Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

# Consultation on Updating Part III of the Northern Ireland Drug Tariff

**February 2024**

## Overview

The Department of Health is seeking views on proposals for updating Part III (List of Medical Devices/Appliances) of the Northern Ireland Drug Tariff. This is in line with a similar consultation relating to Part IX of the English Drug Tariff (EDT), which was carried out by the Department of Health and Social Care.

## Responding to the Consultation

You can respond to the consultation document by e-mail or letter. If this document is not in a format that suits your needs, please contact us and we can discuss alternative arrangements. Before you submit your response, please read below about the effect of the Freedom of Information Act 2000, the Environmental Regulations 2004, the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (EU) 2016/679 on the confidentiality of responses to public consultation exercises.

For further information about how the Department will process the information you provide in response to this consultation please see the following Privacy Notice - https://www.health-ni.gov.uk/sites/default/files/publications/health/DoH-Privacy-Notice.pdf

This consultation has been launched today and will run for 8 weeks, closing on 04 April 2024.

**Responses should be sent to:**

**Written:** Medicines Policy Branch
Department of Health
Room D3.1
Castle Buildings
Stormont Estate
Belfast
BT4 3SQ

**Email:** pharmacyconsultations@health-ni.gov.uk

The consultation response form attached at **Annex A** provides the consultee with an opportunity to answer questions relating to the specific proposals provides and also provides further opportunity for respondents to give additional feedback relating to any equality, human rights or rural access implications.

## Confidentiality and Access to Information Legislation

The Department may publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be published or disclosed on request in accordance with information legislation; these chiefly being the Freedom of Information Act 2000 (FOIA), the Environmental Information Regulations 2004 (EIR), the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (GDPR) (EU) 2016/679. The Department can only refuse to disclose information in exceptional circumstances.

Before you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The FOIA gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential.

If you do not wish information about your identity to be made public please include an explanation in your response. Being transparent and providing accessible information to individuals about how we may use personal data is a key element of the DPA and the GDPR (EU) 2016/679. The Department is committed to building trust and confidence in our ability to process personal information. This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances.

For further information about confidentiality of responses please contact the Information Commissioner's Office on **0303 123 1113** or via https://ico.org.uk/global/contact-us/)

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## Detail of the consultation

### What is the subject of this consultation?

Pharmacy services in the community are a highly valued resource. They have a critical role not only in the dispensing and supply of medicines for the people of Northern Ireland, but in the provision of advice, information and services on the safe and effective use of medicines to help people gain better outcomes from their medicines and live healthier lives.

The Department of Health (DoH) has a statutory duty to remunerate providers of pharmaceutical services in Northern Ireland in a fair, accurate and prompt manner. It has a statutory obligation under Regulation 9 of the Pharmaceutical Services Regulations (NI) 1997, to compile and publish a statement known as the Northern Ireland Drug Tariff (NIDT).

The NIDT sets out the range of dispensing fees available to pharmacists (remuneration) and details the reimbursement figures paid to community pharmacy contractors towards the actual cost of drugs and medical devices (appliances) supplied against health service prescription forms.

Strategic Planning and Performance Group (SPPG) – formerly Health and Social Care Board (HSCB) - is tasked by DoH to develop Drug Tariff arrangements on its behalf. The NIDT is produced monthly by the Business Services Organisation (BSO) on behalf of the Department and can be accessed via the BSO website at Drug Tariff - Business Services Organisation (BSO) Website (hscni.net) and includes:

1. Guidance on the dispensing of prescriptions;
2. Regulations concerning the dispensing of prescriptions;
3. Professional fee rates paid to contractors; and
4. Reimbursement amounts paid to contractors for dispensed drugs and medical devices (appliances) on Health Service prescriptions.

### What is the purpose of this consultation?

The Department of Health and Social Care (DHSC) in England has consulted on proposals for updating Part IX of its Drug Tariff, which contains the list of medical devices which are approved by NHS Prescription Services of the NHS Business Services Authority (NHSBSA) (acting on behalf of the Secretary of State for Health and Social Care) to be prescribed by authorised healthcare practitioners.

The DHSC objectives of the proposals are:

**Objective 1- Ensure Product Quality**
Ensure Part IX consistently includes devices that are of good quality and effectiveness.

