Department of Health & Social Care

Medical Devices in Primary Care

Proposals for updating Part IX of the Drug Tariff – medical devices available for prescribing in primary care

Consultation v1.0 Final

Issued: 06 October 2023

Contents

About this consultation

The Department of Health and Social Care ('the department') and NHS England are committed to delivering the best value medical devices for patients.

Part IX of the NHS England and Wales Drug Tariff ('the Drug Tariff') 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.

Unlike many areas of healthcare, Part IX of the Drug Tariff has been subject to minimal amendment since it was established. During this time, the world of medical devices has evolved dramatically. For example, there have been significant advances in the specialist nature and complexity of medical devices as well as changes in the manufacturing and commercial markets in provision of devices.

Following the publication of the Government's Medical Technology Strategy in February 2023, this document sets out a series of proposals to modernise Part IX of the Drug Tariff to ensure we are delivering the right product, in the right place, at the right price.

Objectives

The objectives of the proposals are set out below:

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.

Background and current context

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.

Medical device usage and spend is steadily increasing. In 2022/23 the NHS spent around £1.4 billion on medical devices listed on Part IX of the Drug Tariff in primary care. With escalating demand and rising expectations for the best products available, it is vital that the NHS achieves best value, and these proposals encourage the use of good quality and cost-effective devices for patients.

We propose targeted changes to modernise the architecture and assessment processes of Part IX of the Drug Tariff. This consultation is not proposing changes to the fundamental role of Part IX which is set in statute and lays out:

- What appliances prescribers operating under NHS General Medical Services can prescribe; and
- What reimbursement price dispensers operating under NHS pharmaceutical services will be paid

Current Legislation and Policy

Regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 sets out that the Secretary of State must compile and publish a statement, referred to as the Drug Tariff in a format that the Secretary of State thinks fit.

The Drug Tariff is published on behalf of, and is a determination of, the Secretary of State for Health. Part IX of the Drug Tariff contains the appliances and chemical reagents, which can be prescribed by prescribing practitioners in primary care operating under NHS General Medical Services.

The Drug Tariff provides information on what contractors will be paid for providing NHS Pharmaceutical Services, including reimbursement of products dispensed, such as appliances, and remuneration for services provided, such as dispensing.

The medical devices in Part IX are grouped together in categories and subcategories. These are either a high-level description of the medical device or the function of the device. Some contain very similar or identical forms of presentation, and others contain devices which are less similar.

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.

The criteria for inclusion of products in Part IX 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.

Scope of this consultation

Within the scope of this consultation

The proposals described in this consultation document refer specifically to Part IX of the Drug Tariff, which contains a list of devices and chemical reagents approved for prescribing by healthcare professionals.

The Department of Health and Social Care's responsibilities in relation to Part IX of the Drug Tariff extend only to England. The National Assembly for Wales operates a common policy with the Department of Health and Social Care and therefore the Drug Tariff currently covers both England and Wales. Scotland maintains and publishes a separate Drug Tariff. Northern Ireland currently reflects the English Drug Tariff and a separate Northern Ireland consultation will be considered by the Department of Health (NI).

Outside the scope of this consultation

- The proposals in this consultation do not apply to Scotland and Northern Ireland.
- The proposals do not apply to any other part of the Drug Tariff outside of how products are listed in Part IX including whether their selling price is considered cost-effective.
- The proposals do not change that GPs providing NHS General Medical Services can prescribe products in Part IX
- The proposals do not change that community pharmacies and appliance contractors providing NHS Pharmaceutical Services will be paid in accordance with the Drug Tariff.

Further topics in the call for evidence section are being asked to seek feedback with the intention to undertake further targeted consultations next year if appropriate. These topics are for feedback only to guide our thinking and are not being formally consulted on at this time.

The policy options

The following section describes the proposed options for how the system could be modernised to make improvements to current arrangements. The proposals have been developed in part through engagement with patient, industry, and clinical stakeholders and our intention is to continue a process of close engagement going forward to inform our approach. Through this consultation process we are seeking feedback on each of these changes.

Having considered feedback, the department 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.

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

If there were no amendments to Part IX of the Drug Tariff, what would you expect to happen to the price and volumes prescribed of products that you are concerned with over the next 10 years? (100 words max)

Under the current process, how much does it cost your business to prepare the information and submit an application for a new product to be listed? (100 words max)

If there were no amendments to Part IX of the Drug Tariff, how would the alternatives to regulation affect your business(es)? (500 words max)

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

Current arrangements

A form of standard specifications already exists within Part IX of the Drug Tariff. 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 current specifications within Part IX of the Drug Tariff only cover approximately 1.75% of listed products and are not subject to review or update.

The standard specifications established within Part IX 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 devices 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.

