Department of Health & Social Care

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

Response to targeted consultation

Issued 28 August 2024

Contents

Contents **2**
Executive summary **4**
Introduction **6**
Key themes and overview of respondents **8**
Approach to analysis 8
Overview of the respondents 8
Themes across the responses 8
Proposal One: Increase the use of comparable categories where it is appropriate to do so **10**
Outline of consultation proposals 10
Summary of responses 11
Government response 13
Proposal Two: Introduce a renewal process to Part IX **15**
Outline of consultation proposals 15
Summary of responses 16
Government response 19
Proposal Three: Apply an enhanced assessment process for products to be listed on Part IX **22**
Outline of consultation proposals 22
Summary of responses 24
Government response 27
Temporary Listings for certain qualifying products **30**
Outline of consultation proposals 30
Summary of responses 31
Government response 32
Introduction of an application fee **34**
Outline of consultation proposals 34
Summary of responses 34
Government response 36
Next steps **37**
Call for evidence **38**
1 - Waste 38

2 - Conflict of Interest 42
3 – Exceptional Price Increases 45
4 – Digital Apps 47
Appendix A Glossary 49
Appendix B: Target audience for the consultation 52

Executive summary

The term medical device refers to 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.

Medical devices play a vital role in patient care and treatment. Healthcare professionals must get the basic qualities of care – safety, effectiveness, and patient experience – right every time. This includes identifying from the vast range of medical devices that are available which products best meet the needs of the individual patient. In 2022/23 the NHS spent around £1.4 billion on medical devices listed on Part IX of the Drug Tariff in primary care.

Part IX of the Drug Tariff was established before the 1980s. In England, regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 sets out the Tariff in a format that the Secretary of State for Health thinks fit. It contains the appliances and chemical reagents, which can be prescribed by prescribing practitioners in primary care operating under NHS General Medical Services and provides information on what contractors will be paid for providing NHS Pharmaceutical Services, including reimbursement of products dispensed.

The Department of Health and Social Care and NHS England are committed to delivering the best value medical devices for patients. The “Medical Devices in Primary Care: Proposals for updating Part IX of the Drug Tariff – medical devices available for prescribing in primary care” consultation sets out a series of proposals to modernise Part IX of the Drug Tariff to ensure we are delivering the right product, at the right price, and in the right place.

The consultation was open between October 2023 and January 2024 and was targeted rather than public owing to the complex subject matter. This document analyses the responses to the consultation and sets out the government’s response to the issues raised.

Following detailed consideration of consultation responses, the government has decided to make the following amendments to the proposals in the consultation:

- Increase the use of comparable categories where appropriate to do so (Proposal One): Consider where Value-Based Procurement (VBP) principles can be applied to the categorisation process, align with existing categorisation frameworks where appropriate, and consider where we can reflect existing nomenclatures.
- Introduce a renewals process to Part IX (Proposal Two): Implement an appeals process for products marked not to be renewed and not automatically renew products marked as 'Low priority’ by national guidance for that reason alone.

- Apply an enhanced assessment process for products to be listed on Part IX (Proposal Three): In the evaluation matrix, align quality attributes with VBP principles where feasible, consider, where applicable, how to take into account the frequency a product is already listed on NHS formularies, and NHS commissioners and independent experts will be considered as potential independent advisory panel members. Social value will be weighted at 10% in the evaluation matrix from the start of implementation.
- Temporary listings for certain qualifying products (Proposal Three): The timeframe of temporary listings will be extended to two years, followed by a three-month assessment period, and a three-month notice period if not being made permanent.
- Introduction of an application fee (Proposal Three): The government will not take forward the application fee due to the feedback on the potential adverse effect this may have on entering the market, particularly for small and medium-sized enterprises (SMEs).

This document sets out the government response to each of the consultation responses in turn.

In the first section, “Proposal One: Increase the use of comparable categories where it is appropriate to do so”, we set out the government’s consideration of the responses received on the question of updating and increasing the number of comparable categories within Part IX.

In the second section, “Proposal Two: Introduce a renewal process to Part IX” we set out the government’s consideration of the responses received on proposals to introduce a renewal process that would apply every 4-5 years to check products are up to date with clinical practice, still meet the requirements and still offer cost effectiveness.

The third section, “Proposal Three: Apply an enhanced assessment process for products to be listed on Part IX” covers responses received on proposals to implement an updated methodology that includes the introduction of independent advisory panels, a weighted evaluation matrix, temporary listings for certain qualifying products and the introduction of an application fee.

The “Call for Evidence” section is not linked to the above proposals. It summarises the feedback gathered from interested parties on the topics of waste, conflict of interest in the dispensing of appliances in the community, exceptional price increases and digital apps.

Appendix A is a glossary which provides key definitions used in the document in alphabetical order. Appendix B outlines the key audience this consultation was targeted at.

The Final Impact Assessment is issued alongside this document.

Introduction

The NHS England and Wales Drug Tariff ('the Drug Tariff') is a monthly publication issued by NHS Prescription Services of the NHS Business Services Authority (NHSBSA) which contains the Secretary of State for Health and Social Care's and Welsh Ministers' determinations for what pharmacists and appliance contractors will be paid for providing NHS pharmaceutical services in England and Wales respectively. Part IX of the Drug Tariff contains the list of medical devices which are approved by NHSBSA (acting on behalf of the Secretary of State for Health and Social Care) to be prescribed by authorised healthcare practitioners operating under NHS General Medical Services.

Part IX of the Drug Tariff was established before the 1980s. In England, regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 sets out the Tariff in a format that the Secretary of State for Health thinks fit[1]. Since then, medical devices have made significant advances in specialist nature and complexity as well as changes in the manufacturing and commercial markets in provision of devices.

The UK Government formally consulted on ''Medical Devices in Primary Care: Proposals for updating Part IX of the Drug Tariff – medical devices available for prescribing in primary care" from 6 October 2023 to 4 January 2024. The formal consultation targeted patient representative groups, clinicians prescribing or recommending medical devices listed on Part IX of the Drug Tariff, NHS commissioners and suppliers and manufacturers involved in the production and dispensing of these medical devices (Appendix B summarises why these were the targeted audiences).

The aim of the consultation was to set out a series of proposals to modernise Part IX of the Drug Tariff which align with the Government's Medical Technology Strategy published in February 2023 and ensure we are delivering the right product, at the right price, and in the right place.

The targeted consultation asked for responses on a range of proposals:

- Proposal One: Increase the use of comparable categories where it is appropriate to do so
- Proposal Two: Introduce a renewal process to Part IX

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

- Proposal Three: Apply an enhanced assessment process for products to be listed on Part IX, temporary listings and application fee

The consultation fully closed on 4 January 2024 (11:59), with 113 responses received in total. In addition, the government has more widely engaged with key stakeholders on these proposals, including the Drug Tariff Committee, Drug Tariff Forum, companies with listings on Part IX, trade associations, clinical groups and patient representatives.

This document analyses consultation responses and provides the government's response. The government will continue to engage with key stakeholders to develop the detail of the proposals; this consultation response document sets out the high-level decisions and what will be taken forward.

Key themes and overview of respondents

Approach to analysis

We have analysed the responses to the consultation and considered the feedback received. In doing so, we looked at the responses given to the multiple-choice and open response questions posed in the consultation survey and the impact assessment survey.

Key themes or topics in the responses were identified across each of the questions asked in the consultation.

Overview of the respondents

We received 113 responses to the consultation, with 92 from the online survey and 21 by email. 54 respondents were from a company, whilst 7 were from an industry body representing multiple companies, 20 responses were from clinicians/clinical groups, 16 from NHS organisations, 8 from a patient group or charity and 8 ‘others’.

We received 44 responses to the impact assessment survey, with 36 from the online survey and 8 by email. 37 of these responses were from a company, whilst 5 were from an industry body representing multiple companies and 2 ‘others’. Whilst these responses are not summarised in the consultation response, they have been used to update the impact assessment.

Themes across the responses

Companies and industry bodies were generally more likely to disagree with the proposals, while clinicians, NHS organisations and patient groups or charities and other respondents were more likely to agree with the proposals. Given the consultation received fewer responses from clinicians, NHS bodies and patient groups or charities, we have split the themes and responses by respondent group where possible, so that we can consider the diverse views from different groups.

A common theme across responses to all the proposals were requests for further information and detail. Many respondents noted that they agreed with the principles of the proposals but needed more information to fully understand the implications.

Some respondents suggested that the government addresses issues linked to dispensing of Part IX products before taking forward the proposals outlined in this consultation. A few respondents argued that some of the market issues raised around the provision of the products on the Tariff should be addressed first, and following that a decision should be made on whether these proposals need to be implemented. A few responses argued that conflicts of interest should be addressed before making amendments to Part IX. One response suggested that products on

Part IX should be under similar restrictions to medicines and not be allowed to be advertised.

The remainder of this document outlines the summary of responses for each proposal and the government response.

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

Outline of consultation proposals

The consultation proposed to update and increase the number of comparable categories within Part IX by enhancing 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 development of any categories would build on relevant clinical work and peer reviewed published evidence where available and be informed by patient input. By aligning the structure and contents of Part IX with clinical best practice and a patient perspective in terms of quality of life we would encourage and promote good quality care.

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?

Do you agree or disagree with this proposal?

Please provide further details

Please share any challenges you think this proposal might encounter?

Please share any amendments you think might improve this proposal?

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

If yes, please list them

Please explain your answer

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

If yes, please provide your suggestions

Summary of responses

About half of respondents (49%; 52 of 106 respondents) agreed with the proposal. 39% disagreed (41 respondents) and 12% didn't know (Figure 1). There were higher levels of support from some groups: 57% of patient groups or charities agreed (4 of 7 respondents), 94% of NHS organisation respondents agreed (15 of 16 respondents) and 65% of clinician respondents agreed (13 of 20 respondents) (Figure 2).