**Objective 2- Ensure Product Value**
Ensure that the Tariff product list is refreshed going forward and existing and new products are only adopted or continued to be used if able to demonstrate value in terms of cost effectiveness to the NHS and patients.

**Objective 3- Support Innovation**
Update processes on new Part IX applications to support the adoption of innovation that can improve patient outcomes and the quality of life for patients.

The DHSC consultation sets out a series of proposals to modernise Part IX of the Drug Tariff to ensure "delivery of the right product, in the right place, at the right time." It seeks feedback on the following proposals:

- Proposal 1: Increase the use of comparable categories where it is appropriate to do so;
- Proposal 2: Introduce a renewal process to Part IX;
- Proposal 3: Apply an enhanced assessment process for products to be listed on Part IX.

As Part III of the NIDT is currently reflective of Part IX of the English Drug Tariff (with a small number of exceptions), any changes made to the English Drug Tariff will be reflected in the Northern Ireland Drug Tariff, and therefore this consultation is being undertaken to seek views on the proposed changes as detailed above.

Subject to the outcome of this consultation, the Department of Health will introduce the changes in the English Drug Tariff into the Northern Ireland Drug Tariff.

## Introduction – Strategic Context

Part III of the NIDT (Part IX, EDT) contains the list of medical devices (appliances) that may be ordered by medical practitioners on the Medical List. 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 (appliances) that are available which products best meet the needs of the individual patient.

The criteria for inclusion of products in Part III, NIDT (Part IX, EDT) are that:

- The products are safe and of good quality;
- They are appropriate for prescribing by General Practitioners and other healthcare professionals in primary care;
- They are cost-effective.

A medical device is any instrument, apparatus, appliance, software, material or other article used specifically for diagnosis and/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. The proper application is for human beings to use for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease.
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- investigation, replacement or modification of the anatomy or of a physiological process.
- control of conception.

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

Any medical device placed on the market in the UK is required to be CE (or UKCA) marked by the manufacturer by law.

With escalating demand and rising expectations for the best products available, it is vital that health and social care (HSC) achieves best value, and encourages the use of good quality and cost-effective medical devices (appliances) for patients.

In 22/23, Northern Ireland spent £54 million on medical devices listed in Part III of the Northern Ireland Drug Tariff in primary care.

The Department of Health is proposing to mirror the DHSC consultation which aims to modernise the architecture and assessment processes of Part III, NIDT (Part IX, EDT). This consultation is not proposing changes to the fundamental roles of Part III, NIDT (Part IX, EDT), which are[1]:

- what medical devices (appliances) prescribers operating under General Medical Services can prescribe.
- What reimbursement price dispensers operating under the HSC pharmaceutical services will be paid.

The proposals described in this consultation document refer specifically to Part III of the NIDT. The proposals do not apply to any other part of the NIDT outside of how products are listed in Part III including whether their selling price is considered cost-effective.

[1] https://bso.hscni.net/wp-content/uploads/2023/10/DT_PART_0-2311.pdf

The following section describes the proposed options for how the system could be modernised to make improvements to current arrangements. Through this consultation process, the Department is seeking feedback on each of these changes.

Having considered feedback, the Department of Health, in line with DHSC, may choose to proceed with none, some or all these measures and may choose to include additional measures flagged through the consultation process. There are interdependencies between these changes. Some proposals could be implemented in isolation, and others could not.

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

A form of standard specifications already exists within Part III, NIDT (Part IX, EDT). The current specifications provide industry technical specifications that ensure fitness for purpose and include some critical defining information about a product. The specifications define physical, not clinical, characteristics.

The standard specifications established within Part III, NIDT (Part IX, EDT) are importantly different from the concept of generic medicines:

- **Generic medicines** are defined by chemically identical active ingredients so they could reasonably be used interchangeably. Although similar they are independently, individually regulated before they can be put on the market.
- **Standard specifications** for medical devices (appliances) are for highly comparable products that, although they may not be identical, meet a specification agreed by the industry Drug Tariff forum and the Department and are reimbursed at a generic price maintained with the industry Drug Tariff forum. The products that comply with a specification are not listed individually in the Drug Tariff.

### Problem with current arrangement

*Difficult to maintain*

The existing form of standard specifications have provided generic reimbursement pricing for a limited set of product categories which has been beneficial. However, these specifications are very time consuming to keep up to date. The physical specifications are limiting and often do not cover products manufactured outside the UK. Combined with the generic reimbursement pricing there is no incentive to manufacture to those specifications solely for the UK market.

