Department of Health & Social Care

Updating Part IX of the Drug Tariff - Medical Devices available for prescribing in Primary Care

Final position paper

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Introduction

The term medical device refers to any instrument, apparatus, appliance, software, material, or other article used specifically for diagnosis or therapeutic purposes. This includes where a device is used alone, or in combination with any accessories, including the software intended by its manufacturer for its proper application.

Medical devices play a vital role in patient care and treatment. Healthcare professionals must get the basic qualities of care – safety, effectiveness, and patient experience – right every time. This includes identifying from the vast range of medical devices that are available, which products best meet the needs of the individual patient. In 2023 to 2024 the NHS spent around £1.4 billion on medical devices listed on Part IX of the Drug Tariff in primary care.

The NHS England and Wales Drug Tariff ('the Drug Tariff') is a monthly publication issued by NHS Prescription Services of the NHS Business Services Authority (NHSBSA) which contains the Secretary of State for Health and Social Care's and Welsh ministers' determinations for what pharmacists and appliance contractors will be paid for providing NHS pharmaceutical services in England and Wales respectively. In England, regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 sets out the Tariff in a format that the Secretary of State for Health thinks fit[1].

Part IX of the Drug Tariff contains the list of medical devices which are approved by NHSBSA (acting on behalf of the Secretary of State for Health and Social Care) to be prescribed by authorised healthcare practitioners operating under NHS General Medical Services. Part IX of the Drug Tariff was established before the 1980s. Since then, medical devices have made significant advances in specialist nature and complexity as well as changes in the manufacturing and commercial markets in provision of devices.

The Department of Health and Social Care (DHSC) and NHS England are committed to delivering the best value medical devices for patients, and therefore consulted on proposals to update Part IX of the Drug Tariff. The consultation on Part IX of the Drug Tariff was open between October 2023 and January 2024 and had a targeted audience rather than being public, owing to the complex subject matter (see Appendix A: Target audience for the consultation).

[1] Equivalent arrangements for Wales are set out in regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

The consultation response was released in August 2024 setting out the government's response to the issues raised. Following circulation of the consultation response DHSC continued to engage with industry over 9 months from September 2024 to May 2025, sharing 2 versions of the enhanced assessment framework and 4 iterations of the draft categorisation for comment to reach the current position. It is likely that the categorisation will continue to be updated for future waves based on further real-time feedback.

In order to increase patient input into the final decisions, DHSC commissioned National Voices to deliver a research project to better understand the patient experience of the medical devices prescribed under Part IX of the Drug Tariff.

This position document sets out the final policy to modernise Part IX of the Drug Tariff. For application guidance suppliers should see the 'Part IX Application guidance 2.0' on the NHSBSA website for a more detailed breakdown of how to apply for a listing or renewal on Part IX of the Drug Tariff.

Proposal One: Increase the use of comparable categories where it is appropriate to do so

The rationale

Previous arrangements were resulting in a long list of devices and chemical reagents on Part IX, in many cases grouped by manufacturer, rather than in comparable categories. The consultation and response to it set out DHSC's plans to update Part IX of the Drug Tariff to make products more comparable by grouping them in comparable categories where appropriate. It set out that this work must be supported by clinical and patient input and build on existing evidence and categorisation where available and suitable.

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Developing the categorisation

The new categorisation was developed with the support of Expert Reference Groups (ERGs) and built on relevant clinical work and nomenclatures where available. It was agreed with, and was informed by, patient input. The draft categorisation was shared with industry partners four times during its iteration between September 2024 and May 2025 to gather feedback for consideration and was updated repeatedly following feedback received from industry and clinicians.

For example, the 'Point of Care Testing and Insulin Delivery' level one category has been renamed 'Point of Care Testing and Hypodermic Equipment' to reflect the other medical devices listed. There are several specific comments from industry on the categorisation which DHSC will address at renewal. The panel put in place for renewal will be passed this feedback to consider alongside the applications.

DHSC recognises that the categorisation may need further amendments as medical devices continue to evolve. Companies can continue to suggest new categories and clusters on application and these will be considered by the panels.

To note, at this time there is no intention to remove linked reimbursement fees that currently correspond to certain products in Part IX. Although the structure of the categorisation will change, the same reimbursement fees will remain linked. Reviewing the fees was out of scope of this work and may be revisited in future.

