community care.	See definition below (paragraph 33-35).	Written explanation as to how product meets criteria
	Confirmation company is still supplying	Written confirmation in application form	
Supplier	Carbon reduction plan	Supplier has the ability to choose either: • A completed Carbon Reduction plan for scope 1, 2, and a subset of scope 3 emissions (those described in the NHS Net Zero supplier roadmap) • Or, a Net Zero commitment.** Guidance on both are available here.	Supply of up-to-date Carbon Reduction plan or Net Zero commitment.
	Modern slavery	Supplier is compliant with the requirements contained within section 54 of the Modern Slavery Act 2015 and associated guidance.	Modern Slavery Statement

*Manufacturers in Northern Ireland should be aware of their registration requirements and be aware of any changes from the MHRA.
** See paragraph 37 for exemptions.

Product requirements

Product requirements - evidence meets the relevant medical device regulatory requirements

31. Manufacturers and suppliers have a responsibility to ensure the medical devices they supply comply with the relevant regulations, and to provide copies of the appropriate certificates as evidence. Manufacturers and suppliers are also responsible for the currency of the listings in the Drug Tariff and must inform NHS Prescriptions of any changes to the original certification submitted which

will affect the listing.

32. The following should be noted:

- In Great Britain, medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended). Medical devices with a valid CE marking continue to be accepted on the Great Britain market until, at the latest, 30 June 2030 depending on device type and classification. For Northern Ireland, the EU Medical Devices Regulation (2017/745) has applied in Northern Ireland since 26 May 2021. The In vitro Diagnostic Medical Device Regulation (2017/746) has applied in Northern Ireland since 26 May 2022.
- All medical devices, including in vitro devices (IVDs), custom-made devices and systems or procedure packs, must be registered with the MHRA before they can be placed on the market in Great Britain (England, Wales and Scotland). Registration requirements differ for Northern Ireland. Please see the MHRA guidance for details.

Product Level Requirements - Appropriateness for prescription in primary and community care

33. Some appliances may be appropriate for use in the community but not eligible for prescribing on an FP10 (standard prescribing form used in England)/electronic prescription and a listing on the Drug Tariff will be rejected.
    - **Could it be loaned** - An example of this is when it would be more appropriate to loan a medical device to a patient rather than prescribing it. Prescribing a product makes it the patient's property. The supply on prescription may not be the most cost-effective route of making the appliance available in the NHS, and NHS Prescription Services may challenge this proposed route of supply, if they think this route of supply would be too costly.
    - **Is the pack size appropriate** - Similar considerations may apply where products which are supplied in pack sizes which are not appropriate for individual use, as for instance a patient may not have the space at home to store products.
    - **Not for social care products** - Prescribed items allowable on an FP10 should be for the treatment of a medical condition – which can include diagnosis and prevention. This does not include items that could be considered more appropriate for the social care of an individual, for example, incontinence and sanitary pads, modified cutlery or crockery, or drinking vessels, wheelchairs and walking sticks etc.
    - **Self-administered/ no enhanced training required** - Appliances considered appropriate for prescribing by GPs and other prescribers will usually be for self-administration by the patient, perhaps with the help of a carer. Some appliances may need to be administered by a doctor or other health professional. These products should not require enhanced training of the doctor or health professional specifically in their use. If a product was only suitable for use in a hospital setting it would not satisfy the criteria.

34. This list is not intended to be exhaustive, and NHS Prescription Services will

advise on suitability, and inform the applicant of the final decision.

35. The above consideration is only likely to be necessary when similar products have not been previously listed in the Drug Tariff. If a similar product is already listed in the Drug Tariff, the criterion would generally be extended to a similar product, unless clinical practice has moved on and it is no longer a product the panel think suitable for prescribing on the NHS.

Supplier requirements:

36. The supplier refers to the manufacturer or distributor that owns the Drug Tariff listing. For example, it is not required to provide two Carbon Reduction Plans, if a distributor is supplying the product on behalf of a manufacturer. Only the company that owns the listing must supply the evidence.

37. Carbon reduction plan or Net Zero commitment

    - Carbon Reduction Plan Template – To align with the NHS net zero ambition, as required in the NHS. This includes the supplier's current carbon footprint and its commitment to reducing emissions to achieve Net Zero emissions by 2050. Supplier develops and publishes on their website.
    - Or, the supplier has the ability to choose to supply a Net Zero commitment. Guidance on both are available here.
    - To note, although we welcome Net Zero Commitment Statements from all suppliers, in line with NHS England procurement guidance, companies with annual Part IX dispensing of less than the value of £135,018 are exempt from supplying a Net Zero Statement if they choose. This means the supplier does not have to submit a carbon reduction plan or a net zero commitment.

38. Modern slavery statement

    - Supplier is compliant with the requirements contained within section 54 of the Modern Slavery Act 2015 and has a written statement. See p.66 of the guidance Transparency_in_supply_chains_a_practical_guide.pdf

Quality evaluation criteria

39. Quality evaluation is comprised of two stages. Stage 1 checks whether the application meets the minimum requirements. The criteria are that the application must be appropriate for the chosen cluster, as agreed by the Independent Advisory Panel. If the application is deemed inappropriate it will be explained to the applicant which cluster that NHS Prescriptions Services and the panel think the product should be listed in and the product will be automatically moved, without the need to reapply. It does not mean that the applicant fails altogether.

40. Quality Stage 1 then checks if the application meets the minimum evidence requirements for the application type, see Table 5. These are all criteria that the applicant either passes or fails and are not scored. For renewals, there are no minimum requirements beyond the prequalification criteria listed in Table 3.

41. Quality Stage 2 assesses the value add criteria should the applicant choose to provide them. A maximum of 30 points can be awarded in total from the value add criteria of quality. The value add criteria are:

    - Product effectiveness;
    - Supporting self care;
    - Supporting system savings;
    - Reducing inequalities.

42. An applicant can choose which 3 of the 4 value add criteria to apply with. A maximum of 10 points is awarded for each of the chosen 3 criteria. These points are added to the 20 points awarded in stage 1.

43. An applicant can choose to only submit the minimum requirement criteria to obtain the 20 points but will not be able to score more than 20 points on quality.

Table 4 – Quality evaluation criteria

Quality Scoring Framework		
Quality scoring criteria		**Score**
Stage 2 value add criteria		Score
Meets the minimum requirement for category and offers **three value add criteria**		Up to 50
Meets the minimum requirement for category and offers **two value add criteria**		Up to 40
Meets the minimum requirement for category and offers **one value add criteria**		Up to 30
Stage 1 minimum requirement criteria	Evaluation criteria	Score
Meets the **minimum requirement** for category.*†	• Appropriate for chosen category, as agreed by Independent Advisory Panel. • Meets minimum evidence requirements, for the application type.	20
Criteria	Evaluation criteria	Score
Does not meet the requirement for the category.	• Lacking safety and quality mark or certification, value add element will not be scored. • Not appropriate for category**. • Does not meet requirements - at discretion of Independent Advisory Panel, if significant concerns.	Fail

*Table 4 outlines an overview of the quality scoring, including an overview of minimum requirements and value add criteria. *See evidence requirements for different types of application – novel/me too etc. † see Annex B for specific minimum requirements for continuous glucose monitors (Detection sensors, interstitial fluid for glucose), blood glucose testing strips, ketone testing strips, lancets and insulin pen needles.**If the panel does not agree with the cluster the supplier has applied to they will let the supplier know where they have placed the product.*

Quality Stage 1 – Minimum requirement criteria

44. The minimum requirements for the quality evaluation vary depending on the type of application (see Table 5). The types of application are:
    - A new application where no comparable product is already listed on the Drug Tariff. This may require a new cluster to be created, and as medical devices continue to evolve may potentially require a new subcategory or level one category.
    - A ‘me too’ application is a new application where there is an existing comparable product already listed. The applicant does not have to justify the clinical use of the device but is expected to provide evidence that their product is as effective as the other listed products.