The problem with the current arrangements

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 the NHS is 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 they are familiar with. 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 impacts suppliers too. 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.

Our proposal for reform

Our proposal is to update and increase the number of comparable categories within Part IX. 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. This proposal is not intended to increase or support the use of generic prescribing, so it differs to the current use of standard specifications on Part IX.

Increasing comparable categories on Part IX would require:

- the development and agreement of the categories;
- the grouping of existing Part IX listings into these categories;
- The development and agreement of a set of minimum attributes for each category.

Not all products within Part IX 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.

We propose that the development of any categories would build on relevant clinical work and peer reviewed published evidence where available and be informed by patient input. For example, clinical and patient input would approve the proposed minimum attributes for a category. By aligning the structure and contents of the Part IX system with clinical best practice and a patient perspective in terms of quality of life we would encourage and promote good quality care. The independent advisory panels, detailed in proposal three, would be responsible for ensuring the attributes for a category remain current and up to date.

The department recognises that the Drug Tariff is not prescribing guidance. However, the intention is to better inform prescribers in the NHS of the total product choice available for prescribing and ensure that the products listed are of good quality and are cost effective. The department believes that the architecture of Part IX is an important part of the information required by the NHS. The intention is not to fundamentally change the role of Part IX but simply to structure it into similar product categories. Whilst the current categorisation allows products to be broadly organised, the new categories would make the comparisons more robust and transparent, enabling the direct contrast of quality characteristics and price.

If this proposal is taken forward, the department would aim to begin implementing this proposal first on the top 25 product categories by prescription volume which account for approximately 75% of activity. This is subject to change where based on clinical and commercial views it makes sense to prioritise other categories. Proposed minimum attributes for the top 25 product categories (and where relevant sub-categories) will be developed for nominated independent panels to review and approve.

Table 1 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. It is also subject to existing work by the National Wound Care Strategy Programme which for relevant categories we would aim to align.

Table 1: *Suggested schedule of categorisation (subject to change based on progress with implementing proposal one if taken forward)*

	Category	**Period of categorisation* (including re-authoring SNOMED codes on Drug Tariff)**
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 - Sept 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. It is estimated that lymphoedema garments would take longer to reauthor on SNOMED due to number of product lines

Option One

This approach would enable products to be assessed against minimum attributes reflecting both the evidence base and clinical and patient need and is our recommended option. It is recognised that this approach will require funding to first produce draft attributes for each category, implement the change within current systems and ensure ongoing maintenance. However, the department believes the intended goals of increasing meaningful choice and value justify the investment.

Option Two

In Option Two the proposal is to maintain the current arrangements in the structure of Part IX. 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.

No changes to primary or secondary legislation are required to implement any of the options in this proposal.

For option one and three, the timeline of implementing this proposal would most likely be staggered in line with the set-up of clinical and patient input to sign-off the categories and attributes. When determined, the new categories would then require building into the structure of the Drug Tariff. The reauthoring of SNOMED codes would be required for affected medical devices on Part IX. The aligning of these codes on prescribing and dispensing systems would need to be extensively

communicated so that system suppliers could make the necessary updates and the electronic prescribing system continues to operate.

NHS Prescription Services in the NHSBSA will be responsible for the ongoing operation of the new arrangements outlined in this proposal.

Options for Proposal One

Option 1: Minimum attributes will be established for the Part IX categories (and where relevant sub-categories), initially targeting the top 25 product categories by prescription volume.

Option 2: Products will be allocated to a category (and where relevant sub-categories) based on the current approach and a judgement over the most relevant category.

Option 3: A detailed technical specification will be developed for each category (and where relevant sub-categories).

Questions

What is your preferred option for this proposal? (multiple choice)

- Option 1
- Option 2
- Option 3
- None
- Don’t know

Do you agree or disagree with this proposal? (multiple choice)

- Agree
- Disagree
- Don’t Know

Please provide further details (500 words max)

Please share any challenges you think this proposal might encounter? (500 words max)

Please share any amendments you think might improve this proposal? (500 words max)

Are there products on Part IX that should be considered as an exception to this process? (multiple choice)

- Yes
- No
- Don't know

If yes, please list them (500 words max)

Please explain your answer (500 words max)

Do you have any alternative suggestions for transparently identifying comparability between products on Part IX of the Drug Tariff? (multiple choice)

- Yes
- No
- Don't know

If yes, please provide your suggestions (500 words max)

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

If Part IX of the Drug Tariff was updated to include new categories, what would be the familiarisation cost (in £) to business in the first year? (e.g. reading, understanding and disseminating the amendments) Please provide an estimate. (100 words max)

If Part IX of the Drug Tariff was updated to include new categories, what would be the set-up cost (in £) to business in the first year? (e.g. purchasing capital, software or data system updates) Please provide an estimate. (100 words max)

What would be the impact of creating comparable categories on prescribing patterns and business sales? Please provide an estimate. (100 words max)

Please outline any other costs (500 words max)

Proposal Two: Introduce a renewal process to Part IX

Current Arrangements

Once a product is accepted onto Part IX the product will remain listed indefinitely unless the supplier requests that the product is removed. NHS Prescription Services are only able to remove products on Part IX 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.