Minimum attributes

Following feedback from the ERGs during the categorisation process, DHSC decided not to proceed with defined minimum quality attributes for each category. The feedback was that it is most important to know what features a product has and then the correct prescribing decision can be made. However, there are some

medical devices that warrant higher minimum attributes for patient safety reasons to be suitable for prescribing. The identified devices are:

- glucose interstitial fluid detection sensors (also known as continuous glucose monitors)
- chemical reagents: blood glucose testing strips for standard meter/ketone meter
- chemical reagents: ketone strips for ketone meter
- lancets for lancing devices
- insulin pen needles

Next steps

At the time of renewal, applicants should indicate which cluster they think their product belongs in. NHS Prescriptions Services and the renewal panels will determine if this is the most suitable cluster for the product and ask further questions if required.

Proposal Two: Introduce a renewal process to Part IX

The Rationale

Previous arrangements meant that once a product is listed on Part IX, there is no further assessment of its continued product quality or value to the NHS. The consultation and response to it proposed that a renewal process would be introduced to keep the Part IX list up to date with clinical practice and ensure value to the NHS.

Final position

Overview

A renewal process will be introduced for Part IX. In line with industry feedback, six months advance notice will be given to suppliers of the requirement to apply for renewal. An indicative schedule is available on the NHSBSA Drug Tariff website, but is subject to change.

From this point, products will no longer be listed indefinitely and will have to apply to remain on the Drug Tariff. Suppliers will have to reapply to renew listings when a renewal notice is issued for the relevant category. DHSC expects this to be every 4-5 years but reserves the right to change this frequency as required. DHSC will use the experience from the first round to help decide this.

The renewal process will be introduced in waves of categories, see the NHSBSA Drug Tariff web page for the planned schedule. Following the first renewal there will be a pause for a review period. With the support of the independent advisory panels, DHSC will use the review period following wave 1 renewal to confirm whether any further improvements or adaptations are needed. Any changes will be shared for feedback. Following the review period, notice of renewal for wave 2 will be given.

Until the relevant category is renewed, applicants of new products or line extensions should apply to the Drug Tariff in line with the current application process (v1.7 of the guidance).

All products on Part IX are subject to renewal, unless stated as exempt under proposal three below.

Removal of products

When a category is renewed, those products that have not been prescribed during the previous 24 calendar months – using data from NHS Prescription Services' database – will be flagged for removal from Part IX and suppliers notified. This will only be applied to products that have been listed for at least two years. NHS Prescription Services will also check prescribing data for Northern Ireland in addition to Wales and England, and not remove any products that have been prescribed in Northern Ireland only.

Where products do not pass at renewal, a six month notice period for removal from the Drug Tariff will be issued.

Templates

As requested by industry, templates to support and streamline applications to the Drug Tariff are provided. These will be accessible on the NHSBSA website Drug Tariff Part IX | NHSBSA, when the wave 1 notice period is issued.

Next steps

Suppliers listed on Part IX of the Drug Tariff should familiarise themselves with the updated application guidance 2.0.

Proposal Three: Apply an enhanced assessment process for products to be listed on Part IX

The Rationale

Previous arrangements meant that it was not clear if products low in value were being added to Part IX or if products that did offer value were being rejected. The consultation and response to it proposed an enhanced assessment framework that scored on quality, social and price.

Previous arrangements did not validate claimed product features and benefits with clinical experts or patient representatives when assessing the evidence, relative efficacy or patient benefit. The consultation and response to it included the creation of independent advisory panels, with members drawn from the clinical profession and patient input, who would assess new applications and renewals.

Final position

The enhanced assessment framework is composed of quality criteria, social criteria and supplier price, with a maximum of 100 points: 50 points for quality, 10 points for social and 40 points for price. The enhanced assessment framework has been updated to include the weighting in the points, to simplify. The overall pass score will be 55 out of 100, with a minimum quality score of 20 and a minimum price score of zero.

Prequalification criteria

The framework includes prequalification criteria (pass or fail) ensuring the product:

- meets the relevant medical device regulatory requirements
- is appropriate for prescription in primary and community care
- is still being supplied by the company

and at the supplier level includes:

- a carbon reduction plan or Net Zero commitment
- statement of how the supplier complies with preventing modern slavery

Following feedback regarding the challenge with resource requirements to complete the evergreen assessments, this has been removed from the prequalification criteria.