*Lack of comparability between products*

The limited use of clinically comparable categories means that HSC organisations are at risk of not receiving the clinical, nor economic benefits from comparison.

Combined with a lack of national recommendations for medical devices and a lack of access for prescribers to systems that recommend a particular product for a particular type of patient, it is difficult to identify which devices are broadly comparable and whether more expensive devices provide added value. Effective comparison could incentivise product enhancements or reductions in price.

The lack of comparability impacts the creation of local formularies which results in differences of product use across the country. The familiarity of brands and influence from free / subsidised products in secondary care, industry sponsored clinicians and vertically integrated Dispensing Appliance Contractors all contribute to influencing what products are included in the formulary.

*Impact on patients*

The lack of comparability impacts patient choice. Patients are reliant on their clinician's advice which can also be limited to brands with which they are familiar. Better comparability would help the clinician to broaden their scope of choice, offering patients more alternatives and better care as a result.

*Impact on suppliers*

The lack of comparability also impacts suppliers. Success in the 'competition for scripts' can be determined as much by sales and marketing capability as by product quality and price. The nature of the process encourages suppliers to over claim the benefits associated with their products and set out unreasonably high expectations of price.

**Proposal 1**

To address the problem outlined above, the Department of Health, in line with DHSC, is proposing to update and increase the number of comparable categories. The aim is to enhance the groupings of products with similar attributes and to enable better, more consistent and more accurate comparison of the prices of similar devices within any given category. The intention is to drive prescribing behaviour based on value which we see as a combination of price and product quality.

Increasing comparable categories on Part III, NIDT (Part IX, EDT) would require:

- the development and agreement of the categories;
- the grouping of existing Part III, NIDT (Part IX, EDT) listings into these categories;
- the development and agreement of a set of minimum attributes for each category.

Not all products within Part III, NIDT (Part IX, EDT) would be appropriate for grouping in this way and may require placing in their own category or general grouping. It is anticipated this would only apply to a very limited number of categories.

If this proposal is taken forward, implementation will begin with the top 25 product categories by prescription volume (English prescribing data). This is subject to change where, based on clinical and commercial views, it makes sense to prioritise other categories. The table below outlines a suggested schedule of the target product categories. These dates would be subject to change as the work would be commissioned if proposals were taken forward in this way.

**Suggested schedule of categorisation (subject to change based on progress with implementing proposal one if taken forward)**

| | **Category** | **Period of Categorisation*** |
|---|---|---|
| 1 | Lancets | Sept 2024 – Nov 2024 |
| 2 | Hypodermic Insulin Needles | Sept 2024 – Nov 2024 |
| 3 | Chemical Reagents | Dec 2024 – Mar 2025 |
| 4 | Dressings | Dec 2024 – Mar 2025 |
| 5 | Arm Slings and Bandages | Apr 2025 – Jun 2025 |
| 6 | Swabs | Apr 2025 – Jun 2025 |
| 7 | Lymphoedema Garments | Jul 2025 – Sep 2025 |
| 8 | Emollient and Barrier Preparations | |
| 9 | Eye Products | |
| 10 | Ostomy Skin Fillers and Protectives | |
| 11 | Detection Sensor-Interstitial Fluid for Glucose | |
| 12 | Catheters, Urinary, Urethral | |
| 13 | Adhesive Removers (Sprays, Liquids, Wipes) | |
| 14 | Night Drainage Bags | |
| 15 | Ileostomy (Drainable) Bags | |
| 16 | Leg Bags | |
| 17 | Dry Mouth Products | |
| 18 | Stockinette | |
| 19 | Colostomy Bags | |
| 20 | Elastic Hosiery | |
| 21 | Peak Flow Meters | |

| | | |
|---|---|---|
| 22 | Irrigation Solutions | |
| 23 | Nasal Products | |
| 24 | Tubing and Accessories (incontinence) | |
| 25 | Lubricant Gels | |

*period of categorisation only included for first seven product groups as these are estimated dates only

***Option One***

This approach would enable products to be assessed against minimum attributes reflecting both the evidence base and clinical and patient need. The minimum attributes will be established for the Part III, NIDT (Part IX, EDT) categories (and where relevant sub-categories), initially targeting the top 25 product categories by prescription volume (English prescribing data). This is the recommended option.