Once a product is placed on Part IX there is no further assessment of its continued product quality or cost-effectiveness. The price may change if the supplier requests a decrease in price or it may increase in line with the annual GDP deflator price mechanism or if it is granted an exceptional price increase (EPI). Refer to the glossary for a description of the GDP deflator mechanism and EPI process.

The problem with the current arrangements

Some listed products are not prescribed

An analysis of Part IX shows that approximately 13% (8,500) of products were not prescribed in the 12 months to September 2022. Continuing to have products on Part IX that are not used means that Part IX is unnecessarily complex with many products that may not even be available. Continuing to include obsolete products means that commissioners do not have the right information to update their formularies.

There is a lack of refresh

As of May 2023, Part IX includes 60,655 separate products - every size of every colour and variant of every product is represented in Part IX. 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 IX 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.

Our proposal for reform

Introduction of a renewal process

A renewal process is introduced to keep the Part IX list 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 NHS are listed. 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 IX.

Frequency

A 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. Table 1 sets out the first prioritised 25 categories by prescription volume. NHS Prescription Services will reserve the right to undertake a review of other categories subject to resource capacity and identified need. Three months advanced notice will be given to suppliers of the requirement to apply for

renewal. This is subject to change as the top 25 categories by prescription volume may change.

NHS Prescription Services in the NHSBSA will retain the right to extend the renewal date for a category.

Table 2: *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

Criteria

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.

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.

Outcome

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. This is intended to cover situations where for example, a distributor no longer exists and have not notified NHSBSA that they are no longer supplying this product.

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 does not apply to different sizes within a range of products where some of the sizes are being prescribed. One scenario this will cover is where a product is not being supplied to the UK market, but a listing on Part IX is used to market a product internationally.

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 NHS is not deriving any economic value from having a particular category of products listed on Part IX, the decision may be taken to remove that category.

The annual pricing increase mechanism agreed for Part IX between the Department of Health and Social Care, NHS Business Services Authority (NHS Prescription Services) and the Drug Tariff Forum is expected to continue to apply. The exact specifics and level of the mechanism will be subject to periodic review as per existing processes. The intention of this proposal is to ensure Part IX is a refreshed tariff that provides the NHS with cost effective and good quality products.

Option One

In Option One the proposal is to target the top 25 categories by prescription volume. This balances the practical resource requirement for the NHSBSA, proposed independent advisory panels and industry to undertake a reassessment process.

Option Two

The alternative is to apply a systematic approach in which virtually all categories are subject to periodic assessment. However, given 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 Three

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 IX of the Drug Tariff would not be subject to review and is not recommended.

No changes to primary or secondary legislation are required to implement this proposal. The timeline of implementation of this proposal would both mirror the creation of new categories and be based on feedback on the options in this consultation. If a decision was made not to introduce new categories, a renewal process could still be considered for implementation against existing categorisation.

NHS Prescription Services in the NHSBSA will be responsible for the ongoing operation of the new arrangements outlined in this proposal.

Options for Proposal Two
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 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 IX 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.

Option 3: The renewal process will be implemented for all products in the same order as the creation of new categories on Part IX. 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.

Questions

What is your preferred option for renewals? (multiple choice)

- Option 1
- Option 2
- Option 3
- None
- Don’t know

Do you agree or disagree with this proposal? (multiple choice)

- Agree
- Disagree
- Don’t Know

Please provide further details (500 words max)

Do you agree that every 4-5 years is a reasonable period of renewal? (multiple choice)

- Yes
- No
- Don’t know

Please explain why, including the category of products you are referring to in your answer (500 words max)

Should any product groups be exempt from the renewal process? (multiple choice)

- Yes
- No
- Don’t know

Please explain your answer (500 words max)

Please share any challenges you think this proposal might encounter (500 words max)

Please share any amendments you think might improve this proposal? (500 words max)

Do you have any alternative suggestions for ensuring Part IX up to date? (multiple choice)

- Yes
- No
- Don’t know

If yes, please provide your suggestions (500 words max)

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

If Part IX of the Drug Tariff was updated to apply a renewal process, what would be the familiarisation cost (in £) to business in the first year? (e.g. reading, understanding and disseminating the amendments) Please provide an estimate. (100 words max)

If Part IX of the Drug Tariff was updated to apply a renewal process, what would be the set-up cost (in £) to business in the first year? (e.g. purchasing capital, software or data system updates) Please provide an estimate. (100 words max)

What would be the estimated annual cost (in £) to your business to comply with the removal of non-prescribed and non-recommended products from the Tariff? (100 words max)

What would be the estimated annual cost (in £) to your business to renew your products on the Tariff? (100 words max)

Please outline any other costs (500 words max)

Proposal Three: Apply an Enhanced Assessment Process for products to be listed on Part IX

Current arrangements

The assessment process is undertaken entirely by NHS Prescription Services. Applications for inclusion onto Part IX 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 products to be assessed as appropriate for prescribing a product must be able to be matched within an existing sub-category within Part IX 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 IX 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.