Figure 1: Do you agree or disagree with this proposal?

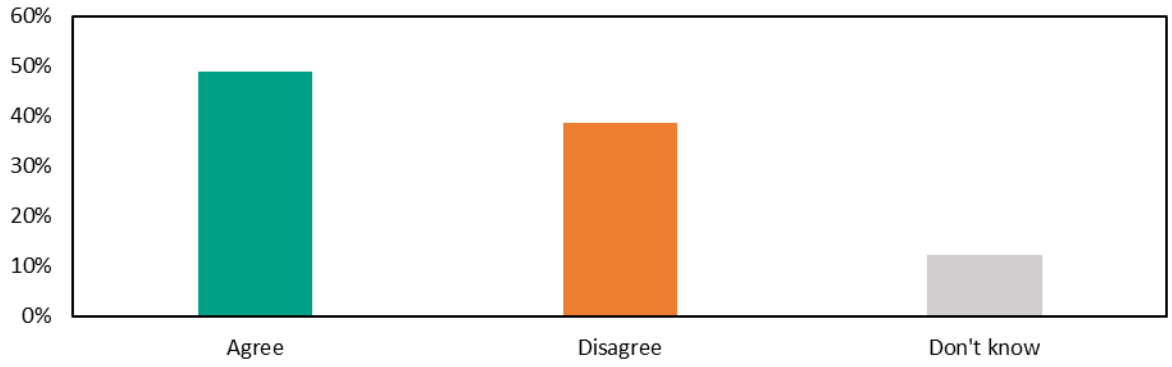
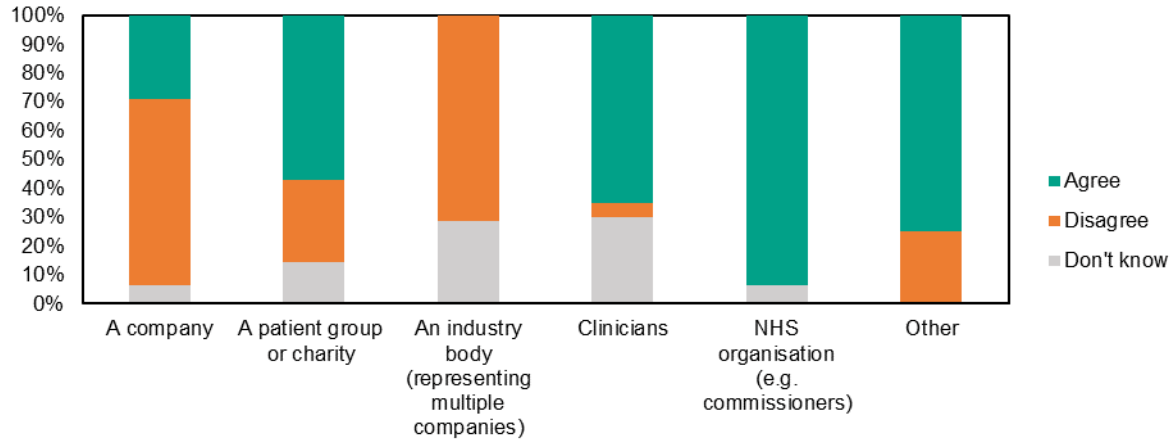


Figure 2: Agree/disagree with the proposal split by respondent type



Respondents agreeing with the proposal argued that it would improve transparency and allow comparison between products, therefore supporting SMEs in entering the market. This will allow for more targeted allocation of resources. Respondents felt this would enable more informed choice and that it would be beneficial to understand where different features of a product result in the same outcome.

Respondents disagreeing with the proposals suggested that it could increase administrative burden, possibly increasing the risk of delays to applications for Part IX. In addition, respondents – particularly companies and industry bodies – argued that it may have a detrimental effect on patients, such as reducing choice, quality and innovation of these products. Some respondents noted that categorisation could create uncertainty for industry and reduce stability. Some respondents also expressed concern that price could become the deciding factor in product choice if there were increased use of categories. However, one respondent argued that categorisation would have little impact on prescribing behaviour and value.

The Option that received the greatest support was None (38%), followed by Option 1 (31%).

Some respondents made suggestions for amendments and alternative options:

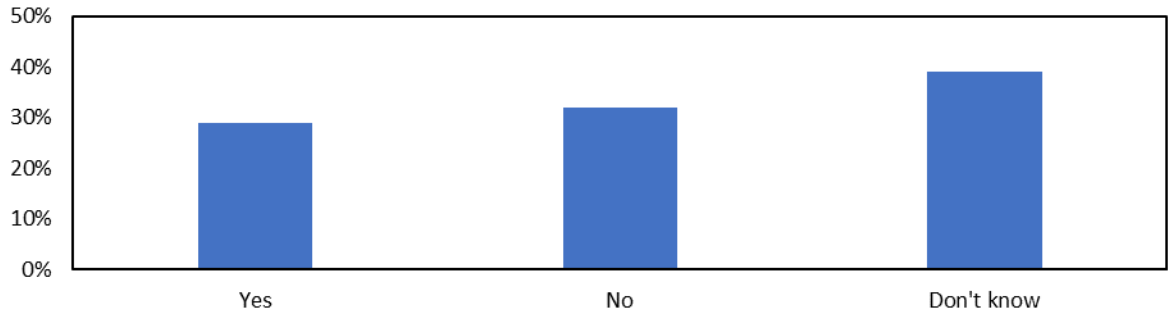
- Following categorisation, share additional information such as pictures of the preferred features, detailed descriptions, variations in sizes and whether a product is innovative.
- Amend the categorisation used, such as focusing on the purpose or outcome of the device rather than the attributes as proposed or grouping categories into extensive therapy areas and mapping against typical patient pathways.
- Adopt pre-existing categories, such as NHS Supply Chain's categorisation or international categories like the Global Medical Devices Nomenclature (GMDN).
- Provide an application template to reduce the administrative burden on companies.

- Use commissioning recommendations as a starting point for categorisation.
- Expand the accessibility and use of categorisation, by enhancing the search and filtering capabilities of the Part IX database and digitising the Tariff.
- Ensure that independent Dispensing Appliance Contractors (DACs)' views are represented in the categorisation process.
- Encourage provision of products through 'off-script' methods such as direct supply.
- Also consider adding other high use product categories to the suggested 25 categories list.
- Consider the risk class of products, including the costs and evidence requirements associated with higher risk classes.

Many respondents (32%) did not think that any products should be considered an exception to the process, with some respondents arguing that creating exceptions introduces inequity. 29% responded that there should be exceptions and 39% didn't know.

Many of the respondents who thought products should be considered as an exception to the process identified those that were niche, bespoke or low volume products, including lymphoedema garments, paediatric products and wound care products. One respondent suggested an exemption for devices intrinsically linked to a particular medicine, e.g. insulin pens. A few respondents suggested innovative products should be exempt due to the challenges in categorising them. Several other products were suggested with no reason given, such as blood glucose testing strips, stoma products and emollients.

Figure 3: Are there any products on Part IX that should be considered an exception to this process?



Government response

The government intends to take forward this proposal to update and increase the number of comparable categories within Part IX by enhancing the groupings of products with similar attributes (Option 1). The government agrees with the responses that suggest that it is sensible to align with existing categorisation frameworks where appropriate and will consider existing nomenclatures, such as

GMDN. The government agrees with suggestions in Proposal three to try to align evaluation with value based procurement (VBP) principles if feasible. VBP considers factors such as benefits to the clinical pathway and value to the patient. We think these can be considered in the categorisation process. This also ensures that comparable items are being categorised together. No products will be exempted from the process, but the department reserves the right to exclude products from categorisation on a case-by-case basis, which may include products that are bespoke.

A discussion of specific issues is set out below.

Administrative burden

The government understands concerns around increased administrative burden on NHSBSA and agrees that this will involve additional work in comparison to the current process. However, the government believes that this categorisation will provide the foundation for further improvements to the Tariff and therefore the benefits of implementing this proposal will exceed the costs. The government will commit additional resources to implement the categorisation, including providing additional resources to NHSBSA, and therefore we do not anticipate that this proposal will result in any delays to applications to Part IX of the Drug Tariff.

To help with the administrative burden on companies applying to Part IX, we will update the guidance for applications to Part IX. If a template is also suitable, we will provide one. Part IX of the Drug Tariff is already available in digital form and we will consider how we can improve the usability for this resource.

Impact on patients and market certainty

The government disagrees that this proposal will have a negative effect on patients. Categorising products will not in itself result in any products not being renewed on the Tariff and the full range of products will continue to be available to patients. We expect that changes to categorisation may help prescribers in selecting the best product for the patient, due to more understanding and visibility of the range of products available. Similarly, we do not expect that this will negatively affect market certainty, as it will mainly result in prescribers having more information available to make product selection. This may also benefit SMEs as prescribers may become more aware of their products as a result of the changes.

Products suggested as an exception to the process

The government recognises some respondents' concerns around specific products not being suitable for categorisation. We believe that we will be able to more effectively identify any products that are not suited to categorisation during the categorisation process itself. Therefore, any exceptions will be identified on a case-by-case basis during the process.

Proposal Two: Introduce a renewal process to Part IX

Outline of consultation proposals

The consultation proposed that a renewal process would be introduced to keep the Part IX list up to date with clinical practice and ensure value to the NHS.

The proposal was for a renewal process to apply every 4-5 years. Six months advance notice would be given to suppliers of the requirement to apply for renewal. There would be a 6-month notice period for products that are determined not to sufficiently meet the requirements before not renewing them. The options and questions asked in the consultation are outlined below.