- An application for a line extension is when a supplier wishes to list further variants, such as different sizes or colours, to an existing listed product range.
- For renewals, given these are already listed products, the minimum requirements are simply the prequalification criteria in Table 3.

Table 5 - Minimum requirements for quality evaluation

Type of Application	Criteria	Evidence Requirement*	Scoring
New application for new type of product ***i.e. where no comparable products currently listed on the Part IX of the Drug tariff***	• Provide evidence of effectiveness of the product, compared to the current standard of care. • Provide evidence demonstrating the product functions as stated.	• Clinical evidence/ real-world evidence • Evidence should be a minimum of 2+ per levels of evidence, Table 18	Pass/Fail
Me too application – new application for existing type of product ***i.e. where there is an existing comparable product in Part IX of the tariff***	• Provide evidence product is as effective as existing products in the cluster.	• Clinical evidence is not generally required if a similar product is already included in the Drug Tariff. • Evidence that the product is the same as the comparable products.	Pass/Fail
Line extensions	• Provide evidence product is as effective as the current listing that new line is being added to.	• Clinical evidence is not generally required if a similar product is already included in the Drug Tariff. • Evidence that the product is the same as the current listing that new line is being added to.	Pass/Fail
Renewals of products already listed on Part IX of the Drug Tariff	• Not Applicable –The requirements are the prequalification criteria**	• Not applicable	Pass/Fail

** These are intended as guidelines. If the supplier can issue other credible evidence to support contribution to this theme this will be evaluated if a clear rationale is provided.*
***If the panel has concerns about existing products on Part IX of the Drug Tariff, they can request further evidence from the supplier.*

Note – see Annex B, for specific minimum requirements for continuous glucose monitors (detection sensors, interstitial fluid for glucose), blood glucose testing strips, ketone testing strips, lancets and insulin pen needles. Devices with apps should meet Digital Technology Assessment Criteria (DTAC) requirements.

Quality stage 2 - Value add criteria

Product effectiveness

45. The question for product effectiveness is - How does your product demonstrate product effectiveness and deliver predictable, consistent outcomes, above and beyond the minimum requirement?

    - As an example, you might include in your application:
        - What evidence supports the product efficacy of your product above and beyond the minimum requirement?
        - How does your product improve patient outcomes compared to alternatives?
    - Evidence to support an application might include the following:
        - Clinical or real-world evidence.
        - Performance metrics showing measurable patient benefits.

Table 6 - Scoring guidance for value add criteria of product effectiveness

Scoring	Points
Good demonstration. The evidence robustly demonstrates product effectiveness beyond minimum requirements and clear, measurable benefits. Supported by evidence: Clinical evidence levels 3, 2-, 2++, 2+, 1++, 1+, 1- as per Evidence Grading guidance, Table 18. The panel reserves the right to exclude Level 2- or Level 3 if deemed unsuitable.	Good (10 points)
Satisfactory demonstration of product effectiveness beyond the minimum requirements. Supported by evidence: Clinical evidence levels 3, 2-, 2++, 2+, 1++, 1+, 1- as per Evidence Grading guidance, Table 18. The panel reserves the right to exclude Level 2- or Level 3 if deemed unsuitable.	Satisfactory (5 points)
Poor demonstration. There is little, weak or unclear evidence on improved product effectiveness.	Poor (0 points)

Supporting self care

46. The question for supporting self care is - How does your product enable patients to manage their own care effectively and reduce reliance on clinical intervention?

    - As an example, you might include in your application:

- Does the product design support ease of use for patients or caregivers?
- What resources (for example, guides, videos) are available to help patients use the product?
- What resources are available to help patients use the product correctly in between clinician visits?

- Evidence to support an application might include the following:
  - User manuals and training resources;
  - Case studies showing reduced reliance on healthcare providers;
  - Patient feedback or satisfaction surveys.

Table 7 - Scoring guidance for value add criteria of supporting self care

Scoring	Points
Good demonstration. The evidence robustly demonstrates improved self-care enablement, with clear patient benefits and evidence of reduced reliance on clinical intervention.	Good (10 points)
Satisfactory demonstration. There is evidence of improved self-care enablement.	Satisfactory (5 points)
Poor demonstration. There is little, weak or unclear evidence on improved self-care enablement.	Poor (0 points)

Supporting System Savings

47. The question for supporting system savings is - How does your product deliver value for money through lifecycle cost savings or reduced healthcare utilisation?

- As an example, you might include in your application:
  - What is the total cost of ownership for your product (for example, lifespan, replacement frequency)?
  - How does your product reduce healthcare costs (for example, fewer hospital visits, shorter stays)?
  - Does the product require less frequent replacement or maintenance compared to alternatives?
- Evidence to support an application might include the following:
  - Cost-benefit analysis showing long-term savings;
  - Evidence of reduced healthcare utilisation (for example, fewer interventions or hospital stays);
  - Lifecycle assessments demonstrating durability or reduced

replacement costs.

Table 8 - Scoring guidance for value add criteria of supporting system savings

Scoring	Points
Good demonstration. The evidence robustly demonstrates increased system savings.	Good (10 points)
Satisfactory demonstration. There is evidence of increased system savings.	Satisfactory (5 points)
Poor demonstration. There is little, weak or unclear evidence on system savings.	Poor (0 points)

Reducing inequalities

48. The question for reducing inequalities is - Detail how the use of your product may reduce inequalities in access, experience or outcomes within the target pathway?
    - As an example, you might include in your application:
        - How is the product designed to accommodate diverse needs (for example, disabilities, comorbidities, cultural differences)?
    - Evidence to support an application might include the following:
        - Case studies addressing access/usage issues for specific populations or evidence of addressing bias.

Table 9 - Scoring guidance for value add criteria of reducing inequalities

Scoring	Points
Good demonstration. Evidence robustly demonstrates that the product is designed to address health inequalities, and evidence of patient benefits.	Good (10 points)
Satisfactory demonstration. Evidence demonstrates that the product is designed to address health inequalities.	Satisfactory (5 points)
Poor demonstration. There is little, weak or unclear evidence the product is designed to accommodate diverse needs.	Poor (0 points)

Social evaluation criteria

49. Social is a newly assessed element included in the enhanced assessment framework. The Government has a huge opportunity and responsibility to maximise benefits effectively and comprehensively through its commercial activity.

50. There are three criteria under social that a supplier can apply with. These are:
    - Circular economy (4 points maximum);
    - Sustainable packaging (2 points maximum);
    - Supply chain resilience (4 points maximum).

Circular economy

51. The Circular economy question is: How does your product support a circular economy? (Does it preserve its value after use, through reuse, remanufacture and/or recycling?)

    - As an example, you might include in your application:
        - Specify how many times your product can be safely reused before disposal
        - Describe to what extent your product, or modular components of the product, can easily be recycled through domestic waste streams
        - Detail any take-back, remanufacture or recycling schemes you operate, including partnerships with waste management providers
        - Provide data on what proportion of your product is made from recycled materials, and any other steps taken to reduce use of virgin raw materials or resources in production
        - Explain how your product reduces the volume of products required or disposed of in the course of the patient's treatment through modular design or a longer use-life than equivalent products
        - Detail what guidance is provided alongside your product on correct disposal
    - Evidence to support an application might include the following:
        - Lifecycle assessments demonstrating the environmental benefits of the product's circularity;
        - Certifications for material recyclability or biodegradability (e.g., ISO 14021);
        - Documentation of take-back schemes, including data on waste reduction or recycling rates;
        - Case studies or examples of how the product contributes to reducing waste in practice.