The problem with the current arrangements

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 IX 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 IX 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.

If none of these proposals are implemented and nothing else changes then spend against Part IX products is projected to rise from £1.3 billion (2022) to £2.2 billion in 2033, based on historical growth, existing price mechanisms and discussions with stakeholders.[1] The intention of the proposal is to ensure the NHS is receiving economic value from existing

[1] Spend forecast is based on historical (2012-22) trends in volumes and prices at a chapter level, in addition to the GDP deflator mechanism. Judgement has been used in the Dressings chapter (which has recently experienced large falls in volumes) and Reagents, based on discussions with stakeholders. Chapter forecasts were then summed to produce an aggregate forecast.

products in order to be able to adopt new technologies that offer improved quality of life and improved patient outcomes.

Our proposals for reform

We propose 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 IX and identified categories. The department wants to 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. We believe strongly in the importance of introducing the patient voice into decision making to ensure products of value are listed on Part IX. The evidence base is still paramount to decision making and would form a key part of the panel's decisions.

The applications to Part IX 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). Subject to consultation responses, 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.

Table 3 provides an example. The department proposes as a starting point that quality is weighted at 50%. The department 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.

The department proposes 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.

The Environment Act 2021 requires Ministers of the Crown, and those making policy on their behalf, to have '*due regard'* to the Environmental Principles Policy Statement (EPPS) when making policy.

Given the amount of spend through the Part IX route, we propose that social value is a newly assessed element included in the evaluation matrix. The Government 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 proposes to develop product level attributes that social value can be assessed on. The department understands at this time there are limits to what companies can do at product level. Therefore, the department 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.

For Part IX it is proposed that social value relates specifically to the "fighting climate change" social value theme. Further details on this theme are detailed in the NHS England guidance found at the following link: https://www.england.nhs.uk/greenernhs/publication/applying-net-zero-and-social-value-in-the-procurement-of-nhs-goods-and-services Any standards used will be aligned with central government guidance on social value and sustainability and World Trade Organisation rules. Ahead of implementation the minimum standard will be confirmed and will be applied consistently for all categories.

Table 3: *Example of how evaluation matrix may be implemented*

Criteria	Weighting
Quality	50%
Price	40%
Social Value	10%

Price

We propose 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. The lowest price product may be a product that represents at least 5% of a category prescription volume to avoid the risk of a non-moving/ slow-moving product distorting the price score for a category. The minimum volume will also take into consideration the characteristics of the category, for example if it is a highly concentrated market the 5% volume of prescriptions may not be applicable.

Quality (and Social Value)

We propose 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 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.

Evaluation matrix - illustration

Table 4: *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). We propose that the independent advisory panels set the benchmark score for the categories. This may vary depending on the attributes of the category.

Option One

Option one is our 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 Two

Categories would be reviewed but without reference to a scoring methodology. 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 it more subjective and introduces the risk of inconsistency in assessment with the absence of a common mechanism being applied and as such is not recommended.

Option Three

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 and is not recommended.

No changes to legislation would be required to introduce an evaluation matrix. The department may choose to use secondary legislation to implement the independent advisory panels to make their decisions binding. This proposal could be implemented in isolation or in

combination with the other proposals. The department would hope that the timeline of implementation would be from September 2024. The department's preference would be to align the assessments with the creation of the new categories, but this proposal can still be considered for implementation ahead of, or without, the set-up of the new categories, with the aim of increasing clinical and patient input into the assessment process.

NHS Prescription Services in the NHSBSA will be responsible for the ongoing operation of the new arrangements outlined in these proposals. The department would direct the NHSBSA to act on advice from the independent advisory panels.

Options for Evaluation Matrix and use of panels (Proposal Three)

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 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 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.

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.

Questions

What is your preferred option? (multiple choice)

- Option 1

- Option 2
- Option 3
- None
- Don’t know

Do you agree or disagree with this proposal?