***Option Two***

This option proposes to maintain the current arrangements in the structure of Part III, NIDT (Part IX, EDT). This would not allow category level reassessments to be undertaken (as per proposal two) but could still work in tandem with other proposals such as proposal three. A basic renewal process could be implemented to check safety and continued cost effectiveness.

***Option Three***

In Option Three the proposal is to go further than minimum attributes and set out detailed technical specifications for each category. This option would require significant resource to produce and maintain and may unduly limit innovation.

## Proposal Two: Introduce a renewal process to Part III, NIDT (Part IX, EDT)

Once a product is accepted onto Part III, NIDT (Part IX, EDT) the product will remain listed indefinitely unless the supplier requests that the product is removed. BSO are only able to remove products on Part III, NIDT (Part IX, EDT) under a limited set of circumstances. One is where they have been requested to do so by the supplier. Another is where a permanent significant risk to patient safety has been identified and a safety alert issued. Thirdly, in Northern Ireland, a small number of products have been removed from Part III of the NIDT due to licensing differences post EU-Exit.

### Problem with current arrangement

*Some listed products are not prescribed*

An analysis of Part IX of the English Drug Tariff (which relates to Part III of the NIDT) shows that approximately 13% (8,500) of products were not prescribed in the 12 months to September 2022. Continuing to have products on Part III, NIDT (Part IX, EDT) that are not used means that Part III, NIDT (Part IX, EDT) is unnecessarily complex with many products that may not even be available.

*There is a lack of refresh*

As of May 2023, Part III, NIDT (Part IX, EDT) includes over 60,000 separate products - every size of every colour and variant of every product is represented in Part III, NIDT (Part IX, EDT). Once a product price is decided, the price mostly only increases because of annual inflationary increments. In most comparable markets, prices for older products would be expected to reduce over time to enable them to compete with newer, innovative products taking their place at the upper end of a category price range.

Both clinical quality expectations and manufacturer product quality have increased over time and are likely to continue to do so. Some products on the list have been there decades. The list then becomes outdated for many products and does not always reflect good value or latest clinical practice. Products which passed the criteria on cost-effectiveness years ago may no longer do so if they were re-assessed today. Broadly, the system could be argued to favour established products over newer alternatives.

No further product checks are undertaken on a product once it is listed on Part III, NIDT (Part IX, EDT) irrespective of developments in clinical practice, publication of new guidance, or patient expectations. For example, a recent NHS England assessment of blood glucose and ketone meters, testing strips and lancets found that some blood glucose meters are discontinued but their corresponding testing strips are still listed on Part IX.

**Proposal 2**

To address the problem outlined above, this proposal seeks to introduce a renewal process to keep Part III, NIDT (Part IX, EDT) up to date with clinical practice, patient outcomes and ensure continued cost-effectiveness. This will help ensure that only products that demonstrate value to patients and the HSC are listed.

i. Each category will be assigned a renewal date in which the listing-holders (manufacturer or distributor) for all the products in that category of products will be required to apply for renewal to remain listed on Part III, NIDT (Part IX, EDT).
ii. The renewal process would apply every 4-5 years. Approximately two categories would be subject to a review every quarter with approximately eight categories reviewed per annum. Three months advanced notice will be given

to suppliers of the requirement to apply for renewal. The table below illustrates how this may look for the top 25 categories by prescription volume (English prescribing data).

**Sample of renewal schedule against top 25 categories by prescription volume (subject to change-this assumes all categorised are ready to begin renewal process Jan 2025)**