Table 10 - Scoring guidance for circular economy criteria of social evaluation

Scoring	Points
Demonstrates strong support for a circular economy through reuse, remanufacture, recycling, reduction or a combination. The product demonstrates equal or significantly greater circular economy support when compared with the best equivalent products on the market. Provides clear disposal guidance that maximises recyclability.	Good (4 Points)
Demonstrates some support for a circular economy through reuse, remanufacture, recycling, reduction or a combination, but to a limited extent. The product demonstrates equal but not significantly greater circular economy support when compared with the majority of equivalent products on the market. Provides clear disposal guidance that maximises recyclability.	Satisfactory (2 Points)
No demonstration that the product supports a circular economy. Or the product is significantly less supportive of a circular economy when compared with the majority of equivalent products on the market.	Poor (0 Points)

Sustainable packaging

52. The sustainable packaging question is: How have you minimised the environmental impact of your product's packaging?

- As an example, you might include in your application:
  - Explain how you have minimised the amount of packaging provided with the product, including secondary packaging;
  - Specify how much of the packaging can easily be recycled through domestic waste streams and explain the presence of any non-recyclable packaging;
  - Specify what proportion of the packaging uses recycled materials.
- Evidence to support an application might include the following:
  - Breakdown of recyclability (% of packaging recyclable via standard household waste vs. specialist facilities);
  - Data on % recycled content (post-consumer recycled materials);
  - Lifecycle analysis or carbon footprint assessment of packaging;
  - Compliance with NHS sustainability goals, UK Plastics Packaging Tax, and relevant ISO standards (ISO 14001, FSC-certified materials).

Table 11 - Scoring guidance for sustainable packaging criteria of social evaluation

Scoring	Points
Demonstrates strong support for the NHS Supply Chain Packaging Programme and Net Zero commitments. Uses minimal, lightweight, and recyclable packaging. Packaging is widely recyclable through household waste streams or closed-loop systems. No unnecessary plastic or non-recyclable materials unless clinically essential, with clear justification.	Good (2 Points)
Demonstrates some support for NHS sustainability targets. Some efforts made to reduce packaging waste, but non-recyclable components are present without clear alternatives. Recyclability is limited to specialist facilities. Some commitment to circular economy principles, but evidence is inconsistent or incomplete.	Satisfactory (1 Points)
Poor demonstration. There is little, weak or unclear evidence the product is designed to ensure packaging is sustainable.	Poor (0 Points)

Supply chain resilience

53. The supply chain resilience question is: How do you ensure a resilient and continuous supply of your product, withstanding supply shocks and disruptions?

    - As an example, you might include in your application:
        - Outline your approach to monitoring and mitigating risk in the supply chain, including sourcing diversification, inventory management, contingency planning, and onshoring or alternative manufacturing sites;
        - Provide examples of measures taken to address specific threats (e.g., geopolitical shocks, manufacturing delays, demand surges and raw materials shortages);
        - Explain to what extent your product is interoperable with other manufacturers' products and consumables;
        - Explain what mitigations are in place to reduce the risk of technology obsolescence.
    - Evidence to support an application might include the following:
        - Risk assessments or business continuity plans detailing contingency measures for supply chain disruptions;
        - Data on inventory levels, sourcing diversification, and supplier reliability, UK-based or alternative manufacturing sites;

- Case studies demonstrating successful mitigation of supply chain disruptions or capacity scaling during demand spikes;
- Certifications or audits related to supply chain standards (e.g., ISO 22301 for Business Continuity Management).

Table 12 - Scoring guidance for supply chain resilience criteria of social evaluation

Scoring guidance	Points
Demonstrates strong supply resilience. Evidence for a robust, proactive approach with comprehensive risk monitoring, sourcing diversification, contingency planning, and inventory management. Provides strong evidence of successful mitigation strategies and ensures high interoperability with other products. Clear measures to prevent technology obsolescence, supported for example by risk assessments, supplier data or case studies	Good (4 Points)
Demonstrates some mitigation strategies exist but are not fully tested or consistently applied. Addresses most important aspects but lacks depth in risk management, contingency planning, or supplier diversification. Product has some interoperability, and technology obsolescence risks are acknowledged but not well-documented. Evidence is partial or inconsistent, with gaps in risk assessments or case studies.	Satisfactory (2 Points)
Poor demonstration. There is little, weak or unclear evidence of strong supply resilience.	Poor (0 Points)

54. For the purpose of this framework, we are using the definition of a circular economy as set out in the Government's Design for Life Roadmap as: "one where materials are delayed from becoming waste for as long as possible, by ensuring products and the materials they are made from are maintained at their highest value for as long as possible".

55. There are various factors that determine how effectively a product supports a circular economy even accounting for the challenges with personalised products provided on the Drug Tariff. When assessing a product's support of the circular economy, we will consider the following factors:

- Which forms of circularity the product supports (reduction, reuse, remanufacture, recycling or a combination).
- The extent of circularity (such as the number of times a product can be reused, or the percentage of recycled materials used).

- The maturity of circular technology within the product category (is the product's circular functionality innovative? For example, a reusable product in a predominantly single-use category).

56. There are various methods of achieving a circular economy which can maintain the value of products and materials to a greater or lesser extent. For this framework, we are interested in the following approaches and the following broad hierarchy will be considered in the scoring of products:

    - **Reuse:** Products that can be safely reused multiple times, reducing the need for single-use products and thereby minimising waste.

    - **Reduction:** Products that reduce the total volume required by patients, either by lasting longer or fulfilling multiple purposes, thus decreasing the need for multiple products.

    - **Remanufacture:** Products that have been remanufactured or can be remanufactured through a take back scheme.

    - **Recycling:** Products that can be recycled through domestic waste streams. The percentage of recyclable materials compared to other products in the category will also be considered when scoring. The government's policy on household recycling can be found here.

    - **Use of Recycled Materials**: Where recycled materials have been used in the manufacture of the product including single use, the percentage of recycled materials used compared to other products in the same category will be considered when scoring.

57. Some products will offer greater support of the circular economy than others. For example, two equivalent products might be reusable, but one might be designed to be reused 10 times while another can be reused 100 times. Alternatively, one product might use 20% recycled material while another uses 70%. This will be recognised so that the products that best support a circular economy are rewarded in the scoring.

58. The purpose of this criteria is to reward and incentivise industry to innovate by developing more sustainable products. We recognise this will take time and that circularity is harder to achieve for some products than others, and conversely, even where products can be made reusable, it may be possible to make further innovations such as using recycled materials or making products recyclable at the end of their use-life. DHSC acknowledges that for specific areas for infection control reasons single use products may be necessary, such as lancets. Accordingly, this framework has been designed to maintain an incentive for innovation that will maximise support for a circular economy. To recognise and reward this innovation, the assessors will therefore compare each product's circular economy support with other equivalent products in the product category, to account for the current maturity of circular innovation.

Price Evaluation

59. Products will be scored between zero and 40 on price, with 40 being awarded to products that are priced at or below the benchmark price.

60. The benchmark price is set against the lowest proposed price of a product in the cluster, that supplies at least 5% of the cluster prescription volumes of products, once prescriptions volumes have been standardised against the cluster UOM. The benchmark must also have passed on quality at the time of renewal. The benchmark price is based on the prices submitted at renewal. The cluster is the comparable group of products, the lowest level on the categorisation. If there is no product with 5% of prescription volumes, the product with the highest prescription volumes will be considered as the benchmark.

61. NHS Prescription Services will group products that are clinically comparable. This means it is appropriate to substitute one product for another in a clinical setting. For example, a pack of 20 syringes is clinically comparable to a pack of 10 syringes. NHS Prescription Services will compare the prices and prescriptions of products in a cluster by setting a Unit of Measurement (UOM) that considers how products are interchangeable. For example, a pack of 20 syringes is twice as large as a pack of 10, so the price per syringe will be considered when comparing prices. Similarly, when confirming which product sets the benchmark price with 5% of volumes of prescriptions, the total number of syringes prescribed will be considered. These principles provide BSA with a consistent but flexible approach to comparing products, ensuring products in every cluster will be compared according to their clinical comparability. These principles provide BSA with a consistent but flexible approach to comparing products, ensuring products in every cluster will be compared according to their clinical comparability.