- Agree
- Disagree
- Don’t know

Please provide further details (500 words max)

Do you think the proposed benchmark is fair? (multiple choice

- Yes
- No
- Don’t know

Please provide further details (500 words max)

Do you think basing the lowest price on a product that represents at least 5% of prescribing volumes is fair? (multiple choice)

- Yes
- No
- Don’t know

Please provide further details (500 words max)

Please share any challenges you think this proposal might encounter? (500 words max)

Please share any amendments you think might improve this proposal? (500 words max)

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

What would be the administrative and set-up cost to your business of complying with the proposed evaluation matrix? (500 words max)

If some of your products did not pass the proposed evaluation matrix and you did not re-list those products, what could be the annual impact on your business' profits? (500 words max)

The Impact Assessment estimates that prices could decrease by an average of 14% under the evaluation matrix proposal. Price adjustments would vary depending on the price of the product and similar products. What would be the annual impact on your business' profits of a fall in prices of this level? (500 words max)

If your product did not pass the evaluation matrix, how likely would you be to resubmit? (multiple choice)

a. Very likely
b. Likely
c. Not sure
d. Unlikely
e. Very unlikely

What would be the impact on the wider sector (e.g. employment and investment in R&D) of complying with the evaluation matrix at entry and renewal stages? (500 words max)

Temporary Listings for certain qualifying products

In order to address the possibility that we are missing out on some innovative products because they do not have sufficient real world evidence of use in the NHS the department proposes a temporary listing mechanism.

Products which are significantly different to existing Part IX products and do not yet have sufficient real-world evidence in the NHS, may be listed on the Tariff for a temporary period of 12 months before reassessment to remain on Part IX. This provides a total temporary listing of 18 months if the product is not renewed.

These applications would still need to provide evidence of clinical effectiveness and safety and be determined as suitable for prescribing. For example, it could still be determined that the product should only be used under secondary care oversight and not available for prescribing in the community.

The benefits of this proposal are that smaller companies who do not have the resource to undertake additional clinical trials beyond that required for regulatory approval or may have undertaken clinical trials in other countries can still have their products considered without incurring extra costs.

Option One

In Option One, there is no introduction of temporary listings. This will be based on feedback recognising that the logistics of this proposal may be too unfavourable for dispensing contractors or prescribers.

Option Two

In Option Two, reassessment would occur after being listed for 12 months. This would provide a 3 month window for an independent panel (if taken forward) or for NHS Prescriptions Services to assess the evidence within the NHS and decide whether to keep listed. If the decision is not to keep the product on Part IX there will be a further 3 month notice period for prescribers and dispensing contractors. Option Two is the department's recommendation.

No changes to primary or secondary legislation are required to implement this proposal. Should the proposal proceed, this could be implemented in April 2024.

NHS Prescriptions Services in NHSBSA will be responsible for the ongoing operation of the new arrangement outlined in this proposal.

The intention of this proposal is to support adoption of innovative products into the NHS to benefit patients, including where this is developing at pace, or from SMEs.

Options for Temporary Listings (Proposal Three)
Option 1: No change; No temporary listings introduced

Option 2: Allow temporary listings for 12 months with a reassessment at 12 months (total of three months) and three months' notice period if not renewed

Questions

What is your preferred option? (multiple choice)

- Option 1
- Option 2
- Don't know

Do you agree or disagree with this proposal? (multiple choice)

- Agree
- Disagree
- Don't Know

Please provide further details (500 words max)

If at the end of the 12-month period it was determined that the product should not remain listed, what notice period for de-listing makes this a more feasible option? (500 words max)

Please share any challenges you think this proposal might encounter? (500 words max)

Please share any amendments you think might improve this proposal? (500 words max)

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

What would be the overall cost to business of introducing a temporary listing mechanism? (100 words max)

What would be the overall benefit to business of introducing a temporary listing mechanism? (100 words max)

What would be the overall cost to the NHS of introducing a temporary listing mechanism? (100 words max)

Introduction of an application fee

A new application fee would be introduced to Part IX. The intention of the proposal is that it would be used to fund the proposed independent advisory panels and the increased frequency of assessments as a result of the proposed renewal process.

Option One
As a guide, for new applicants to cover the current application processing cost, the fee would be approximately £175 per product. This could be an underestimate when including the costs of the independent advisory panels. The fee is proposed to be capped to a maximum fee of £1,000 for SMEs and £10,000 for non-SMEs (in the event of multiple applications submitted within the same year).

Option Two
If a fee was introduced to also cover renewal costs, the fee would be approximately £242 per product (AMP level) at the time of renewal. New entrants would still need to pay the fee of approximately £175 per product. This could be an underestimate when including the costs of the independent advisory panels. The fee is proposed to be capped to a maximum fee of £1,000 for SMEs and £10,000 for non-SMEs (in the event of multiple applications submitted within the same year).

The application fee would be a non-refundable fee if the application was rejected. The fee does not guarantee an accepted listing.