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?

Do you agree or disagree with this proposal?

Please provide further details

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

Please explain why, including the category of products you are referring to in your answer

Should any product groups be exempt from the renewal process?

Please explain your answer

Please share any challenges you think this proposal might encounter

Please share any amendments you think might improve this proposal?

Do you have any alternative suggestions for ensuring Part IX up to date?

If yes, please provide your suggestions

Summary of responses

Slightly more respondents agreed with the proposal than disagreed (Figure 4). 42% of respondents agreed with the proposal (43 out of 102 respondents) while 40% disagreed with the proposal (41 out 102 respondents). 18% didn't know.

There were higher levels of support from some groups: 67% of patient groups or charities agreed (4 out of 6 respondents), 94% of NHS organisation respondents agreed (15 out of 16 respondents) and 58% of clinician respondents agreed (11 out of 19 respondents) (Figure 5).

Figure 4. Do you agree or disagree with this proposal?

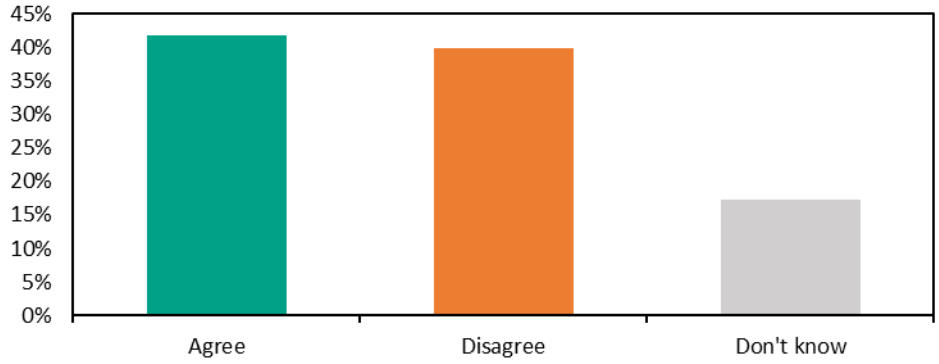
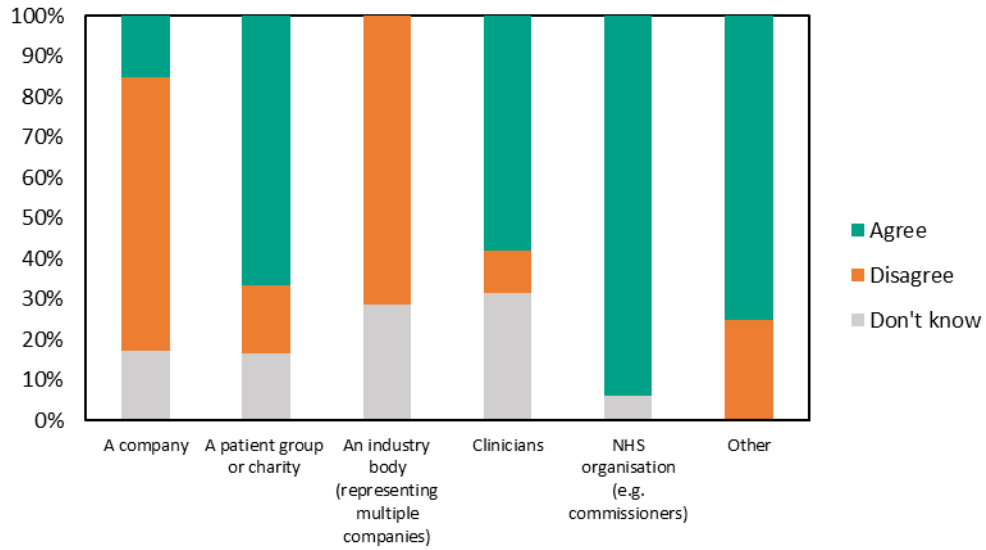


Figure 5. Agree/disagree with the proposal by respondent type



Respondents agreeing with the proposals argued that a renewals process is needed due to the large size and structure of Part IX. Respondents agreeing also noted the importance of checking the products still meet clinical best practice and offer value to the NHS. This was particularly noted by patient groups and NHS organisations. Many acknowledged it was sensible to remove non-prescribed products as it likely meant that the product had been superseded by another product.

Respondents disagreeing with the proposals made the following overarching comments:

- There may be a negative impact on patients if products are removed, such as reduced choice and continuity of care. Additional resources would be required to switch patients onto alternative products if their current one is not renewed.
- Additional resources would be required to review all existing listings, with costs incurred by government and suppliers and the potential for delays to supplier applications. Some respondents noted concerns over how much supporting evidence will be required by industry for renewals.

- Renewals may create uncertainty for industry, which may negatively affect innovation. Respondents argued that a five-year period may not be enough time to recoup development costs and there may be a lack of clarity if requirements to remain on Part IX change over time.
- There is already a mechanism to remove some products from Part IX, so some respondents argued that the proposed changes were not needed.
- There are already other mechanisms to address poor performing products including formularies and clinical judgement; formularies can also take into account the diverse needs of local populations.
- Lower priced products may not provide cost-effective patient care or better clinical outcomes.
- Reduced prices may impact supply chain discounts.
- Reducing the number of products available may weaken supply resilience. Some respondents argued that you cannot assume that smaller suppliers can fill the gap if a larger supplier's product is removed.

Out of the options, 'None' received the greatest support (41%), followed by Option 1 (29%).

Many respondents made suggestions for amendments and alternative options:

- Implement an appeals process for products marked as not being renewed.
- Share a clear, transparent methodology for the renewal process. Some respondents noted specific concerns about the detail of the methodology, such as the treatment of older products and how the service element linked to the provision of the product affects volumes.
- Don't automatically remove low priority prescribing items, as there are specific patient use cases.
- Extend the length of time that a product is not prescribed before it is not considered for renewal, from 1 year to 2 years, to allow for niche, bespoke and low volume products. One respondent suggested adding a dormant category for a further year rather than not renewing the product.
- Provide longer notice of the intention to not renew a product; some respondents thought that longer than 3 months' notice should be given.
- Implement reminders for suppliers to delist inactive products themselves.
- Establish a feedback mechanism for clinicians and patients to ensure the renewal process remains patient-centred and responsive to healthcare needs. This includes monitoring and evaluating the impact of the renewal process on suppliers, dispensers and patients.

Respondents agreeing with the proposed renewal period of 4-5 years argued that it was consistent with the expected cycle of product developments and treatment options (e.g. stoma and urostomy) and that a renewal process would keep the category up to date, encourage range rationalisation and product innovation.

Many respondents disagreed with the proposal for a 4–5-year renewal period. Respondents disagreeing with the proposed 4–5-year renewal period focused on the following themes:

- Renewals every 4-5-years would be too frequent and therefore could affect continuity of patient care.
- Frequently changing patients' products could be burdensome for clinicians.
- This may not allow sufficient time for new product development and could reduce the incentives to enter the UK market or delay entry until after the renewal round for that category is complete.
- The renewal period should differ by product, with less frequent renewal periods for lower volume products and more frequent renewals for products that are likely to be more frequently upgraded, e.g. glucose monitors.
- Depending on requirements at renewal, three months' notice to companies to renew may not be sufficient notice.

The majority of respondents (58%) did not think that any products should be considered as an exception to the process. Most of the 17 respondents who did think that some products should be exempted were companies or clinicians. These responses focused on products which are niche, bespoke or low volume such as bespoke/made to order lymphoedema items, hosiery and wraps, compression garments and paediatrics products. Respondents also named catheters and stoma products for exemption from the renewal process. A few respondents suggested wound care products could be exempted due to how crucial continuity of care is for patients. One respondent suggested exemptions for products that are interoperable with other products. Finally, a few suggestions were made for specific product exemptions with no reason given.

Government response

The government intends to take forward this proposal to implement a renewal process to keep the Part IX list up to date with clinical practice and ensure continued value to the NHS. No products will be exempted from the process, but the department reserves the right to exclude products from renewal on a case-by-case basis, which may include bespoke variations of products. This therefore means we are taking forward option 2.

For clarification, option 2 proposed that products that have not been prescribed for the past two years will be removed. The government therefore agrees with the suggestions to look at the past two years of prescribing data. In addition, this proposal would only be applied to products that have been listed for at least two years. We will also check prescribing data for Northern Ireland in addition to Wales and England.

In response to feedback from respondents, the following amendments will be made to the proposal:

- An appeals process will be implemented for products marked not to be renewed.
- Products classed as ‘low priority prescribing’ will not automatically be rejected from consideration for renewal.
- The decision on the renewal period of 4-5-years proposed in the consultation will be made after the categorisation work has progressed. This will help the government assess whether different categories are more suited to different renewal periods. Many respondents disagreed with the 4–5-year renewal period for a wide range of reasons. Further information is required before this decision is made.
- The government will aim to provide a minimum of three months’ notice to companies for their product’s renewal date and will clarify in advance what information is expected to be submitted by companies on renewal.

A discussion of specific issues is set out below.

There is already a mechanism to remove products from the Tariff
Under existing guidance on Part IX, there is a mechanism to remove discontinued products on notification or confirmation. The product in question will be marked with a three-month notice of deletion and removed from the Drug Tariff once this period has expired. However, suppliers often do not notify NHSBSA of this, meaning that these products remain listed although they are unavailable. Under existing guidance NHSBSA can remove a product listed in the Drug Tariff without the agreement of the manufacturer when a permanent (not affiliated to a certain batch) significant risk to patient safety has been identified and a safety alert issued as a result, or in cases where a legal challenge has occurred over a product which has been listed.