Quality criteria

The quality criteria include minimum requirements (20 points) for the type of application and suppliers choose a maximum of 3 out of 4 quality value add criteria (30 points) covering:

- product effectiveness
- supporting self-care
- supporting system savings
- reducing inequalities

In line with feedback, updates were made to provide clarity on the specific information required for the minimum requirements for different types of application. The framework has also been updated to clarify that the higher requirements for evidence only apply to new applications for a new type of product.

In line with feedback, the quality evaluation criteria were updated, removing 'innovation' as a separate value add criteria, as innovation is already integral to the other value add criteria. Additional minimum requirements have been added for continuous glucose monitors (glucose interstitial fluid detection sensors), blood glucose testing strips, ketone testing strips, lancets and insulin pen needles at the recommendation of clinical expert groups.

Social Criteria

The social criteria (maximum 10 points) includes:

- circular economy
- sustainable packaging
- resilient supply chains

The "social value" criteria has been renamed to "social" to avoid confusion, given the social criteria is distinct from the social value procurement model. In line with responses to the consultation, social will account for 10% of points from the start. Following subsequent feedback on the draft enhanced assessment framework, sustainable packaging has been added as a subsection to the social criteria. DHSC is working to eliminate unnecessary single use products and build a circular economy for medical products by 2045 as set out in the Design for Life roadmap Design for Life roadmap - GOV.UK. There are several ways products can support this vision, so while we acknowledge that some products listed on the Drug Tariff are less suited than others to reusable solutions, we have ensured that products can

still score points if they demonstrate support for a circular economy such as longer use-life, recyclability and use of recycled materials.

Price assessment

Products will be scored between 0 and 40 on price, with 40 being awarded to products that are priced at (or below) the benchmark price. The benchmark price is set as the lowest proposed price of a product in the cluster that supplies at least 5% of the cluster prescription volumes of products. To qualify as the benchmark the product must also have passed on quality at renewal. 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 is inappropriate.

For every 1% a product is higher than the benchmark price, 1.25 points are deducted. This means that products that are 32% more expensive than the benchmark would receive zero points. Products that are more than 32% more expensive than the benchmark will receive negative points and fail the enhanced assessment framework. When suppliers are informed they have failed they will however be given a chance to reduce their proposed price. The supplier will be contacted via the email address provided on application.

Panels

Independent advisory panels will assess the quality element of the applications. In line with feedback from the NHS, members will include clinicians, NHS commissioners, independent experts and academics, as well as include patient input. DHSC will seek to appoint a panel chair recognising that to cover so many devices, several panel members will be required.

Evidence

The 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.

New product applications to a category being renewed

Application periods for future listings will not be restricted to set periods in the year. This is subject to review to check this is feasible for NHS Prescriptions Services. However, if a new product application is submitted in the 4 months before their relevant category is due to be renewed for the first time, the application will be

assessed along with the applications for renewals, and the renewals assessment form will need to be completed in line with the Part IX application guidance 2.0.

Exemptions from renewals and the enhanced assessment framework

Listings in Part IXA technical specifications will be exempt from the process. Following feedback from the ERGs, 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.

Appeals process

In line with feedback, once the final scores are issued to applicants, an appeals process has been included. An applicant has the right to appeal their quality or social score where they do not pass overall. To make the process manageable, suppliers will not be allowed to appeal their quality or social scores if they have passed. DHSC thinks this is a fair decision as the scores are not being published in the tariff. An applicant can also appeal the cluster their product has been listed in.

An appeal should be made within 5 working days from receiving the decision to ensure the independent advisory panel is available to comment if required. DHSC recognises this is a short time period but no further information is required from the applicant at this point; it is a simple requirement to log an appeal and state whether it is on the quality or social score.

NHS Prescriptions Services will check the scoring for consistency with other applications and check the notes reflect what is in the application.

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 product will be placed in the cluster the panel think most appropriate.

Wider alignment

DHSC have ensured that, where appropriate, there is consistency with Value Based Procurement principles. DHSC are developing standard guidance for MedTech Value Based Procurement for application in secondary care procurement from early 2026. The enhanced assessment framework for Part IX of the Drug Tariff is relevant to setting the reimbursement price of products prescribed in primary care and allows

the Tariff list to be produced, it does not however rank or advise on products for purchase.