62. Each benchmark price will be reviewed by NHS Prescription Services to ensure that it is appropriate. They may request additional information from suppliers to understand whether a price is appropriate. NHS Prescriptions Services can manually set the benchmark price if they believe the resultant benchmark price from the methodology in paragraph 60 is inappropriate. For example, it may be considered that the price has increased too much from the current listed price, the price may be artificially low, or the product price is not reflective of the cluster.

63. Proposed prices that are higher than the confirmed benchmark price are deducted points for every percentage that they are above the benchmark price. The deduction rate is 1.25. Therefore, for every 1% higher the proposed price is from the benchmark price, 1.25 points are deducted, to a maximum of 40 points.

64. Some products may be listed at a lower price than the benchmark price if the listing is applied for after the benchmark is set (after renewals for example) or if the proposed price is the lowest but does not qualify as the benchmark price.

65. Products that are more than 32% higher in price than the benchmark will fail the enhanced assessment process, regardless of how the application scored in the Quality and Social elements. At this stage it will be explained to the supplier that the

price is too high and the supplier will have an opportunity to reduce their proposed price.

66. If a product initially fails on price, the applicant will have one opportunity to lower its price below the maximum pass price, otherwise, the applicant will fail the enhanced assessment framework. NHS Prescription Services will then issue the six months' notice of removal from Part IX.

67. Following renewal, should a supplier wish to lower their price in the future, the supplier can apply to NHS Prescription Services to do this. The benchmark price for other future applications for the relevant cluster will remain as confirmed at renewal, until the next renewal.

68. Pack size, product size and cost per use will be taken into account when reviewing the price.

69. Renewals supersede any upcoming annual increase in price. Annual price increases can be applied for a year after the renewed prices are published. Suppliers will be able to apply for an annual price increase for their product 10 months following publication in the Drug Tariff of renewed prices, if the supplier is wishing to increase their price in line with the annual price increase policy (see annex D).

70. In the case of new products in which a new cluster is required, there will be no benchmark price. The Independent Advisory Panel and NHS Prescriptions Services will be guided by Annex A to determine if the proposed price is a "reasonable price". If questions arise over whether the proposed price is reasonable, NHS Prescription Services will email the applicant to explain exactly what the concerns are and will be prepared to clarify to the applicant what type of evidence would be likely to address those concerns. Depending on the nature of the NHS Prescription Service's concerns, such evidence may need to include data to demonstrate clinical benefits.

Disclosure of scores

71. When the renewal round is complete, suppliers will receive their scores for quality, social, price and total score as well as the confirmed benchmark price. This will happen irrespective of whether the application achieves the pass score or not.

72. Scores of other suppliers will not be shared. Neither will information on product scores be shared with anyone else including prescribers. Prices are published on the Drug Tariff so suppliers will continue to be able to see publicly listed products and corresponding prices. They are recognised as being commercially confidential and so will only be disclosed in the normal circumstances where the disclosure of such information is required by a rule of law.

Decisions on Part IX listing

73. Two types of listing decision are available:

    i. Acceptance – a GP or other prescriber may prescribe on the NHS for any patient or condition for which they consider the appliance appropriate.

ii. Rejection – the appliance may not be prescribed by a GP or other prescriber on the NHS.

74. Under the enhanced assessment framework, an applicant can appeal against the following:
    - Their product's quality score;
    - Their product's social score;
    - That their product is in the incorrect cluster or category.

75. An applicant cannot appeal against the following:
    - Another supplier's product score;
    - Their own scores if the applicant's product has passed the assessment and is listed.

76. Following disclosure of the scores (for new applications and renewals) the applicant should email partixrenewals@nhsbsa.nhs.uk within 5 working days with their intention to appeal, providing information on what is being appealed against. If any further information is required, applicants will be notified at this point. If the applicant wishes to provide further information they will be given a timetable for doing so.

77. NHS Prescription Services and Independent Advisory Panels review appeals, and the score will be adjusted where applicable. NHS Prescription Services aim to complete any appeals within 20 working days. This timeframe is subject to review after the first wave.

78. As outlined in paragraph 19, where NHS Prescriptions Services or the panel disagree with the cluster the applicant has selected, they will get in touch with the applicant to explain and potentially require further information. Suppliers should respond within 5 working days. Where the supplier is not responsive to these requests the supplier will be placed in the cluster the panel think most appropriate.

79. For applications not involving the enhanced assessment process please see guidance v1.7.

Evidence Required

80. See specific evidence requirements as per minimum quality, quality value add and social criteria.

81. The type of supporting evidence required will depend on the circumstances of each application. All applications for inclusion of a product onto Part IX of the Drug Tariff must demonstrate patient benefit as well as appropriateness for NHS prescribing in primary and community care.

82. NHS Prescription Services and the DHSC welcome applications from manufacturers producing innovative devices and appliances. Applicants will need to be aware that evidence supporting innovative products is likely to need to be more robust with proven demonstrable clinical benefits for patient care. Further discussions with external agencies and the Independent Advisory Panel may also

be necessary which may extend the expected and usual timelines for the application processes.

83. As outlined in the minimum requirements, all applicants will need to be aware that the need for evidence is likely to be greater if Part IX does not already contain similar products. Where questions arise over the appropriateness of a listing, NHS Prescription Services will explain their concerns and clarify to the applicant what evidence might allay those concerns. Applicants are referred to Annex C for further information and guidance.

84. As outlined in the minimum requirements, NHS Prescription Services will accept different levels of evidence appropriate to the device being considered. Applicants are advised that NHS Prescription Services cannot provide detailed advice with regard to the type of evidence appropriate to their submission product. The onus is on individual applicants to make the case.

85. As NHS Prescription Services and the Independent Advisory Panel are acting in the role of assessor, no face-to-face meetings or telephone conversations will be held with applicants. Correspondence must be conducted via e-mail. This is to ensure transparency, a clear audit trail and impartiality. If it is felt that a verbal conversation would be easier for clarification, NHS Prescription Services will initiate the appointment.

86. When a manufacturer submits a chemical reagent for consideration, they must make an annual declaration of the free services that they will provide in order to support the use of their product. For instance, the supply of educational material, meters and the provision of helplines. This is done using the CRSDF01 form available on the NHS Prescription Services' website. If the reagent is listed, it is the responsibility of the listing holder to update this information on an annual basis.

87. NHS Prescription Services maintain the right to request the physical product to support the evidence for the assessment.

Promotional Policy

88. Any appliances approved for listing must comply with current UK legislation regarding clinical claims. Reference can be made in plain text to the availability of the product on NHS prescription on non-promotional material and should only be made in the technical information specifically designed for the advice of healthcare professionals. This includes:
    - entries in the BNF, MIMS, Chemist and Druggist;
    - articles in peer reviewed journals;
    - the standard company data sheet;
    - product data sheets on company websites (which must be password protected).

89. Suppliers must not use terminology on any packaging, websites or promotional material which implies further involvement with the NHS or Drug Tariff, such as

approved, supported, endorsed, authorised or certified.

90. Any “direct to patient” marketing or advertising material (in either hard copy or electronic format, including social media websites) promoting an appliance listed in Part IX must not make reference (express or implied) to an NHS approved listing. Any breach of this provision may result in the product being recommended for de-listing. It is also important to remember that these products may require amendments to be made to their packaging to make them suitable for supply on prescription. The language and context of the packaging should be appropriate to the supply of the device on prescription.

The Freedom of Information Act

91. The Freedom of Information Act 2000 came into force in January 2005 and gives any person legal rights of access to information, which is held by a public authority. The Freedom of Information Act 2000 contains 23 exemptions under which a request for information may be refused. Submissions from manufacturers may fall under a number of exemptions from the Freedom of Information Act 2000. Manufacturers are recommended to ensure that all submissions for inclusion onto Part IX of the Drug Tariff are marked “Commercial – in Confidence” if they wish information on their applications to be withheld.