The government does not believe that this existing guidance covers the full scope of our proposal. Our proposal is to remove items that have not been prescribed for two years without the manufacturer’s agreement. Our proposal is also to remove products where further national work by NHS England or equivalent national guidance identifies it as a product that should not be prescribed. This does not include local decisions by Integrated Care Boards not to prescribe.

Adverse impacts on patient choice and continuity of care

The government agrees that patient choice and continuity of care are important, which is why the proposal is to have a long length of time (2 years) that a product is non-prescribed before it is not renewed and has been amended to include an appeals process for products marked to not be renewed. This will ensure that any products that are not renewed have been thoroughly assessed, including giving companies an opportunity to appeal if they wish. Products that are not renewed as a part of this proposal will be those that have not been prescribed for 2 years and therefore we do not expect this to negatively affect patient choice and continuity of care, as by definition patients would not have been using them via this prescription route.

The government believes that keeping the Part IX list up to date with clinical practice and ensuring continued value to the NHS is in the best interest of patients.

Administrative burden

The government understands concerns around increased administrative burden to NHSBSA and agrees that this will involve additional work in comparison to the current process. However, the government believes that the renewal process will deliver significant benefits in updating Part IX of the Drug Tariff. The department will commit additional resources to implement the renewal process, including funding independent advisory panels, and therefore we do not anticipate that this proposal will result in any delays to the Part IX Drug Tariff processes.

The government also understands concerns that companies and industry bodies have raised around increased burden to business. The draft requirements for submitting renewal applications will be shared with industry for comment. This process is not intended to require new evidence of clinical effectiveness to be submitted by companies as these products will already be in circulation (which is the key difference to new product applications).

Increase in uncertainty

The government acknowledges that some companies may experience an increase in uncertainty if their products have not been prescribed for a long time. However, this renewal criteria is clear and objective, which will help to reduce the uncertainty. Products which are not renewed due to not being prescribed are unlikely to be significantly affected since prescription is not a route of supply. We believe that regularly updating the Part IX list will benefit patients and prescribers, with minimal increase in uncertainty.

Products suggested as an exemption to the process

The government recognises some respondents' concerns around specific products. We believe that we will be able to more effectively identify any products that are not suited to the renewals process during the categorisation process. Therefore, any exemptions will be identified on a case-by-case basis during the categorisation process.

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

Outline of consultation proposals

The consultation proposed to update the assessment methodology. This proposal included the creation of independent advisory panels, with members drawn from the clinical profession and patient representatives, which would assess new applications and renewals.

The consultation proposed an evaluation matrix to be composed of supplier price, quality and social value. This proposal recognised that the weighting applied may have to vary per product category, but consulted on 40/50/10 for price/quality/social value. Quality and social value scores would range between 0 and 5. For social value, we proposed that it would be composed of product level environmental attributes and begin with a zero weighting to give companies time to adjust. The price score was proposed to be between 0-5, with 5 being allocated to the lowest price in the category. The lowest price product would be a qualifying product that has at least 5% of prescribing volumes. For every 1% a product is above the lowest price, the price score would be reduced by 0.1.

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?

Do you agree or disagree with this proposal?

Please provide further details

Do you think the proposed benchmark is fair?

Please provide further details

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

Please provide further details

Please share any challenges you think this proposal might encounter?

Please share any amendments you think might improve this proposal?

Summary of responses

Half of respondents (50%; 50 of 101 respondents) disagreed with the proposal (Figure 6). 37% agreed (37 respondents) and 14% didn't know.[2] There were higher levels of support from some groups: 93% of NHS organisations agreed (14 out of 15 respondents), 57% of patient groups or charities agreed (4 out of 7 respondents), 47% of clinician respondents agreed (9 out of 19 respondents) and 57% of 'other' respondents agreed (4 out of 7 respondents) (Figure 7). Most responses from companies and industry bodies disagreed with the proposal.

Figure 6. Do you agree or disagree with this proposal?

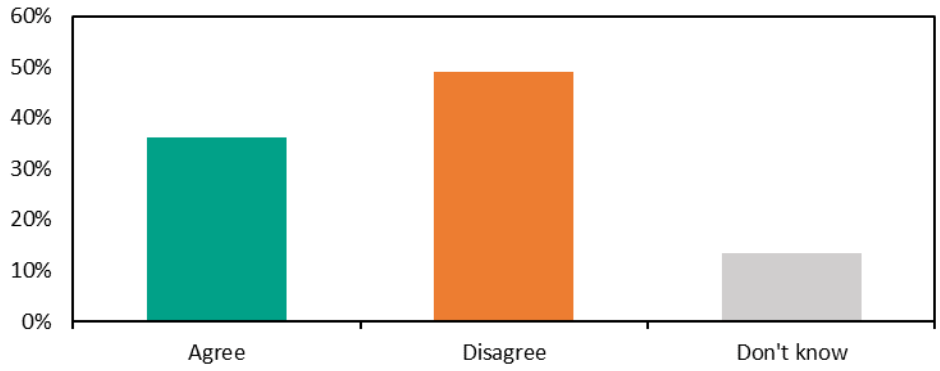
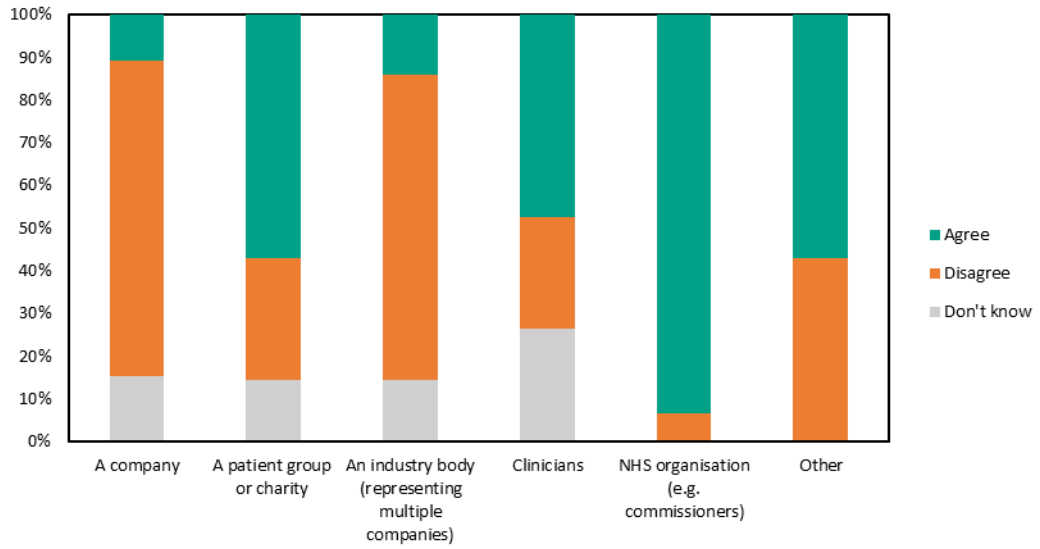


Figure 7. Agree/disagree with the proposal by respondent type



Reasons for agreeing with the proposal focused on the need for additional clinical input and patient input via the independent advisory panels, with support across the

[2] Percentages do not sum to 100% due to rounding.

respondent groups. Many responses from NHS organisations argued that the evaluation matrix represented a fair and transparent approach and that the regular assessment would help achieve value for money. Some responses from companies and industry bodies supported the need “for more responsive evaluation being necessary to ensure fair market representation”. Several responses supported the inclusion of social value in product assessment and argued that this should be included and weighted from the start.

Several concerns were noted, particularly by respondents who disagreed with the proposal:

- It may be challenging to objectively evaluate some products, particularly highlighting difficulties in finding objective panel members in both clinical and patient cohorts.
- The proposal could harm innovation, as manufacturers may be deterred from investing in product development if they do not think that they will secure a listing on Part IX.
- The proposal could reduce patient choice due to fewer products being available and fewer services being available to patients if the company could not afford to provide it as a result of a reduction in prices.
- Some responses from companies and industry bodies disagreed with the proposal due to concerns that prices could decrease which could reduce company profits or margins for wholesalers and independent Dispensing Appliance Contractors (DACs).

The Option that received the greatest support was None (47%), followed by Option One (24%).

Many respondents made suggestions for amendments and alternative options:

- Several respondents suggested that wider factors should be considered over price, such as clinical outcomes, services linked to provision of these products or alignment with NHS priorities, e.g. prevents readmission to hospital. This could be achieved by aligning with the MedTech strategy plans for value-based procurement.
- Some responses suggested involving NHS commissioners more in the decision-making process, which would help thoroughly assess products, including whether they are suitable for prescribing in primary and community care. Suggestions included adding representatives on the panels (including patients and clinicians) and ensuring assessments are informed by existing work on NHS formularies or the NHS England Commercial Directorate.
- One response suggested that manufacturers should be included on the independent advisory panels.
- Several responses from companies and industry bodies suggested amendments to the weights and scoring, including increasing the quality weight from 50 per cent to 60-65 per cent, using different weightings based on

product characteristics and including features important to patients in quality scoring.

- Some responses suggested that social value could be weighted at 10 per cent from the start, and could include specific factors, such as UK manufacturer, patient satisfaction or labour standards in addition to the proposed environmental attributes.
- A few responses suggested the evaluation matrix could be used to inform NHS formularies - with clinicians supported to select the most cost-effective products and conflicts of interest addressed - rather than implementing changes into the Drug Tariff.
- A few responses suggested special consideration for innovative or reusable products. Some companies suggested tailored application processes and requirements for different levels of innovation of product.
- A few responses from companies suggested increasing training for healthcare professionals and NHSBSA to increase understanding of new products.
- One respondent suggested processes could be amended, e.g. linking datasets, increasing communication as a part of applications.
- One response suggested that high spend products should be subject to full economic evaluation.
- One respondent suggested that a longer term and holistic view of how the introduction and evaluation of medical devices for use within the NHS should be taken.
- One company responded that prices could be frozen in line with the GDP deflator for 2-3 years instead of the evaluation matrix.