| | **Category*** | **1st Round of Renewal** | **2nd Round of Renewal** |
|---|---|---|---|
| 1 | Lancets | End 2024 | 2030 |
| 2 | Hypodermic Insulin Needles | End 2024 | 2030 |
| 3 | Chemical Reagents | 2025 | 2030 |
| 4 | Dressings | 2025 | 2030 |
| 5 | Arm Slings and Bandages | 2025 | 2030 |
| 6 | Swabs | 2025 | 2030 |
| 7 | Lymphoedema Garments | 2025 | 2030 |
| 8 | Emollient and Barrier Preparations | End 2025 | 2031 |
| 9 | Eye Products | End 2025 | 2031 |
| 10 | Ostomy Skin Fillers and Protectives | 2026 | 2031 |
| 11 | Detection Sensor-Interstitial Fluid for Glucose | 2026 | 2031 |
| 12 | Catheters, Urinary, Urethral | 2026 | 2031 |
| 13 | Adhesive Removers (Sprays, Liquids, Wipes) | 2026 | 2031 |
| 14 | Night Drainage Bags | 2026 | 2031 |
| 15 | Ileostomy (Drainable) Bags | 2026 | 2031 |
| 16 | Leg Bags | End 2026 | 2032 |
| 17 | Dry Mouth Products | End 2026 | 2032 |
| 18 | Stockinette | 2027 | 2032 |
| 19 | Colostomy Bags | 2027 | 2032 |
| 20 | Elastic Hosiery | 2027 | 2032 |
| 21 | Peak Flow Meters | 2027 | 2032 |
| 22 | Irrigation Solutions | 2027 | 2032 |
| 23 | Nasal Products | End 2027 | 2033 |
| 24 | Tubing and Accessories (incontinence) | End 2027 | 2033 |
| 25 | Lubricant Gels | 2028 | 2033 |

*where work has been carried out on assessing product groups the order of implementation may not align directly with volumes prescribed

*illustrative categories based on 2022 data

iii. If the category is due for renewal within 12 months of a supplier listing a product for the first time, it is not expected the supplier will need to submit new information. However, the product will still be considered within its category on cost-effectiveness and so a supplier may wish to submit an updated renewal application.

iv. Checks would be made to ensure the product is still safe and the European CE/UKCA certificates are up to date. The product would be assessed to check it meets the requirements set out for a product's allocated category (where applicable) and is cost effective**.**

Products that are determined not to sufficiently meet the requirements and/or are not cost-effective, will not be renewed and will be subject to a 6-month notice period to allow stockholdings to be adjusted and patients to switch to alternative products.

The reason for a product not being renewed will be provided to suppliers. Suppliers will be able to re-submit a new application within the notice period to secure a renewal decision. If at renewal, a supplier is unable to be contacted or does not respond, then those particular products will not be renewed.

A product that has been listed for more than two years and has not been prescribed in either England, Wales or Northern Ireland for 12 months will not be renewed. This doesn't apply to different sizes within a range of products where some of the sizes are being prescribed.

Products that are no longer recommended for prescribing under NHS low priority prescribing or equivalent national guidance will not be renewed. This proposal does not refer to guidance where the product is only recommended to be prescribed to certain patient cohorts. That is expected to continue to be adhered to by prescribers.
If it is determined that the HSC is not deriving any economic value from having a particular category of products listed on Part III, NIDT (Part IX, EDT), the decision may be taken to remove that category.

The intention of this proposal is to ensure Part III, NIDT (Part IX, EDT is a refreshed tariff that provides the HSC with cost effective and good quality products.

For all options the annual price increase mechanism is expected to remain.

***Option 1***

The renewal process will be implemented for prioritised categories of products only, for example most dispensed categories (based on the English prescribing data for the year prior to renewal). In the first round of renewal, this will also be determined by the order

of the creation of new categories. Products that have not been prescribed for the past two years will not be renewed. Suppliers who do not respond to the renewal process will have their product removed.

***Option 2***

The renewal process will be implemented for most of the products on Part III, NIDT (Part IX, EDT) with some exceptions. In the first round of renewal this will also be determined by the order of the creation of new categories. Products that have not been prescribed for the past two years will not be renewed. Suppliers who do not respond to the renewal process will have their product removed. However, given that over 90 primary categories are in place and a majority by number of the categories only represent a small percentage of prescription volume, this approach is not recommended.

***Option 3***

A third option would be to only undertake a reassessment for a brand-new category. This approach would mean a large majority of the products listed in Part III, NIDT (Part IX, EDT) of the Drug Tariff would not be subject to renewal. Products that have not been prescribed for the past two years will not be renewed. Suppliers who do not respond to the renewal process will have their product removed. This approach is not recommended.

## Proposal Three: Apply an enhanced assessment process for products to be listed on Part III, NIDT (Part IX, EDT)

The assessment process is undertaken entirely by NHS Prescription Services. Applications for inclusion onto Part III, NIDT (Part IX, EDT) are currently assessed against three criteria:

1. the products are safe and of good quality;
2. they are appropriate for prescribing by General Practitioners and other healthcare professionals in primary care; and
3. they are cost-effective and offer value for money.