The introduction of a fee for Part IX applications would require primary legislation. It may therefore not be taken forward. The timeline of

implementation is therefore uncertain but would be estimated to take until at least April 2025 to introduce if the proposal was to proceed.

Options for application fee (Proposal Three)
For both options the fee is proposed to be capped to a maximum fee of £1,000 for SMEs and £10,000 for non-SMEs (in the event of multiple applications submitted within the same year).

Option 1: Fee is applied to new products only and the fee level is set based on current application processing costs plus funding of the independent advisory panels for reviewing new applications.

Option 2: Fee is applied to new entrants and renewals and the fee level is set based on annual costs of processing new applications and renewals plus funding of the independent advisory panels.

Questions

What is your preferred option? (multiple choice)

- Option 1
- Option 2
- None
- Don’t know

Do you agree or disagree with this proposal? (multiple choice)

- Agree
- Disagree
- Don’t Know

Please provide further details (500 words max)

Please share any challenges you think this proposal might encounter (assuming it can be implemented)? (500 words max)

Please share any amendments you think might improve this proposal? (500 words max)

Consultation Impact Assessment Questions (Optional) - Please read attached Impact Assessment when answering:

What would be the impact of the application fee on business operating margins? (100 words max)

Would there be any indirect or wider impacts from introducing an application fee? (500 words max)

Call for evidence

This call for evidence is not linked to any proposals but seeks feedback on four issues. It invites all interested parties to provide feedback on:

1. Waste in the dispensing of appliances in the community
2. Conflict of interest in the dispensing of appliances in the community
3. Exceptional Price Increases
4. Digital Apps

The department is seeking views on what the current and future priorities should be. This set of questions should not be taken to indicate that the department has a settled position on the relevant priorities.

1 - Waste

We want to further understand areas of, or the extent of, unnecessary waste around the prescribing and dispensing of medical devices in the community. For example, this could result from over-prescribing, incorrect repeat prescriptions, excess packaging and poor on-going management and support for patients and patients' families.

Questions

Have you experienced examples of waste in the provision of your products? Select all that apply (multiple choice)

- Over prescribing as a result of quantity of items in the box
- Over prescribing of additional items not required or not used
- Repeat prescription process (frequency products are sent)
- Incorrect products being sent or no longer needed
- Change of prescription is not frequent enough based on improvement/change of condition
- Single use products where you are aware reusable ones exist
- Other – please explain your answer
- None

Please provide more detail (optional) (500 words max)

In your opinion which of these areas would you like to see prioritised over the next few years? Select all that apply (multiple choice)

- Innovation that increases the amount of reusable products
- Improvements to clinical pathways linked to product use
- Improvements to the repeat prescription process
- None of the above

Please explain your answer (optional - 500 words max)

For dispensing contractors and industry

Have you identified areas of waste in the dispensing of products? Select all that apply

- Differing instructions from certain suppliers to change product more frequently than necessary
- Repeat prescription process
- Not enough nurse visits to patient to agree correct product
- Single use products where you are aware reusable ones exist
- Other
- None

Please explain your answer (optional-500 words max)

2 - Conflict of Interest

We want to understand if there are conflicts of interest in the prescribing and dispensing of medical devices and if there are unfair barriers to entry for suppliers.

The NHS Managing Conflicts of Interest guidance states that sponsored post holders (e.g. nurses) must not promote or favour the sponsor's specific products, and information about alternative products and suppliers should be provided.

To support the dispensing of Part IX products in the community a large proportion of prescriptions are managed through vertically integrated

dispensing appliance contractors (DACs) which are owned by product manufacturers.

Questions

For dispensing contractors/industry/commissioners
Are you aware of any current difficulties in applying the NHS Managing Conflicts of Interest guidance in any areas linked to the supply of medical devices in the community? (multiple choice)

- Yes
- No
- Don't know

Please explain your answer (500 words max)

If yes, how do you think these problems could be addressed, what alternative models could be explored? (500 words max)

For patient representatives/commissioners
Do you think that patients have a meaningful choice of products within the range available to them? (multiple choice)

- Yes
- No
- Don't know

If no, what do you think are the challenges? (500 words max)

What changes need to be made to address these challenges? (500 words max)

3 – Exceptional Price Increases

The current process to apply for an exceptional price increase is based on a narrow focus on raw material increases, does not provide the opportunity for two-way engagement, and does not provide an appeal mechanism. The Department recognises the importance of ensuring a sustainable market and to reduce the burden on industry by ensuring

greater consistency in how issues such as price increase requests are managed across the NHS for the same product.

The current agreed annual price mechanism used on Part IX is agreed by the department and NHS Prescription Services because it is agreed that these products still provide value with these small annual increments.