The majority of respondents either disagreed (45%) with the proposal for a benchmark score of 3.4 or didn't know (34%). Respondents agreeing with the proposed benchmark score (21%) argued that a benchmark needs to be set somewhere and 3.4 is a reasonable suggestion. Respondents disagreeing with the proposed benchmark score focused on the following themes:

- Lack of information makes it challenging to understand the potential impact of a benchmark score.
- The benchmark score is too high and could result in price and profit reductions that could adversely affect patient services currently provided alongside provision of products and reduce supply resilience if suppliers exit the market.

The majority of respondents either disagreed (40%) or didn't know (42%) with the proposal for the lowest price to be based upon products with at least 5% prescribing volumes. Respondents agreeing with the proposal argued that if you do not base it on at least 5% prescribing volumes it might stifle production of cheaper devices at the same quality. Some respondents who were not sure what the percentage should be, commented that they agreed with the principle of not letting slow moving or

unpopular items distort the pricing. Respondents disagreeing with the proposal focused on the following themes:

- The proposal will be unfair to small businesses with lower profit margins, as it may result in reductions in prices.
- Companies raised concerns that smaller companies may not be able to meet the increased demand if other suppliers have to withdraw from this market as a result of this proposal.

Some respondents made suggestions for amendments and alternative options:

- Several responses from companies suggested that 10 per cent prescribing volumes is used as the benchmark for the lowest priced qualifying product in a category. One respondent suggested that the category average price is used as the benchmark price instead.
- Some responses suggested that the number of formularies that products are listed on is factored into setting the lowest price.
- Independent advisory panel meetings could be held in public to increase transparency.

Government response

The government intends to apply a 40/50/10 price/quality/social value weighting to an assessment methodology with a proposed benchmark score of 3.4. The lowest price would be a qualifying product that also represents at least 5% of prescribing volumes. We understand the concerns raised by respondents, particularly companies and industry bodies, and we will therefore take a gradual approach to implementing the amendments. As some respondents noted, there is a need to select the benchmark and lowest price methodology to allow us to progress and review the methodology.

In response to feedback, the following amendments will be made:

- Quality and social value attributes will be aligned with VBP principles where feasible.
- Social value will be set at a 10% weighting in the evaluation matrix from the start.
- We will consider how the independent advisory panel’s assessment can take into account, where applicable, the frequency that a product is listed on NHS formularies.
- NHS commissioners who are close to formulary production and independent experts, e.g. in academia, will be considered as potential panel members.

As stated in the consultation, 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.

A discussion of specific issues is set out below.

There is a need to achieve value for money in NHS purchasing of medical devices

The government recognises the concerns from companies and industry bodies around potential reductions in prices. Many of these concerns reference the estimated impact on spend set out in the Impact Assessment. This estimate was based on 4 sample product categories. It also assumed equal quality across products, i.e. that no products would be of higher quality than the minimum requirements (and as such all products were scored at 3.0). Feedback in the consultation and discussions with companies indicates that this assumption is unrealistic, with many arguing higher priced products are usually higher quality. The assumptions in the Impact Assessment have been updated to reflect this feedback and extended to cover more categories. This indicates a wide range of potential reduction in spend of between 2% and 22% on aggregate, with an estimated 0% change for some specific example categories. Products where higher prices are justified by better quality are not expected to experience large reductions in prices.

Criticism that this is focused on price cuts and threatens patient choice

The government agrees that it is important to build in the principles of value-based procurement where feasible. Work on developing the quality attributes will align with these principles where appropriate.

The government agrees with suggestions to include social value weighted at 10 per cent from the start of implementation. This means that quality would be weighted at 50% and social value at 10%, giving more opportunity to encourage non-price elements.

The government agrees with protecting a wide range of patient choice of medical devices and, in addition to the patient input already proposed on the independent advisory panels, accepts the suggestion to consider how to take into account if a product is already listed on a formulary. In addition, NHS commissioners who are close to formulary production and independent experts, e.g. in academia, will be considered as potential panel members.

Criticism that medical devices cannot be objectively assessed

The government disagrees that medical devices cannot be objectively assessed, and notes that assessment is made in other processes, such as in purchasing decisions in secondary care, including by NHS Supply Chain. The government acknowledges the concerns with introducing a new process and as proposed in the consultation will review its position after completing the first category of products.

Members of the independent advisory panels will have to declare any conflicts of interest.

Criticism that this could harm innovation because of uncertainty around securing a listing on Part IX

In most markets there is not a guarantee that products that suppliers develop will go on to be purchased. Under the current assessment process for listing on Part IX, there is no certainty that a product will be listed. Similarly, the enhanced assessment process will not guarantee that products that suppliers develop will secure a listing on Part IX.

This proposal is designed to increase innovation. The enhanced assessment process will allow comparison between products based on their merits. This should increase transparency and competition, therefore encouraging new products and SMEs to enter the market.

We will share with suppliers what the quality and social value attributes are, and additionally suppliers will be able to see how they have scored.

Temporary Listings for certain qualifying products

Outline of consultation proposals

The consultation proposed a new mechanism which allows products to be temporarily listed if they have insufficient evidence of value of community use of the product. This proposal has the intention to support the adoption of innovative products into the NHS to benefit patients, and support SMEs who may have less resource to meet all the criteria requirements on the first application.

The consultation proposed that products would be listed on the Drug 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. This would help suppliers with products significantly different to those listed in Part IX, to gather sufficient evidence to apply to be permanently listed on the tariff, while also allowing patients the opportunity to try new, potentially innovative products. These applications would still need to provide evidence of clinical effectiveness and safety and be determined as suitable for prescribing.

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?

Do you agree or disagree with this proposal?

Please provide further details

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?

Please share any challenges you think this proposal might encounter?

Please share any amendments you think might improve this proposal?

Summary of responses

Many respondents (43%) disagreed with the proposal (Figure 8). 33% agreed and 24% didn't know. There were higher levels of support from some groups: 75% of patient groups or charities agreed, 60% of NHS organisation respondents agreed and 41% of clinician respondents agreed (Figure 9).

Figure 8. Do you agree or disagree with this proposal?

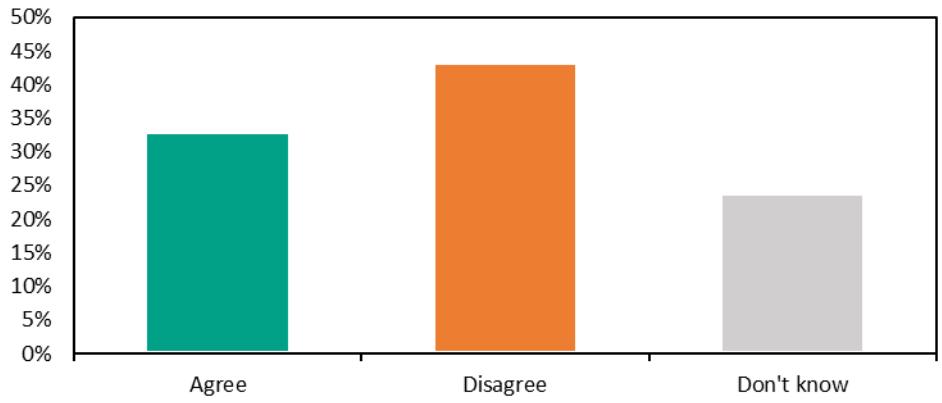
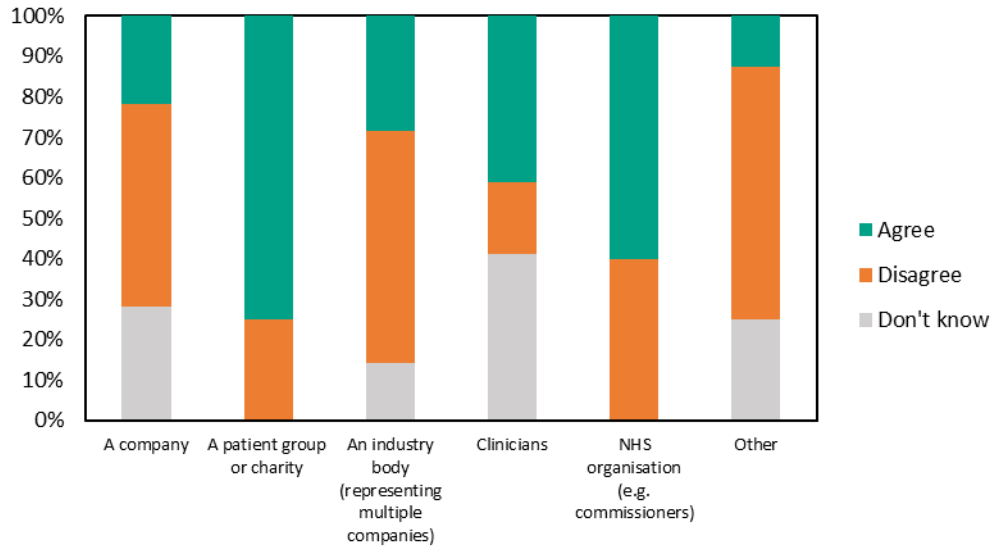


Figure 9. Agree/disagree with the proposal by respondent type



Respondents agreeing with the proposals argued that it will allow patients to access innovative and better value products quicker. Respondents also noted that the existing process requires the level of data only a mature product would have built up, so temporary listings may particularly help smaller companies enter the market and add products to the Drug Tariff.

Many of the respondents who disagreed with the proposal argued that the proposed temporary listing timeframe of 12 months is too short and should be extended.