For products to be assessed as safe and of good quality valid certification must be submitted from an approved notified body under either the European CE or UKCA regulatory frameworks (for inclusion in Part III NIDT, products must have a CE mark).

For products to be assessed as appropriate for prescribing a product must be able to be matched within an existing sub-category within Part III, NIDT (Part IX, EDT) and the supporting product information must set out the relative features and benefits of the product.

For products to be assessed as cost-effective the applicant must state the comparator products in their evidence and the price should be in line with those already listed.

Alternatively, a new category or sub-category can be created in Part III, NIDT (Part IX, EDT) if no category exists which already adequately describes the product in broad terms – either clinical function or physical make-up. Cost is considered across a typical treatment regime and evidence must be supplied to substantiate the claims. The comparator in this instance is the current standard practice, and evidence must be submitted to demonstrate the cost-benefit of using this product over a current standard product across a typical treatment regime. Price will then be agreed.

**Problem with current arrangement**

*Cost-effectiveness can be difficult to determine*

The assessment process to confirm cost-effectiveness is limited to ensuring either a product is compared against existing Part III, NIDT (Part IX, EDT) products in the most relevant sub-category with the highest listed price used as the benchmark or by the claims of added benefits by the company to justify a cost above the highest listed price for the most relevant sub-category. Claimed product features and benefits are not validated with clinical experts or patient representatives to assess the evidence, relative efficacy or patient benefit.

Evidence is sometimes poorly presented or difficult to obtain. This combined with the absence of expert clinical review, or a patient perspective means that the justification for a price based on an added value benefit cannot always be adequately assessed.

*The assessment process does not adequately challenge the market price*

Consequently, there is a risk that 1) products may be added into Part III, NIDT (Part IX, EDT) which do not offer value and 2) products are rejected on the grounds of unit cost or unclear information, possibly resulting from an inexperienced or under resourced applicant, when the product may in fact deliver a wider cost benefit and/or may offer a significant improvement to the quality of life of patients that is of real value.

The intention of the proposal is to ensure the HSC is receiving economic value from existing products in order to be able to adopt new technologies that offer improved quality of life and improved patient outcomes.

**Proposal 3**

The Department of Health, in line with DHSC has proposed that the assessment methodology is updated as follows:

**Introduction of independent advisory panels**
Different panels would be created to represent the major product groups on Part III,

NIDT (Part IX, EDT) and identified categories. This will increase the input from people with lived experience into the decision making on the range of products available on prescription. Therefore, representation on the panels would be drawn from both the clinical profession and patient representatives. Clinical and patient representatives will need to declare any potential conflicts of interest. The panels would not include representation from suppliers.

The applications to Part III, NIDT (Part IX, EDT) and category renewals would be assessed by the independent advisory panels.

**Introduction of a weighted evaluation matrix**

The proposed evaluation matrix will be comprised of three elements:

- product quality,
- supplier price and
- social value.

It is proposed that a weighting is applied to each element to balance cost with qualitative factors (product quality and social value). It may be appropriate for the weighting to vary per product category. It is proposed that the matrix is applied to both new applications for listing and category renewals.

The Department of Health, in line with DHSC proposes as a starting point that **quality** is weighted at 50%. However, The Department of Health, in line with DHSC understands that each category will have different characteristics. Product quality is proposed to be assessed against the attributes determined for each category which along with the evidence base will be subject to agreement from an independent advisory panel comprised of both clinical and patient representation.

It is proposed that supplier **product price** would then be weighted at 40% with the lowest price product within a category receiving the maximum mark and remaining products scored proportionately. Supplier product prices will be converted to unit prices to reflect differences in pack size to ensure like-for-like comparison.

Finally, it is proposed that **social value** is a newly assessed element included in the evaluation matrix. The Health Service has a huge opportunity and responsibility to maximise benefits effectively and comprehensively through its commercial activity. A missed opportunity to deliver social value may lead to costs that the taxpayer has to absorb elsewhere. Social value is proposed to be composed of environmental attributes and be weighted at 0 - 10%. The Department of Health, in line with DHSC proposes to develop product level attributes that social value can be assessed on. The Department of Health, in line with DHSC, understands at this time there are limits to what companies can do at product level.