92. Section 41 of the Freedom of Information Act provides an exemption of the right of access under the Freedom of Information Act if release would be an actionable breach of confidence. This exemption qualifies the right of access under the Freedom of Information Act 2000 by reference to the common law action for ‘breach of confidence’. According to that action, if a person who holds information is under a duty to keep that information confidential (a ‘duty of confidence’), there will be a breach of confidence if that person makes an unauthorised disclosure of the information. The concept of ‘breach of confidence’ recognises that unauthorised disclosure of confidential information may cause substantial harm. For example, the disclosure of a person’s medical records could result in a serious invasion of that person’s privacy, or the disclosure of commercially sensitive information could result in substantial financial loss. The law protects these interests by requiring the information to be kept confidential: if information is disclosed in breach of a duty of confidence, the courts may award damages (or another remedy) to the person whose interests were protected by the duty.

93. Section 43 (2) of the Freedom of Information Act 2000 exempts information, disclosure of which would be likely to prejudice the commercial interests of any person. It also includes a specific exemption for trade secrets. It protects not only the commercial interests of third parties but also the commercial interests of the public authority that holds the information. Under the terms of the Act, ‘Commercial’ can be taken to mean relating to an activity in the way of a business, trade or profession.

94. Further information on the Freedom of Information Act 2000 is available from https://www.gov.uk/make-a-freedom-of-information-request/the-freedom-of- information-act .

Annual and exceptional price increases

95. The DHSC has reached agreement with industry representatives on a number of issues in connection with Part IX. Included in this guidance is - Annex D, an agreement reached between DHSC, NHS Prescription Services and the Part IX Drug Tariff Industry Forum on price rises. In reaching this agreement the Part IX Drug Tariff Industry Forum represented all relevant manufacturers.

96. If the product range includes ongoing Exceptional Price Increases (EPIs) at the point of review, NHS Prescription Services reserve the right to postpone the renewal period until the point at which the EPI expires if they deem it appropriate.

97. Renewal periods, once commenced, supersede any ongoing Annual or Exceptional Price Increases (as covered in Annex D), with the date at which the new price is listed becoming the new anniversary date for the product.

98. As with current processes, applications for an annual price increase will be closed for 10 months from the date of listing, with companies then allowed to apply 2 months in advance and increases applied from month 12. Applications for an EPI are open immediately after the renewal process (see Annex D for acceptable circumstances).

99. Suppliers due to have products renewed can apply for their annual price increase while renewals are ongoing, if they are eligible. The latest possible date to apply for an annual price increase is during the renewal period. This is because this would allow at least one month's uplift on the tariff before the price is updated in line with the renewal price.

100. For arrangements for the reimbursement and remuneration of services relating to appliances within Part IX of the Drug Tariff, please see https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug- tariff

101. If a manufacturer wants to align the anniversary dates for price increases across a product range, NHS Prescription Services can manage this request by applying the procedure outlined in Annex D. Please note that once a category has been renewed the new anniversary date of listing is the date that the agreed renewal price is published.

The Application Procedure

102. Until a category is due for renewal, applicants should complete the application forms (DT1A and DT1B) for each product or product range they seek to include in Part IX and follow guidance v1.7. One copy of each form, and a copy of the relevant CE documents should be sent via email to pixie@nhsbsa.nhs.uk.

103. At the time of renewal or following renewal, applicants should complete the application forms (DT1C) for each product or product range they seek to include in Part IX. This form will be available on the NHSBSA Drug Tariff website. Any questions should be emailed to partixrenewals@nhsbsa.nhs.uk.

104. All applications should be submitted electronically to NHS Prescription Services. Initially the forms, together with the relevant CE documents are checked for accuracy. If any information is missing, the information will be requested from the applicant. NHS Prescription Services will acknowledge each form within 5 working days of receipt.

105. Once the initial application process has been completed, further instructions will be sent by NHS Prescription Services to the applicants if digital photographs or samples are required, and whether PDF copies of the packaging are required.

106. **Note to manufacturers** – check that your application form is fully completed before sending it to NHS Prescription Services.

107. Manufacturers or suppliers should inform NHS Prescription Services if any changes are made to their products that affect the entry within the Drug Tariff or NHS dictionary of medicines and devices (dm+d), for example: a name change, a change in manufacturer/distributor of the product, a change in the packaging, a change to the product specification, a code change, or if the product has been discontinued. In the first instance, NHS Prescription Services should be notified of changes/discontinuations using the DT3 form available on the NHSBSA website. A new application may need to be submitted if certain details of the original product specifications change. Such changes may include change of pack size (only where the pack size is listed in the Drug Tariff) or change in size, for example a change in dimensions of a dressing. If an application is being made for an additional colour to be added to an existing lymphoedema product range at the same price, a full application is not necessary. However, the manufacturer/supplier must notify NHS Prescription Services of the full product details including order code to enable population of the dm+d. NHS Prescription Services does not require a DT1 form, certificates or a product sample in this instance.

108. Manufacturers and suppliers are responsible for the accuracy of the listing, and this includes any changes to the CE or UKCA certification which will affect the validity of the listing.

109. If the supplier of the device is a distributer and there is a change of distributer NHS Prescription Services must be informed immediately. Evidence will need to be provided by both parties showing that the responsibility for distribution has been transferred. NHS Prescription Services will not attempt to resolve any disputes relating to such changes and will refer the matter to the DHSC.

110. Applicants should be aware that data from applications is shareable between NHSBSA, DHSC and independent panel members to support the application and evaluation process, or to support the management of DHSC's health or social care systems and services, on a need to know basis.

111. Application data will be shared with other bodies such as the DHSC, and independent panel members for the purpose of supporting the application and evaluation process, on a need to know basis. The application data is recognised as being commercially confidential and so will only be disclosed as above (paragraph 110), or in the normal circumstances where the disclosure of such information is

required by a rule of law.

Procedure to Remove Products from Part IX

112. This procedure applies to products listed in Part IX. Those products, which have not been prescribed during the previous 24 calendar months – using data from NHS Prescription Services' database – will be eligible for removal from the Drug Tariff at the time of renewal. To note – this does not apply to different SKUs of the same product (e.g. specific sizes and colours).

113. The criteria and procedure to be applied are set out in Annex E. It may also be necessary for NHS Prescription Services to remove products listed in the Drug Tariff without the agreement of the manufacturer. Although this is very rare it may occur when a permanent (i.e. not only affiliated to a certain batch) significant risk to patient safety has been identified and a safety alert issued as a result, or in cases where a legal challenge has occurred over a product which has been listed. In these situations, NHS Prescription Services will contact the owner of the listing and explain why the item is being removed from the Drug Tariff.

114. This also applies to products that fail at renewal, either does not achieve the minimum requirements for quality, as set out in Table 5, or does not achieve the overall pass score. Additionally, where suppliers do not apply for the Drug Tariff at the time of renewal, notice of removal will be issued.

115. To note, the notice of removal for discontinued products is 3 months, whereas the notice for removing products that have failed the assessment at renewal is 6 months. NHSBSA reserve the right to extend the notice period of removal if appropriate, for example reasons affecting supply. Manufacturers cannot apply to relist the product until the product has been removed from the tariff.

Contact Details

116. Any questions on renewals, for example if a supplier wants to check which wave or level one category their products belong in, please contact: partixrenewals@nhsbsa.nhs.uk

For further details please contact:

The Drug Tariff Team
NHS Prescription Services
NHS Business Services
Authority 2nd Floor Annexe
Bridge
House 152
Pilgrim
Street
Newcastle Upon
Tyne NE1 6SE

Email: pixie@nhsbsa.nhs.uk

Contact details for the appliance trade associations are in Annex F, some commonly asked questions are answered in Annex G.

Glossary

AMP
Actual Medicinal Product. This is the supplier's named product as opposed to a generic level description.

Appliances
An appliance is intended to be used for a medical purpose either by helping in the diagnosis, prevention, monitoring, treatment or alleviation of disease. It does not achieve its intended action by modifying the body's response in the same way as a drug. It is often used interchangeably with the word 'medical device' to refer to the type of medical device listed on Part IX.