Questions

What would you like to see changed in relation to the existing Exceptional Price Increase (EPI) process? Select all that apply

- Increased transparency
- Wider criteria for consideration of an EPI
- An appeal process
- Other

Please explain your answer (500 words max)

Can you suggest another way of handling impacts of cost pressures that is fair to both the NHS and to companies? (500 words max)

4 – Digital Apps

Digital apps are not currently supplied under Part IX. Some apps are funded by the NHS under particular programmes. We are also aware that other countries, most notably Germany, that have introduced a prescribing route (DiGA) for approved apps for people covered by statutory health insurance.

As it is becoming more common to have medical devices that work in tandem with digital apps as well as stand-alone therapeutic apps, we want to explore if there are benefits to listing apps in a similar way to Part IX medical devices. The intention is not to provide the apps via pharmacy or dispensing contractors. It would be a reimbursement list that allows clinicians to prescribe digital apps to patients under the NHS. The department would work out how this is best administered.

Questions

What do you see as the benefits in prescribing medical apps from a practical perspective? Select all that apply (multiple choice)

- Central assessment of apps
- Approved apps listed in one place
- Central pricing
- Enables wider provision of apps
- Increases choice for patient treatments
- Increased confidence in people using the apps
- Other

What do you see as the challenges/disadvantages in prescribing medical apps from a practical perspective? (500 words max)

Responding to the consultation

This document includes options related to proposals for updates to operational arrangements to Part IX of the Drug Tariff.

The closing date for the consultation is midnight 01 December 2023. To complete the online consultation response document, please use the links in the email. Alternatively, to respond via email, email to: PartIX-Consultation@dhsc.gov.uk

It will help us to analyse the responses if respondents fill in the online consultation response document, but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than in pdf format.

DHSC Privacy Notice

1.The Data Protection Act 2018 and the United Kingdom General Data Protection Regulation (UK GDPR)

This legislation replaces previous current data protection law, giving more rights to you as an individual and more obligations on those controlling and processing your data for any purpose. This notice is to explain your rights and give you the information to which you will be entitled under this legislation.

2. Contact our Data Protection Officer

The Department of Health and Social Care (DHSC) is the data controller for the department itself and also for its executive agencies (the UK Health Security Agency, and the Medicines and Healthcare Products Regulatory Agency).

The Data Protection Officer is Lee Cramp who can be contacted:

In writing:

Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

By email: data_protection@dhsc.gov.uk

DHSC Personal Information Charter.

3. Reasons and purposes for processing personal data

We need to handle personal data about you so that we can provide better services. High standards in handling personal data are very important to us because they help us to maintain the confidence of everyone who deals with us. When we handle your personal data, we undertake to:

- make sure you know why we need it
- only ask for what we need, and not to collect too much or irrelevant information
- protect your information and ensure no one has access to it who should not
- let you know if we are going to share it with other organisations
- make sure we do not keep your information for longer than necessary
- assure you that your individual rights under UK GDPR can be exercised
- ensure that measures are put in place to allow appropriate consent to be obtained for holding personal data of anyone aged under 13

We additionally undertake to:

- value the personal data entrusted to us and make sure that we abide by the law when it comes to handling your personal data
- ensure we consider security at the outset of any new project where we are planning to hold or use personal data in new ways, and to continue to review existing systems to ensure they are compliant with new laws
- provide training to staff in how to handle personal data, maintain proper oversight of our information assets and respond appropriately if information is not used or protected properly
-

4. Why we process personal data

We process personal data to enable us to:

- promote our policies, procedures and services to the public

- maintain our accounts and records
- support and manage our staff

We also process personal data to include administration of health and social care services, management and administration of land, property and residential property and undertake research.

We operate a CCTV system on our premises for the prevention of crime and the safety and security of our staff and premises.

Processing of information is also undertaken to adhere to NHS guidance and regulations.

5. Lawful basis for processing your personal data

The UK GDPR and Data Protection Act 2018 set out the available lawful bases for the processing of personal data.

In most cases, as a government department, DHSC may process personal data as necessary for the performance of a task carried out in the public interest or in the exercise of the department's official authority. If another lawful basis applies, we will tell you.