Therefore, The Department of Health, in line with DHSC proposes to introduce environmental attributes to signal future direction and begin with a zero weighting to give companies time to adjust, with a view to increasing to 10% weighting.

*Price*

It is proposed that the price score range from 0-5 with 5 being allocated to the lowest price in the category. For every 1% a price is above the lowest price it is minus 0.1. Price would be assessed within a product's category. For example, if the lowest price (product A) is £10 and product B is £12, 20% higher, then the score for product B is 3.0. The allocated score will then be weighted by 40%.

Volumes of prescriptions will be considered when determining the lowest price. If a product has had no prescribing against it in the past year it will not be part of the determination of the lowest price.

*Quality and Social Value*

It is proposed that the quality and social value scores range from 0 to 5 with the specific scores as set out below.

5 = Meets the minimum requirement for category and offers two or more additional clinical or patient benefits.
4 = Meets the minimum requirement for category and offers one additional clinical or patient benefit.
3 = Meets the minimum requirement for category.
2 = Meets most of the requirement but with identified clinical or patient quality concerns.
1 = A number of clinical or patient concerns with the product.
0 = Does not meet any of the requirement for the category.

The BSA NHS Prescriptions team will initially score the applications against the attributes set out by the advisory panels during the categorisations. The independent advisory panel would then assess to ensure clinical quality, cost effectiveness and patient outcomes.

Example scenario of evaluation matrix

| **Criteria** | **Weighting** | **Minimum Pass** | | **Submission 1** | | **Submission 2** | | **Submission 3** | |
|---|---|---|---|---|---|---|---|---|---|
| | | Score | W. Score | Score | W. Score | Score | W. Score | Score | W. Score |
| Price | X40 | 4 | 1.6 | 5 (£10) | 2.0 | 5 (£10) | 2.0 | 1 (£14) | 0.4 |
| Quality | X50 | 3 | 1.5 | 3 | 1.5 | 1 | 0.5 | 5 | 2.5 |
| Social Value | X10 | 3 | 0.3 | 3 | 0.3 | 3 | 0.3 | 5 | 0.5 |
| Total | 100 | | **3.4** | | **3.8** | | **2.8** | | **3.4** |
| Outcome | | | | | List | | Reject | | List |

The above table illustrates how the methodology would operate in practice. Assuming a benchmark score of 3 for Quality and Social Value was taken as well as a benchmark score on price of +20%, then a minimum weighted pass score of "3.4" would be set. Under this methodology a product that was the lowest cost and meets the quality requirements would be listed (submission 1), a product that was lowest cost but had a number of quality concerns would not be listed (submission 2) and a product that was high cost (in relation to the lowest cost product) but achieved a high-quality score would be listed (submission 3). It is proposed that the independent advisory panels set the benchmark score for the categories. This may vary depending on the attributes of the category.

**Option 1**
Apply a 40/50/10 price/quality/social value (or variant) weighting to an assessment methodology with a proposed benchmark of 3.4. The lowest price would be a product that represents at least 5% of prescribing volumes. The Department of Health, in line 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 appropriate. The first review point would be after the first category is assessed.

Option one is the preferred option. A price/quality scoring system would provide clarity and transparency to industry on how products are assessed. Option One incentivises quality products and consideration of social value attributes. An independent advisory panel would create the attributes that products are scored against. The attributes would build in consideration of evidence.

**Option 2**
Do not formally score products but undertake a qualitative assessment. The independent advisory panel would review products on a case-by-case basis, taking into account evidence. The benefit of option two over the status quo and option one is that an independent advisory panel would review new applications on a case-by-case basis taking account of evidence. The downside to this approach is that it is more subjective and introduces the risk of inconsistency in assessment with the absence of a common mechanism being applied. As such, this option is not recommended.

**Option 3**
Apply a 40/50/10 price/quality/social value (or variant) weighting including a product with minimum 5% prescribing volumes to determine lowest price and then use outputs to inform a panel review with the right to pass or fail a submission irrespective of the achieved score.

In this option, a structured assessment based on the scoring methodology would be conducted, but the output would be advisory only with an independent advisory panel having the flexibility to moderate both pass and fail scores. The benefit is that the panel can override a decision not to list or renew a product where there is a high clinical or

patient demand. This approach is more subjective and introduces the risk of inconsistency. As such, this option is not recommended.