Next steps

Work will begin to recruit to the independent advisory panels for the first wave of renewals. The panels will have expert membership across the range of products under assessment. The opportunity will be advertised and members appointed.

DHSC acknowledges that this is a new way of assessing a category, therefore there will be review points built in to assess if this methodology is to be refined or improved upon. The first review point will be after the first wave categories are assessed.

Temporary Listings for qualifying products

The Rationale

Previous arrangements meant that it was possible that patients were missing out on devices because sufficient real world evidence of use in the NHS was not available. The consultation proposed a new mechanism which would allow products to be considered for a 12 month temporary listing where they might have previously been rejected. The intention is that this applies to applications for devices that do not have a direct comparator already listed on Part IX and if they do not have sufficient real world evidence of use in the NHS.

The intention of this is to support the adoption of innovative products into the NHS to benefit patients, including where innovation is happening at pace. The intention is that these applications still provide evidence of clinical effectiveness and safety and are suitable for prescribing. The proposal is likely to particularly benefit Small to Medium sized Enterprises (SMEs), who may have less resource to meet all the criteria requirements on first application. The proposed temporary listing will provide support for innovation that meets an unmet need or is able to improve quality of life for patients. This should make it easier for new suppliers or products to gain access to the market.

Final position

A temporary listing mechanism will be introduced, which allows products to be temporarily listed if they meet the essential criteria but do not have sufficient real world evidence of use in the NHS.

Companies considering a temporary listing should apply for a new, full listing to Part IX. If the NHS Prescriptions Services team assess that it is an innovative product, significantly different to those listed in Part IX, that meets an unmet need but does not have sufficient evidence from the NHS, a temporary listing may be offered (in place of the application being rejected).

These applications would still need to provide evidence of clinical effectiveness and safety and be determined as suitable for prescribing. As part of the consideration for temporary listing, a product specific evidence generation plan will be requested.

Timeframes

In line with feedback, 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 that warrant immediate removal as per current policy). 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. As with all of the proposals, temporary listings will be subject to review.

Following the two year temporary listing, the application will be assessed against the old guidance if the category has not yet been renewed or under the new enhanced assessment framework if the relevant category has gone through renewal.

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.

Next steps

Companies considering a temporary listing should apply as usual to the Drug Tariff via NHS Prescriptions Services. Temporary listings can be applied for from July 2025, across all categories.

Introduction of an application fee

Final position

As confirmed in the response to the consultation, the government has decided to not take this proposal forward and therefore an application fee will not be introduced.

Appendix A: Target audience for the consultation

The consultation was targeted rather than public. This appendix outlines the groups that formed the target audience.

Clinical Groups: Either formal or informal professional associations of clinicians that specialise in a particular area, for example, stoma nurses.

Community Pharmacy England: The representative body for all community pharmacy owners in England.

Dispensing Appliance Contractors (DACs): DACs dispense certain appliances listed in Part IX of the Drug Tariff against prescriptions issued by GPs and specialist prescribers. The Part IX tariff sets the amount that they are reimbursed for dispensing the product. Some DACs are independent and some are vertically integrated with their manufacturer. There are 111 DACs in England. A patient can usually use any DAC to obtain qualifying appliances.

Industry Body: There are a few Trade Associations that represent industry member's interests in issues linked to Part IX of the Drug Tariff.

NHS Organisation for example Commissioners: Whilst a listing on Part IX means that a medical device can be prescribed, NHS commissioners can create local formularies of preferred products for prescribing. This is based on a mix of clinician and patient preference and cost effectiveness including any service element linked to a product. It will also take into account NHS net zero policy.

Patient Groups: Various charities represent patient interests in a broad range of issues related to the clinical conditions that require the products listed on Part IX of the Drug Tariff.

Suppliers (for example a company with a listing on Part IX of the Drug Tariff or a manufacturer of these products): Suppliers wishing to supply devices and chemical reagents for prescribing in primary care by GPs providing NHS General Medical Services, must first seek approval from NHS Prescription Services (acting on behalf of the Secretary of State) for inclusion of that product in Part IX of the Drug Tariff.