Reasons for this included concerns that evidence could not be gathered within the 12-month timeframe and the devaluing impact on wholesalers' and dispensers' stock and inventory levels. Some respondents suggested that temporary listings could have a negative impact on patients if products are then not listed permanently. A few respondents suggested that the process may result in additional administrative burden for NHSBSA.

The Option that received the greatest support was Option 2, followed by 'Don't Know'.

Some respondents made suggestions for amendments and alternative options:

- The main amendment proposed was to extend the timeframe of the temporary listing. Other suggestions included a phased transition for de-listing temporary products, applying different temporary listings timeframes based on product categories and size of the supplier and implementing a risk sharing mechanism between industry and NHS for initial inventory.
- Some respondents suggested amending the process so that there is more information and transparency, such as greater engagement between suppliers and decision-making authorities (e.g. NHSBSA, DHSC) and the creation of a portal where innovations can be shared publicly and feedback can be gathered
- Some respondents suggested that the temporary listing application includes specific considerations, such whether the product meets an unmet NHS need and NICE input to help define parameters for success and review evidence.
- A few responses suggested other measures to encourage innovation, including defining innovation, increased guidance on how to list (and delist) innovative products on Part IX and creation of a real-world evidence framework.
- One response suggested that products are permanently listed but exempted from the evaluation matrix for five years instead of temporarily listed.
- One response from a company suggested creating a new category for innovation that is outside current categories and listing items that may have qualified under this proposal there instead.

In addition to the timeframe for the temporary listing, many respondents noted their preferences for a longer notice period. 30% of responses suggested a preferred notice period of over 12 months, 10% between 6 and 11 months and 10% between 3 and 5 months. Many respondents either did not respond to this particular question or stated that they didn't know.

Government response

The government intends to introduce a new mechanism which allows products to be temporarily listed if they meet the essential criteria but have insufficient evidence of value of community use of the product. The timeframe of the listing will be extended to 2 years, followed by an assessment period of three months and then a notice

period of three months if not being permanently listed. As with all of the proposals, temporary listings will be subject to review points.

The intention of this proposal is to support the adoption of innovative products into the NHS to benefit patients, including where innovation is happening at pace. The proposal is likely to particularly benefit SMEs, who may have less resource to meet all the criteria requirements on first application. The current application process is not designed to identify transformative products and support their adoption. The proposed changes to update processes on applications will provide more support for innovation that is able to offer quality of life improvements for patients. This should better enable new suppliers or products to gain access to the market by removing regulatory barriers.

A discussion of specific issues is set out below.

The length of the temporary listing is too short

The government acknowledges this feedback and in response has extended the length of time that products are temporarily listed to 2 years. Given the smaller number of products that we anticipate will use this process, we do not think it is proportionate to vary the time based on product type.

Negative impact on patients when products are removed

This proposal gives patients the opportunity to use products that otherwise would not be available during the period where the company is collecting further evidence. The government believes that this additional benefit to patients outweighs the potential negative impact of a product being removed, especially since products would only be removed if they are not able to provide sufficient evidence of their impact.

Increase administrative burden

We anticipate that temporary listings will only be used in specific circumstances where products do not have sufficient evidence to be permanently listed on the Drug Tariff. Therefore, individual companies can make the decision on whether it is more beneficial for their product to be listed on the Drug Tariff for 2 years (when it would otherwise not be listed at all).

Other measures to increase the adoption of innovation

The government is committed to increasing the adoption of innovation. That is why we are streamlining the innovation pathway to take products from initial concept through to use in the NHS to support patient care. We are providing clearer signals to industry on the innovation patients need, reforming the regulatory framework for medical devices, expanding our assessments of product categories, introducing clarity over funding routes and making procurement an enabler for innovation, not a barrier.

Introduction of an application fee

Outline of consultation proposals

The consultation proposed the introduction of a new application fee to fund the proposed independent advisory panels.

Based on current processing costs and the expected additional NHSBSA resource costs, the base estimate is £175 for new applications and £242 for renewals. The fee is proposed to be capped to a maximum fee of £1,000 for SMEs and £10,000 for non-SMEs.

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?

Do you agree or disagree with this proposal?

Please provide further details

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

Please share any amendments you think might improve this proposal?

Summary of responses

46% of respondents disagreed with the proposal (42 of 91 respondents). 32% agreed (29 respondents) and 22% didn’t know (Figure 10). There were higher levels

of support from some groups: 80% of NHS organisations agreed (12 out of 15 respondents), 50% of patient groups or charities agreed (2 out of 4 respondents), and 50% of 'other' respondents agreed (4 out of 8 respondents).

Figure 10. Do you agree or disagree with this proposal?

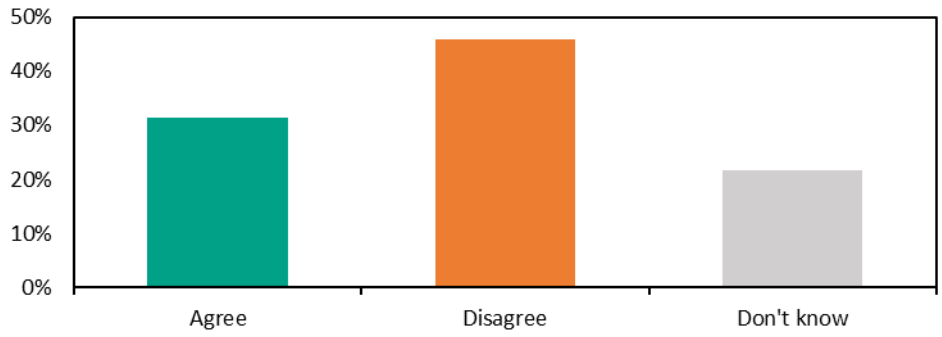
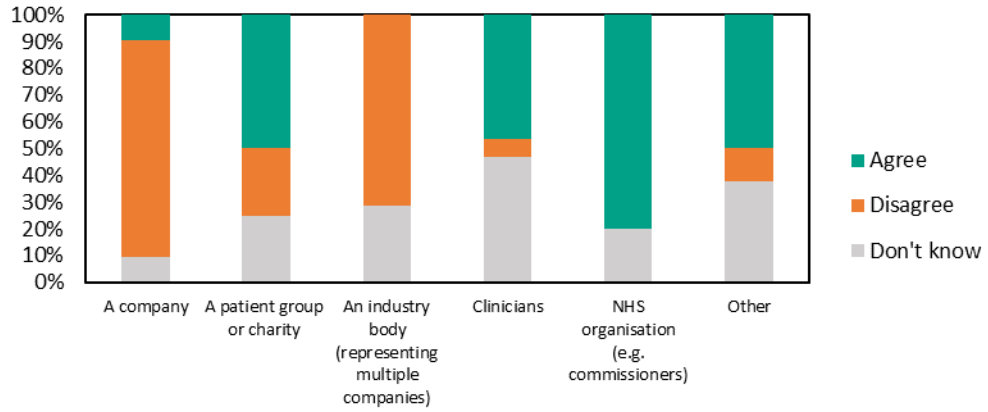


Figure 11. Agree/disagree with the proposal by respondent type



Respondents agreeing with the proposals argued that it would encourage the rationalisation of product lines, including reducing the number of low volume products. Some respondents liked the capped maximum fee.

Respondents disagreeing with the proposals argued that it would adversely affect suppliers, being particularly unfair to smaller companies with lower levels of profit. Many responses also argued that the proposed application fee is too high.

The Option that received the greatest support was 'None', followed by Option 2.

Suggestions for amendments and alternative options included:

- Varying the level of the fee, such as a proportionate fee to the cost of product, market share or size of the business, for example, no fee for microbusinesses and review regularly.
- Amending the timeframe, including delaying the introduction of fees, only charging the fee one year after listing and regular fee reviews.

- Action to reduce the operational cost of the Tariff, such as suppliers uploading their own data and reducing administrative burden, or ringfence the money raised by the fee for the operation of the specific category that the product is submitted to.
- One respondent suggested taking action to ensure that any fee is not passed down to DACs and wholesalers through the reduction of discounts offered.
- One respondent suggested introducing a fee for the removal of products from the Tariff.
- Two responses suggested increasing the support NHSBSA gives companies with the application process.
- One NHS organisation respondent suggested not allowing a large number of applications from any individual company.
- One company suggested using any extra resource to increase adoption of technology instead.

Government response

Based on the responses to the consultation, the government has decided to not take this proposal forward and therefore an application fee will not be introduced. However, the government wants to make the independent advisory panels sustainable in the long term. To make the funding of the panels sustainable the government intends to introduce set periods in the year when particular categories of products can apply to be listed on the tariff. The intention of this is to gain efficiencies by focusing on particular products, to mitigate concern around the application timeline increasing. The government will factor this into the implementation of proposals and will aim for three periods a year when products can apply to be listed for each category.

Next steps

We intend to continue to engage with stakeholders – including industry, patient groups, NHS organisations and clinicians – as we move forward with the proposals and develop the detail of their implementation. While developing the policies outlined in this document, we regularly met with representatives from industry (including trade associations and the Drug Tariff Committee), clinical groups and patient groups. If you would like to join this engagement as the detail of the amendments is developed, please contact: medtech@dhsc.gov.uk

Over the next 6 months, we will develop product classification and attributes, which are key to the comparable categories. This will allow us to develop a deeper understanding of how the proposals that we are taking forward will affect products on the Tariff. At this point we will review the comparable categories, including updating the modelling of the impact of the changes in spend (outlined in the Impact Assessment) and benchmark prices. We will also analyse scenarios for the renewal period. As a part of this review, we will engage with stakeholders, including industry, to gather feedback on these proposed comparable categories and quality and social value attributes. We will shortly write to stakeholders, as well as communicate through our stakeholder forums, to inform stakeholders how they can input and provide feedback on the detail.