Benchmark price
The benchmark price is used to assess the price of products within a category. Products are scored out of 40 for price, with full marks awarded to products priced at or below the benchmark. This benchmark is based on the lowest proposed price among comparable products (in the same cluster) that account for at least 5% of prescriptions at the time of renewal (see paragraph 60 for full explanation).

Category
There are eight top-level (level 1) categories that group products by clinical area (For example, Wound and Skin Care). Categories, sub-categories and clusters were developed with input from expert clinicians, patients and industry.

Cluster
The cluster is the comparable group of products and the lowest level on the categorisation. A cluster may only contain one product if the product is unique with no suitable alternatives.

Sub-category
A sub-category is the type of product and guides the user to the cluster they are looking for.

Chemical reagent
Part IX of the Drug Tariff includes chemical reagents which can be supplied as part of the pharmaceutical services contract. They include detection strips for urine, blood glucose and ketones, and chemical reagent strips for measuring the international normalised ratio (a measure indicating how quickly the blood clots).

Deduction rate
The deduction rate determines the number of points that are lost, for every percentage a product price is above the benchmark price.

Dictionary of Medicines and Devices (dm+d)
A dictionary of descriptions and codes which represent medicines and devices in use across the NHS including all products listed on Part IX of the Drug Tariff. Maintained by NHS England Digital.

Dispensing

Dispensing refers to the process of preparing and giving medicines or devices to a named person which has been ordered on a prescription written by a suitably qualified healthcare professional.

Dispensing Appliance Contractor (DAC)
A DAC is contracted by the NHS Commissioning Board (NHSCB) for England (at present) and the Local Health Board (LHB) for Wales to commission the provision of pharmaceutical services relating to the supply of medical devices. They can supply any medical appliance listed in Part IX of the Drug Tariff (except for chemical reagents in Part IXR) on an NHS FP10 prescription and will be reimbursed and remunerated according to the rules laid out in the Drug Tariff.

Exceptional Price Increase (EPI)
NHS Prescription Services will consider applications for additional price rises for a category or categories of products where cost pressures are being incurred in exceptional circumstances. Further detail on the process and requirements for submitting an EPI application can be found in Annex D.

FP10

An FP10 is an NHS prescription form that can be issued by General Practitioners, hospital doctors and other Healthcare Professionals who have qualified as an Independent Prescriber or are working as a supplementary prescriber under a clinical management plan. Most NHS prescriptions in primary care are now issued via the Electronic Prescription Service, but reference is still made to the original paper form of the standard NHS prescription as the concepts it embodies are familiar to NHS prescribers and dispensers.

Medicines and Healthcare products Regulatory Agency (MHRA)
The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency of the DHSC.

NHS Business Services Authority (NHSBSA)
NHS Prescription Services at the NHSBSA produces the NHS England and Wales Drug Tariff monthly on behalf of the DHSC.

Pharmacy Contractor
A pharmacy contractor is a person with whom the NHS Commissioning Board (NHSCB/NHS England) for England (at present) and the Local Health Board (LHB) for Wales has entered into arrangements for the provision of pharmaceutical services in respect of the supply of drugs, devices and chemical reagents. They can supply any drug (except those listed in Part XVIIIA of the Drug Tariff), and any appliance listed in Part IX of the Drug Tariff on an NHS FP10 prescription and will be reimbursed and remunerated according to the rules laid out in the Drug Tariff. Whilst the terms of service for pharmacy contractors providing NHS dispensing services set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 require a pharmacist to dispense any drug (except those in Part XVIIIA) ‘with reasonable promptness’, for devices the obligation to dispense these arises only if the pharmacist supplies such products ‘in the normal course of his business’, and they have the option to signpost patients to other suppliers.

Primary Care
Primary care services provide the first point of contact in the healthcare system, acting as the 'front door' of the NHS. Primary care includes general practice, community pharmacy, community clinics, dental, and optometry (eye health) services.

Secondary Care
Secondary care is sometimes referred to as 'hospital and community care' and can either be planned (elective) care such as surgery, or urgent and emergency care such as treatment following an accident.

SNOMED CT
A structured clinical vocabulary for use in an electronic health record and used by the Dictionary of Medicines and Devices (dm+d). Each Part IX listing has a SNOMED code which is unique to the product and is asked for on the template for renewal applications.

Standard Drug Tariff Specification
These specifications/generic descriptions currently include official standards published by the British Pharmacopeia, the British Pharmaceutical Codex or a similar recognised British, European or International Standards. In the future they could include a defined set of agreed standards for a group of devices which have the same function, quality and clinical outcome for patients.

ANNEX A - STATEMENT BY THE DEPARTMENT OF HEALTH AND SOCIAL CARE ON THE ENTRY PRICING OF PRODUCTS

It is recognised that considerable investment in research and development costs might be incurred in developing new products or treatment regimes. In some instances, applicants might be seeking higher prices to reflect the investment they have incurred. However, DHSC and NHS Prescription Services have a duty to ensure that the NHS gets value for money. Therefore, companies should provide satisfactory evidence of improved outcomes/savings/patient benefits commensurate with the requested price. NHS Prescription Services, having accepted that a product is suitable for listing, will negotiate a price on the evidence submitted by the applicant.

ANNEX B – ADDITIONAL MINIMUM REQUIREMENTS

There are some medical devices that warrant higher minimum attributes for patient safety reasons and to be suitable for prescribing. The identified devices are: glucose interstitial fluid detection sensors (Continuous Glucose Monitors), blood glucose testing strips, ketone testing strips, lancets and insulin pen needles. The minimum requirements are outlined in the tables below.

Table 13 – Additional minimum requirements for detection sensors, interstitial fluid for glucose

Question	Outcome
Is the Continuous Glucose Monitor (CGM) system currently available in the UK? (Yes/No)	Yes = Pass, No = Fail
Please provide a copy of the clinical data available	
Does the indicated age range match the subject age range tested in the clinical data? (Yes/No)	Yes = Pass, No = Fail
Does the clinical data show minimum paired readings in high and low ranges for the populations tested (which includes 70-75% T1 diabetes) with. a. At least 8% <4.4 mmol/L - performance metrics for CLSI AND b. At least 5% >16.7 mmol/L - performance metrics for CLSI? (Yes/No)	Yes = Pass, No = Fail
If the sensor, transmitter or sensor/transmitter if combined fails, do you supply a free of charge replacement? (Yes/No)	Yes = Pass, No = Fail
If the transmitter is a separate component to the sensor, what is the transmitter shelf life (unopened)? (Months)	≥ 12 months = Pass < 12 months = Fail Not applicable = Pass
What is the sensor (or sensor/transmitter if combined) shelf-life (unopened)? (Months)	≥ 12 months = Pass < 12 months = Fail
If the CGM system requires the use of an app, are there any charges for using the app? (Yes/No/Not applicable as app not required)	Yes =Fail, No = Pass Not applicable = Pass
Can the CGM system be used with a handset/reader rather than a smartphone? (Yes/No)	Yes = Pass, No = Fail
Is the handset/reader provided free of charge? (Yes/No)	Yes = Pass, No = Fail
Does the CGM system measure only in mmol/l units and cannot be changed? (Yes/No)	Yes = Pass, No = Fail
Is the user able to delete readings from the meter memory? (Yes/No)	Yes = Fail, No = Pass
Does the CGM system allow data sharing with someone else who is a healthcare professional or carer? (Yes/No)	Yes = Pass, No = Fail
Is there a warning for a high result? (Yes/No)	Yes = Pass, No = Fail
Is there a warning for a low result? (Yes/No)	Yes = Pass, No = Fail
Is the sensor (or sensor/transmitter if combined) waterproof? (Yes/No)	Yes = Pass, No = Fail
Please state waterproof level e.g. IPX7, IPX8 etc	IPX7 and above = Pass

	IPX6 and below = Fail
Does the company have a UK presence for technical support by freephone telephone and other communication methods e.g. internet?	Yes = Pass, No = Fail
Is support material for healthcare professionals and service users provided free of charge?	Yes = Pass, No = Fail
Is the app linked to the device compliant with UK GDPR	Yes=Pass, No=Fail