6. The information we process

We process information about:

- our employees and former employees
- our customers and clients
- our suppliers and service providers
- our advisers, consultants and other professional experts (including NHS professionals)
- complainants and enquirers
- students and pupils
- elected representatives
- holders of a public office
- academics
- members of supporters of unions
- NHS and other healthcare professionals
- health and care organisations

- legal representatives of the organisation
- applicants to committees
- applicants for permits, licenses, certificate and permit holders
- authors, publishers, editors, artists or other creators
- members and/ or supporters of voluntary organisations and advisory groups
- committees and health associations
- licence and certificate holders
- social care providers
- individuals falling within the terms of reference of a public enquiry
- members of advisory groups and committees
- contracts
- offenders and suspected offenders
- members of the public and those inside, entering or in the immediate vicinity of areas under surveillance by CCTV
- members or supporters of health-related organisations
- NHS staff
- research applicants
- researchers
- university staff and students
- patients
- individuals on civil registers
- members of the general populace

7. Who we share personal data with

We sometimes need to share the personal data we control (and our data processors may also share information) with other organisations. Where this necessary we are required to comply with all aspects of data protection legislation. What follows is a description of the types of organisations we may need to share personal data we process for one or more reasons.

Where necessary, required and within the law we may share information with:

- family, associates and representatives of the person whose personal data we hold
- employment and recruitment agencies
- current, past and prospective employers
- educational establishments and examining bodies
- other government departments
- credit reference agencies
- suppliers and service providers
- debt collection and tracing agencies or organisations
- financial organisations
- devolved government departments
- health and care organisations
- trade, employer associations and professional bodies
- other statutory law enforcement agencies and investigative bodies
- health, social and welfare advisers or practitioners
- survey and research organisations
- police forces and other law enforcement organisations
- the Government Internal Audit Agency and other auditors as required
- the Civil Service Commission
- the Advisory Committee on Business Appointments
- the Office of the Commissioner for Public Appointments

8. Data retention

Outside of specific exemptions under the legislation your personal data shall be retained for no longer than the purposes for which it is being processed.

9. Your rights

The data we are collecting is your personal data. You have the right to:

- see what data we hold about you (this is known as a ‘right of access request’)
- ask us to stop using your data, but keep it on record
- have some or all of your data deleted
- have some of your data corrected
- lodge a complaint with the Information Commissioner’s Office (ICO) if you think we are not handling your data fairly or in accordance with the law

10. Right of access requests

Data protection legislation allows you to find out the personal data we hold about you on computer and IT records (formerly known as a 'subject access request').

The legislation requires us to respond to a valid request within one month. However, in the event we are unable to meet this timescale (for example due to a large volume of information to be assessed) we will keep you informed of progress towards fulfilling your request.

To request access to personal data we hold about you, please write to our Data Protection Officer using the contact details in section 2 above.

11. Automated decision-making or profiling

We may use automated decision-making or profiling in certain circumstances as required or permitted by law to enable us to deliver efficient services.

This does not affect your individual rights as outlined in section 9, 'Your rights'.

12. Contacting the Information Commissioner's Office

For independent advice about data protection, privacy and data-sharing issues, you can contact the independent ICO at:

The Information Commissioner
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Tel: 0303 123 1113

Appendix A Glossary

AMP

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

Chemical reagent

Part IXR of the Drug Tariff lists those 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).

Cost-effective

As per the Part IX Drug Tariff guidance, in addition to whether the product should be reimbursed at all, there are two parts to addressing cost-effectiveness:

The cost of using the product in a given treatment regime compared with the cost of the most effective alternative treatment regime (or no treatment regime if there is none currently available).

The price of the product compared with the price of similar products. (Whether or not a product is "similar" to other products may itself be a matter for discussion between NHS Prescription Services and the applicant – certainty in relation to this may not be possible for either side in advance of a formal application being made.)

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 a person with whom the NHS Commissioning Board (NHSCB) for England and the Local Health Board (LHB) for Wales has decided 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) process:

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 department 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 can contact NHS Prescription Services for advice on how to proceed.

GDP deflator mechanism

A company can apply for an annual price increase under the agreed GDP deflator mechanism on Part IX. The maximum price rise that a company can apply for under the GDP deflator mechanism is calculated as being the forecast of the GDP deflator for the next financial year (on the date the application is received) **minus Factor X**, where X is currently **0.75** – Factor X is subject to review. Currently if a company applies for their annual increase it is based on the 2024/25 forecast figure so they will receive an increase of 0.82% (1.57% -0.75%).

Generic medicines

Generic drugs are copies of brand-name drugs that have the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug. In other words, their pharmacological effects are the same as those of their brand-name counterparts. Cost is the main difference between generic and brand name prescription drugs, with generic drugs costing less.

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.

Medical devices

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.

NHS England and Wales Drug Tariff (Drug Tariff)

NHS Prescription Services at the NHS Business Services Authority produces the NHS England Wales Drug Tariff monthly on behalf of the Department of Health and Social Care. The Drug Tariff outlines: what will be paid to pharmacy and dispensing appliance contractors for NHS services provided either for reimbursement or for remuneration; the rules to follow when dispensing; the value of the fees and allowances paid; the drug and appliance prices paid.

Pharmacy contractor

A pharmacy contractor is a person with whom the NHSCB for England and the 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.

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.