Following the creation of comparable categories, these will be implemented into the NHSBSA coding system and the renewals and enhanced assessment processes will be introduced, starting with one pilot category.

In many of the proposals, further work is required before we can understand the full implications of their implementation, which is why there will be review points built in to assess the methodology and parameters. There will be a review point after the first category is assessed. The Impact Assessment outlines the Monitoring and Evaluation plan, which includes reviewing the operationalisation of the proposals as they are implemented and a process evaluation.

Call for evidence

The call for evidence sought feedback on four issues:

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 Call for Evidence section of the survey received fewer responses than the consultation survey, with 92 respondents answering at least one question.

We will use this feedback to develop any future work on these issues, in collaboration with other organisations in the health system, such as NHS England and the Joint Digital Policy Unit. Therefore, this section outlines the summary of responses but does not include a government response to the feedback received.

1 - Waste

In the call for evidence, we outlined our aim of further understanding 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?

Please provide more detail

In your opinion which of these areas would you like to see prioritised over the next few years?

Please explain your answer

For dispensing contractors and industry

Have you identified areas of waste in the dispensing of products?

Please explain your answer

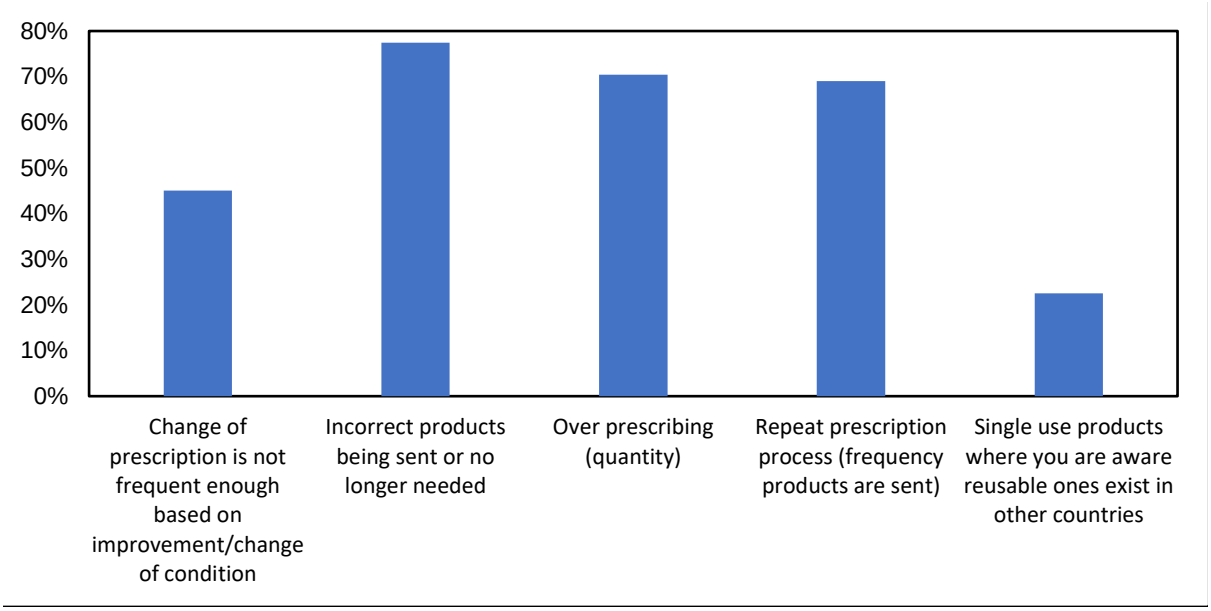
Summary of responses

The majority of respondents (86%; 71 of 83 respondents) had experienced examples of waste in the provision of their products, while 14% (12 of 83 respondents) had not.

Of those 71 respondents who had experienced waste, the most common causes were:

- Incorrect products being sent or no longer needed (77% - Figure 12). Possible reasons included prescribers not having sufficient knowledge of products and recommended usage, with some respondents suggesting that there should be consideration over who is best placed to prescribe these types of products (beyond GPs).
- Overprescribing was the next most common example of waste (70%), with some respondents noting concerns around the influence of companies and Dispensing Appliance Contractors (DACs), which some believed may be driven by profit motivation rather than clinical need. Respondents suggested that DACs may contribute to waste due to prompting prescription requests, ordering incorrect quantities and giving free samples (to encourage requests for further products). Overprescribing by company nurses - particularly of accessory products – was raised by several respondents.
- The ‘repeat prescription process’ was selected as a contributor to waste by 69%, while the ‘change of prescription is not frequent enough based on improvement/change of condition’ was selected by 45% and provision of ‘single use products where you are aware that reusable ones exist in other countries’ by 23%.

Figure 12: Examples of waste in the provision of products experienced by respondents



For dispensing contractors and industry

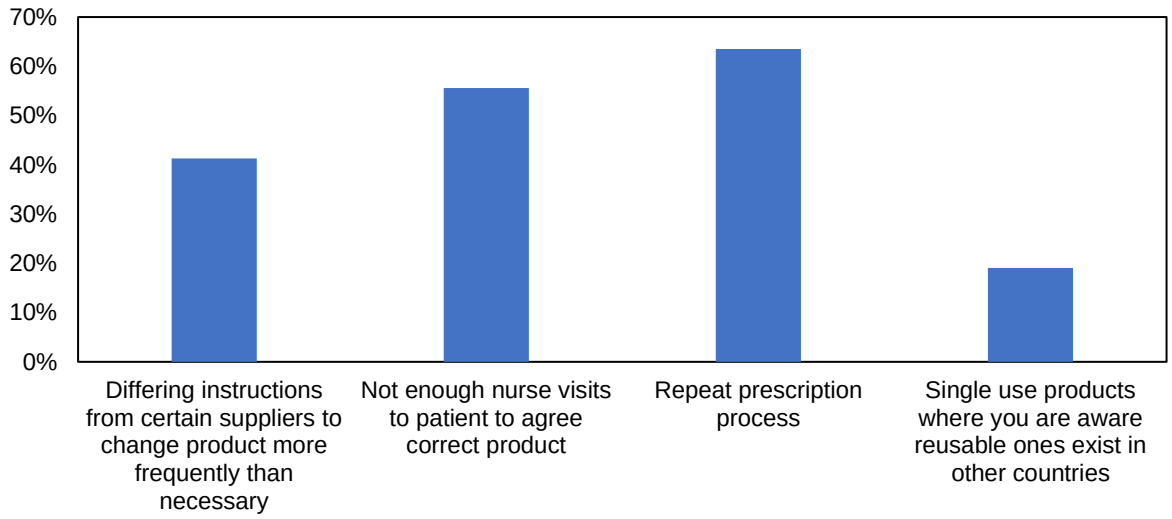
The majority of dispensing contractors and industry respondents (84%; 63 of 75 respondents) had identified waste in the dispensing of their products, while 16% (12 of 75 respondents) had not. Of the 63 respondents who had identified waste, 63% selected the 'repeat prescription process' as a contributor to waste. 56% selected 'not enough nurse visits to patient to agree correct product', with some respondents noting that patients having better access to an NHS nurse would allow for assessment and reassessment of patient needs and thereby potentially reduce wastage. 41% of respondents selected 'differing instructions from certain suppliers to change product more frequently than necessary' and 19% 'single use products where you are aware reusable ones exist in other countries'. In addition, some respondents argued that prescribers not having sufficient knowledge of products/recommended usage can lead to waste.

Suggestions for addressing these concerns included:

- Several respondents highlighted that waste is linked to conflicts of interest and suggested greater transparency from DACs and sponsorship models. Suggested solutions flagged for consideration included only having NHS (non-sponsored) nurses visit patients to assess their needs and allow patient choice, ensure adequate funding of stoma specialist nurses, increased nurse and GP training, greater transparency on repeat prescription and stricter controls on prescribing services.
- A few respondents suggested reviewing the clinical and healthcare pathway to recognise savings and improved patient outcomes, including more frequent reviews of patient requirements.

- A few responses suggested solutions including smaller pharmacy packs for dressings products or using patient or prescribing management systems.
- A few respondents suggested focusing on optimal choice of products highlighting that lower quality products can lead to increased consumption of products.
- A few respondents suggested that it is common for DACs to include their manufacturer's own accessories in prescriptions; this can mean either that unnecessary accessories are prescribed or more expensive versions are prescribed. This is often added by a dispenser and goes to the GP for approval and not via a nurse.
- Some responses felt that stoma and continence products would not be able to move away from single-use products. A few suggested we incentivise manufacturers for investing in research and development of low environmental impact, sustainable reusable products and clear identification of methods for correct disposal.

Figure 13: Types of waste identified by dispensing contractors and industry respondents.