Table 14 – Additional minimum requirements for blood glucose strips for standard meter/ketone meter

Blood Glucose Strips for Standard Meter/Ketone Meter	Rationale	Scoring
Compliance with ISO Standard ISO 15197:2015	All blood glucose strips need to comply with ISO standards. However, compliance with ISO 15197:2013 confers compliance with 2015 so this would be in.	Pass/Fail
No known plans for blood glucose strips to be discontinued	To ensure that service user is able to obtain the blood glucose strips	Pass/Fail
Strip expiry date >12months if container not opened	To minimise wastage through expired strips	Pass/Fail
Warning for sample under-fill detection	Considered essential that meters are able to determine if there is sample under-fill detection on the blood glucose strip	Pass/Fail

Table 15 – Additional minimum requirements for ketone strips for ketone meter

Ketone Strips for Ketone Meter	Rationale	Scoring
No known plans for blood ketone strips to be discontinued	To ensure that service user is able to obtain the ketone testing strips and continue to use existing meter	Pass/Fail
Strip expiry date ≥12 months if container not opened	To minimise wastage through expired strips	Pass/Fail
Warning for sample under-fill detection	Considered essential that meters are able to determine if there is sample under-fill detection.	Pass/Fail

Range of ketones measured is at least 0.1-8.0mmol/l	To ensure meter is able to detect wide range of ketone levels	Pass/Fail

Table 16 – Additional minimum requirements for all lancets for lancing devices

Lancets for Lancing devices	Rationale	Scoring
Lancets are single use only	Infection control	Pass/Fail
No known plans for lancets to be discontinued	To ensure that service user is able to obtain the lancets to use in the lancing device	Pass/Fail

Table 17 – Additional minimum requirements of insulin pen needles

Insulin Pen Needles	Scoring
Are there any known plans to discontinue this product? (Yes/No)	No = Pass Yes = Fail
Are the insulin pen needles single or multi-use? (Single/Multi)	Single use = Pass Multiple use = Fail
Is support material or training for healthcare professionals and service users provided free of charge? (Yes/No)	Yes = Pass No = Fail
Do you provide technical support by UK based freephone telephone and other communication methods e.g. internet? (Yes/No)	Yes = Pass No = Fail

ANNEX C - *GENERAL GUIDANCE ON THE TYPE OF TRIAL DATA AND ECONOMIC EVALUATION THAT SHOULD BE PROVIDED TO SUPPORT APPLICATIONS*

The economic evidence should compare the costs and health benefits/consequences of the medical device with those of the most relevant comparative intervention(s) for a UK NHS setting. Comparative analyses such as cost-effectiveness analysis, cost-benefit analysis and cost- consequences analysis are all acceptable methods of economic evaluation.

Comparators

- The most appropriate comparator(s) will represent current standard practice within the NHS. If the new technology is being introduced as an alternative to existing products and therapies, the appropriate comparator(s) will represent the costs and health benefits of the current practices using the existing products and therapies.
- If this is a new technology for which no current alternative product or therapy exists a “do nothing” approach may be appropriate which will represent the disease/care pathway without intervention.
- If the new technology is associated with a number of different applications, for therapeutic areas or patient subgroups, the analysis should represent this. There may be different comparators for the different applications, therefore the economic analysis will need to represent them all.
- The choice of comparator(s) will need to be justified within the evidence submitted.

Data

- The effectiveness and resource use data can be collected alongside clinical trials or taken from existing published evidence or based on observational data. All are accepted methods of data collection as long as data sources are clearly stated and limitations and uncertainties of the data and methods are addressed in the evidence.
- All data sources and methods will need to be explained and referenced.
- The relevant costs of the alternative interventions should at least represent the associated healthcare costs (the inclusion of societal costs should be presented as a separate analysis).
- The range of costs to include in the analysis may depend on the nature of the comparison.
- Justification should be given for the exclusion of any cost categories.
- When measuring the costs and consequences of the interventions being evaluated different methods can be used.
- Data can be used from clinical trials and also estimated from alternative data sources.
- Useful databases and information sources include:
- The National Institute for Health and Care Excellence (NICE) Evidence Series incorporating the National Library for Health, providing links to clinical guidance, journals and databases, and the Cochrane Library

- https://www.evidence.nhs.uk/about-evidence-services/journals-and-databases
- PubMed/ MEDLINE http://www.ncbi.nlm.nih.gov/pubmed/
- CINAHL http ://www.cinahl.com/
- ISI Web of knowledge http://www.isiwebofknowledge.com/
- The Cochrane Collaboration http://www.cochrane.org/
- National Institute for Health Research, Centre for Reviews and Dissemination (CRD), York University https://www.crd.york.ac.uk/CRDWeb/
- Google Scholar http://scholar.google.co.uk/
- SIGN guidelines http://www.sign.ac.uk
- TRIP database https://www.tripdatabase.com/
- Department of Health hospital episode statistics at https://digital.nhs.uk/data-and- information/data-tools-and-services/data-services/hospital-episode-statistics
- Personal Social Services Research Unit. Unit costs of health and social care http://www.pssru.ac.uk/
- Center for the evaluation of value and risk in Health https://cevr.tuftsmedicalcenter.org/

Sensitivity Analysis

- Sensitivity analysis should be undertaken as part of the economic analysis to address uncertainty surrounding parameters, model structure and methodology, where applicable, and the impact on outcome measures and the cost-effectiveness of the new technology.

- One approach to sensitivity analysis is scenario analysis. This is where a series of scenarios are created that represent a combination of alternative parameter values to those of the best representation using published data (the reference case). This will usually at least include a scenario that represents the best case and worst case scenarios, plus any other scenarios that require investigation.

- Another approach is threshold analysis. Threshold values of key parameters or outcomes are identified and combinations of alternative parameter values are assessed to determine what would cause these thresholds to be exceeded and whether these are realistic scenarios.

Types of clinical evidence

- Clinical evidence is not generally required if a similar product is already included in the

Drug Tariff.

- Clinical evidence should be included where the product claims to demonstrate clinical benefits or where the product's physical characteristics claim clinical significance. Table 18 outlines the levels and types of clinical evidence.

- National Institute for Health and Care Excellence (NICE) are considering the evidence requirements on Part IX products. Therefore, DHSC reserves the right to change the Part IX evidence requirement as appropriate.

Table 18 – levels and types of evidence. [Level 1++ providing the most robust evidence]

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies (for example, case report, case series)
4	Expert opinion

ANNEX D - PART IX OF THE DRUG TARIFF: AGREEMENT ON ANNUAL INCREASES

- The agreement is between the Department of Health and Social Care (DHSC), the NHS Business Services Authority (NHS Prescription Services), which administers the arrangements on behalf of the Secretary of State, and the Part IX Drug Tariff Forum deemed for this purpose to represent companies marketing products listed in Part IX of the Drug Tariff.

- The agreement is not intended to be legally binding on DHSC, NHS Business Services Authority (Prescription Services), the Part IX Drug Tariff Forum or the company's marketing listed products. Neither is the agreement intended to create legal rights or obligations in respect of any person. The Part IX Drug Tariff Forum will use its best endeavours to ensure that the companies adhere to the agreement.

- NHS Prescription Services will ensure that any companies which apply for a Part IX listing, are informed that price rises will be determined in accordance with this agreement.

- This agreement applies to price rises for which NHS Prescription Services' agreement may be sought periodically in respect of listed products. The agreement applies to branded products. Generic products receive an automatic annual price increase in June.

- Companies may seek price rises for a particular product once a year or any longer period which they may determine. If price rises are sought at intervals longer than one year, the amount will not be greater than if they were sought at annual intervals. However, this will not prevent NHS Prescription Services from considering financially neutral applications from companies wishing, for example, to change the dates of their pricing year. Upon renewal the anniversary date of listing will change to the date of the published renewal price

- The maximum price rise will be calculated as being the forecast of the gross domestic product (GDP) deflator for the next financial year minus Factor X where X is currently 0.75. Factor X is subject to review. For applications made in accordance with this agreement, the maximum calculated will apply to individual products and NHS Prescription Services will grant the maximum amount unless the company applies for less. However, higher rises for some products will not be granted even if offset by lower increases for other products.

- The forecast of the GDP deflator to be applicable will be the Treasury forecast for the following financial year current on the date the written application for a price rise is received by NHS Prescription Services. Information relating to the latest forecast on the GDP for the following financial year can be found at www.hm-treasury.gov.uk/data_gdp_index.htm. The current GDP deflator is shown here. Please note this is for the **following financial** year and **not** the calendar year.

- Companies should send applications for price rises to NHS Prescription Services two months before the publication deadline of the Drug Tariff in which the price rise takes effect. A price increase request received in October 2019 would be effective for the January 2020 Drug Tariff. The price increase applied would be the **forecast GDP deflator for the following financial year**. The current GDP deflator being used for price adjustments is also shown on our website at www.nhsbsa.nhs.uk/PrescriptionServices/1818.aspx

- The calculation of price rises shall be to one tenth of one penny (the unrounded sum). The price rise will be granted to the nearest penny (the rounded sum), sums of 0.5 of a penny being rounded up. The next periodic calculation shall be from the unrounded sum. No price rise will be granted where the calculation of the unrounded sum does not produce a new rounded sum. NHS Prescription Services will notify companies of both the unrounded and rounded sums.

- Once a price has been agreed through a renewals process, applications for an annual price increase will be closed for the following 10 months (from the date of listing). A company can then apply 2 months in advance for an annual increase, with increases applied from month 12. The renewals process supersedes previous anniversary dates of listings when a company may have ordinarily applied for an annual increase.

- NHS Prescription Services will consider applications for additional price rises for a category or categories of products where cost pressures are being incurred in exceptional circumstances. The only criteria agreed with the DHSC currently are raw material shortages where suitable alternatives are not available or the imposition of statutory duties with a recognised cost impact. If a company considers that an exceptional price increase is warranted because of an unforeseeable shortage of a key raw material, they should contact NHS Prescription Services for advice on how to proceed. Upon receipt of a request in writing a formal acknowledgement of receipt will be sent to the sender within 5 working days. NHS Prescription Services will determine the period, not less than three months, for which successful applications will be applied. If there is an ongoing EPI at the point of review, NHSBSA can postpone the renewal period until the end of the EPI period if they deem it appropriate.

- The parties to this agreement will attempt to resolve any disputes in good faith. Any changes or additions to the agreement will only take effect if expressed in writing.

- There will be no formal appeal procedure if a price increase has been refused.

ANNEX E - MECHANISM FOR REMOVING ITEMS FROM DRUG TARIFF PART IX

1.1 Discontinued Drug Tariff Part IX Medical Devices

On notification or confirmation in writing that a Medical Device listed in Part IX has been discontinued, the appliances in question will be marked with a three-month notice of deletion and removed from the Drug Tariff once this period has expired.

The notice of deletion will also be included in the preface to the Drug Tariff one month prior to the removal of the product from Part IX.

1.2 Review for continued listing of Medical Devices in Part IX

The NHSBSA will request that a manufacturer/supplier confirms the following with regard to all their product listings in the Drug Tariff -

- The product(s) is/are still available under the terms agreed when it/they was/were first listed and there have been no changes to these.
- All certification is up to date.
- In the event of any changes to the above, NHSBSA will be notified immediately in writing.

The manufacturer will be offered three options:

1) Do nothing and in the following month a three-month notice of deletion will be published in the Drug Tariff for all of the listed products,

2) Write to the NHSBSA within 28 days confirming that:

(i) The product(s) is still available under the terms agreed when it was first listed and there have been no changes to these,
(ii) All certification is up to date, and
(iii) In the event of any changes to the above, the NHSBSA will be notified immediately in writing.

3) Write to the NHSBSA confirming that the product should be removed from the Drug Tariff.

The NHSBSA will provide manufacturers with a list of products they have listed in the Drug Tariff; those products with a low level of prescribing will be highlighted for particular attention. A standard form is available on the NHSBSA website for download and completion as declaration that continued listing is required.

In the event of the manufacturer being either -

a) unable to comply with the conditions of listing in Part IX of the Drug Tariff, or

b) failing to return a completed declaration form within the specified time period,

the affected product(s) will be marked with a three-month notice of deletion and once this period is completed, future listing of the products will require submission and approval of a new application for Part IX of the Drug Tariff.

1.3 Medical Devices included under a generic category

Some medical devices can be prescribed if they meet the technical specification for a generic category and these products are not listed by their brand name e.g. Absorbent Cotton BP 1988 and Gauze Swab Type 13 Light BP 1988, Sterile. NHS Prescription Services will inform the DHSC if no medical devices have been prescribed under the generic category on prescription form FP10 in the previous twelve calendar months.

Following a period of 28 days the generic category will be marked in the next edition of the Drug Tariff with three months' notice of deletion. The notice of deletion will also be included in the preface one month prior to removal from the Drug Tariff.

1.4 Failure to apply at renewal or failure at renewal

This also applies to products that fail at renewal, either due to not meeting the minimum requirements for quality, as set out in Table 5 - Minimum requirements for quality evaluation, or due to not meeting the overall pass score. Additionally, where suppliers do not apply for Part IX of the Drug Tariff at the time of renewal, the products will be marked to be delisted. There will be 6 months' notice of deletion, NHSBSA reserve the right to extend this notice period if necessary. During the notice period the price will remain at the current listed price. Manufacturers cannot apply to relist the product until the product has been delisted and removed from Part IX of the Drug Tariff.

1.5 Appeal procedure for removal of products

There will be no formal appeal procedure for removal of a product beyond initial appeal stage (see paragraphs 77), following formal decision. Manufacturers and suppliers will use the application procedure to reapply for a product to be listed in Part IX of the Drug Tariff if this is appropriate.

ANNEX F - TRADE ORGANISATIONS

ABHI
Association of British Healthcare Industries www.abhi.org.uk
Tel: +44 (0)20 7960 4360
Email: enquiries@abhi.org.uk

BHTA
The British Healthcare Trades Association www.bhta.com
Tel: +44 (0)20 7702 2141
Email: info@bhta.com

BIVDA
British In Vitro Diagnostics Association www.bivda.org.uk
Tel: +44 (0)8456 188 224
Email: enquiries@bivda.co.uk

SDMA
www.dressings.org.uk/
E-mail: sdma@dressings.org.uk

UTA
Urology Trade Association
https://urologytradeassociation.com
Email: uta@whitehouseconsulting.co.uk

ANNEX G – FREQUENTLY ASKED QUESTIONS

Q1. ***I am unsure if my product is part of the categories being assessed in wave 1, how do I check?***

Please check which can be on the NHSBSA website, in the first instance. Please check the indicative schedule for Part IX Waves which can be on the NHSBSA website, in the first instance. You can email partixrenewals@nhsbsa.nhs.uk to check if you should apply for renewal of your products in wave 1. Please provide your products' listed name identical to the name published in the latest version of Part IX of the Drug Tariff.

Q2. ***My product has not been prescribed for the past 2 years, what should I do?***

You can email partixrenewals@nhsbsa.nhs.uk to state that you are not sending in an application for renewal because you know it has not been prescribed in the past 2 years. If you are uncertain then please state this and NHSBSA will check. For example, if certain sizes or colours of the same product have not been prescribed but one of them has, this does not count as 'product not prescribed'. If you do not apply then as per the guidance your products will be marked for removal with 6 months' notice provided.

Q3. ***I want to apply for a listing before the renewal period, can I do this?***

This partly depends on how close to the renewal period it is. A new product listing can take a while if not all the correct information is provided or if the NHS Prescription Services team have further questions. It may therefore be recommended that you apply under the enhanced assessment framework (using the new application form) and are assessed during the renewal period. You can email partixrenewals@nhsbsa.nhs.uk to check timings.