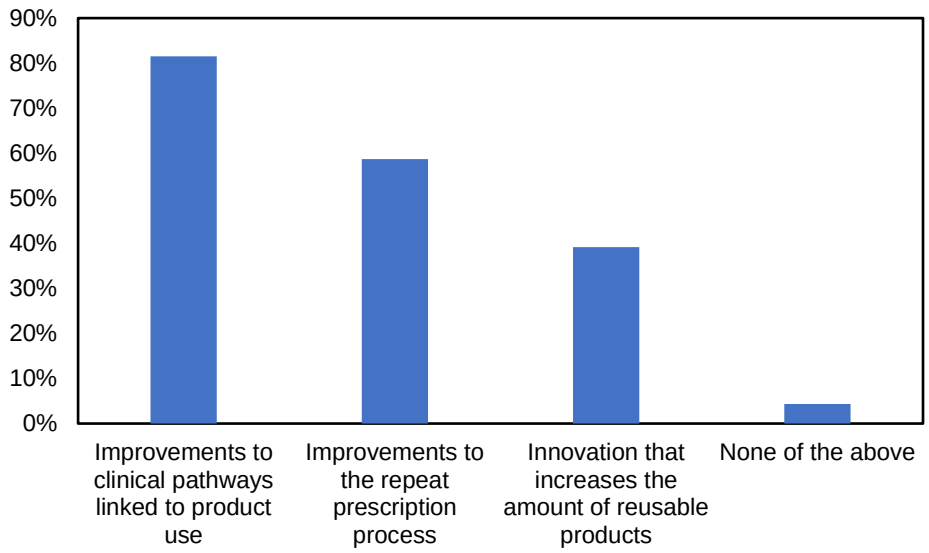
In terms of priorities over the next few years, the majority of respondents (82%; 75 of 92 respondents) selected 'improvements to clinical pathways linked to product use'. A patient group responded that annual clinical examinations with a stoma nurse would be most beneficial so the patient understands which products they need. One company flagged that it can take 5-6 years before a patient for whom their products are applicable gain a diagnosis and suitable treatment. One clinician group responded that nurses need to understand and navigate which dressings do what and make decisions of care based on this. Decision making pathways, for example in a wound management app can help with this and combined with dressings being available in the clinical area rather than a supply route to an individual patient.

Over half (59%; 54 of 92 respondents) selected ‘improvements to the repeat prescription process’. One NHS organisation responded that wound care should not be on a repeat prescription as if the patient is on the appropriate clinical pathway of care, the wound should be healing and the products used will change.

Around a third (39%; 36 of 92 respondents) selected ‘innovation that increases the number of reusable products’. Several responses highlighted difficulties in making some of the products listed on Part IX reusable, sighting operational, regulatory and patient safety barriers. Some respondents commented that many of the products listed on Part IX are already reusable.

4% of the 92 respondents selected none of the options. One respondent argued that before any changes are made to the prescribing process a full evaluation of waste and any associated impacts is needed.

Figure 14: in your opinion which of these areas would you like to see prioritised over the next few years?



2 - Conflict of Interest

In the consultation we outlined our aim 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.

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?

Please explain your answer

If yes, how do you think these problems could be addressed, what alternative models could be explored?

For patient representatives/commissioners

Do you think that patients have a meaningful choice of products within the range available to them?

If no, what do you think are the challenges?

What changes need to be made to address these challenges?

Summary of responses

For dispensing contractors, industry and commissioners

Of the questions aimed at dispensing contractors, industry and commissioners, 53% (46 of 87 respondents) were aware of difficulties in applying the NHS Managing Conflicts of Interest Guidance. 18% (16 of 87 respondents) were not aware of any difficulties, while 29% (25 of 87 respondents) responded don't know.

Many respondents outlined concerns around conflicts of interests with nurses, particularly raised by industry bodies. Many responses noted that sponsorship of nurses reduces competition and benefits big companies. Suggestions for how to address this included:

- More transparency and monitoring of potential conflicts of interest. Suggestions included requiring clinicians to make declarations of interest when receiving any benefits or education from suppliers. A few respondents suggested increased monitoring, including implementing conflicts of interest policies into the CQC inspection regime.

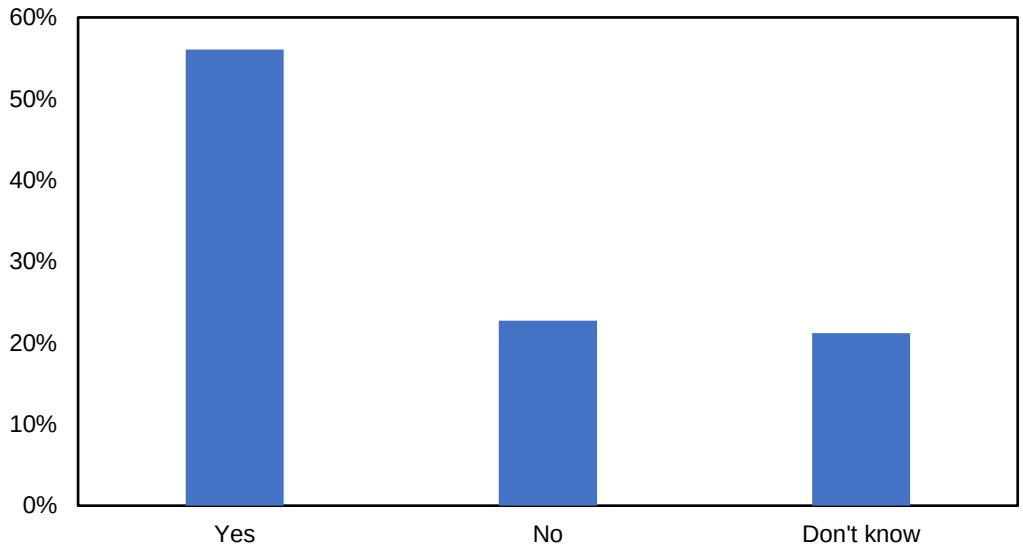
- Encourage greater adherence to current conflicts of interest policies, by increasing communication and advice to healthcare workers, monitoring outcome metrics and providing best practice for commercial and sponsorship arrangements. One respondent suggested aligning to trade associations' codes of practice.
- Prohibit sponsorship of nurses and restrict sample distribution. However, other respondents noted that banning sponsorship of nurses may result in NHS trusts not being able to afford specialist nurses which are currently funded under a sponsorship model. Some suggested that a prohibition of sponsorship should be accompanied by alternative funding arrangements.
- Suppliers with sponsorship in their contracts should address the issue themselves, with one response from a company noting that they had already taken action to address the issue within their organisation. Actions included ensuring that nurses do not have a financial incentive to use the company's products. One respondent suggested that improved engagement between DHSC or NHSE and other stakeholders could support this.
- An NHS respondent highlighted that sponsored nurses are excellent clinicians but there is an inevitable risk of bias towards their sponsor's products due to familiarity and training in those products.

A few respondents outlined concerns around conflicts of interest with DACs. Some respondents felt that it is already a conflict of interest that the DACs often manufacture the products that they dispense. To address this, suggestions included considering a different dispensing model and comparing independent DACs to vertically integrated DACs.

For patient representatives and commissioners

Of the questions aimed at patient representatives and commissioners, 56% (37 of 66 respondents) of patient representatives/ commissioner respondents agreed that patients have a meaningful choice of products within the range available to them. 23% (15 of 66 respondents) disagreed and 21% (14 of 66 respondents) did not know.

Figure 15: Do you think that patients have a meaningful choice of products within the range available to them?



Respondents outlined concerns around the importance of providing information to patients to understand their choice of DAC in provision of products, which was particularly raised by patient groups/ charities. Some respondents suggested that to address this, there should be more consultation with patients and patient groups, including with companies that are developing innovative products. One respondent suggested that a central platform to highlight newly added products should be established. Some respondents argued that meaningful choice is inhibited due to too much choice, with a suggestion that patients only need to be told about clinically indicated products.

3 – Exceptional Price Increases

The current process to apply for an exceptional price increase is based on a narrow focus on raw material increases. The department recognises the importance of ensuring a sustainable market and of reducing 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.

Questions

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

Please explain your answer

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

Summary of responses

The majority of respondents wished to see increased transparency in the EPI process (83%; 60 of 72 respondents), with concerns raised around a lack of information on how EPIs are assessed and reasons for EPIs being rejected. Respondents noted that a lack of transparency creates additional admin burden, as companies spend more time collating evidence to submit for EPIs that may not be relevant and may need to submit several times. Many respondents also wanted an appeals process (61%; 44 of 72 respondents) where an EPI request is rejected, which some respondents argued could help improve accountability. 58% (42 of 72 respondents) of respondents wished to see wider criteria for consideration, such as energy, labour and transportation costs.

Several companies argued that expanding the criteria is important to prevent suppliers from exiting the market, particularly SMEs that are less able to absorb cost increases and products that have been on Part IX for a long time. Several respondents suggested that improved consistency is needed in EPIs, both in terms of consistency in pricing across organisations (NHS Supply Chain, Part IX and NHS Shared Business Services) and prices within product categories. One respondent wanted increased awareness of the existence of the EPI process. Responses from NHS organisations argued that suppliers should demonstrate that they have taken steps to mitigate increased costs in order to be awarded an EPI. NHS organisations also flagged the significant impact price changes can have on existing budgets.

Suggestions for alternative ways of handling impacts of cost pressures included calculating EPIs awarded based on independent data sources of relevant cost pressures. Several respondents suggested amending the GDP deflator process that annually uplifts prices for Part IX (a process separate and in addition to EPIs), such as moving to other measures of inflation (e.g. Retail Price Index, Consumer Price Index), removing the ‘minus x’ factor and using actual rather than forecast GDP deflator figures. Respondents argued that a higher GDP deflator would limit the need for EPIs. Several respondents suggested a price reversal mechanism, where price increases granted by EPIs would be temporary (note that this is already the process under the current EPI guidance). Some respondents suggested focusing on methods of setting prices more broadly rather than one-off EPIs, such as aligning with value based procurement principles. One respondent suggested freezing prices for 5 years.

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 have introduced a prescribing route – most notably Germany's Digitale Gesundheitsanwendungen (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 provide digital apps to patients under the NHS. The department and NHS England would work out how this is best administered.

Questions

What do you see as the benefits in prescribing medical apps from a practical perspective?

What do you see as the challenges/disadvantages in prescribing medical apps from a practical perspective?

Summary of responses

In response to being asked what the benefits of a central list of approved medical apps was:

- 71% (53 of 75 respondents) selected 'increasing choice for patient treatments', with some respondents additionally noting that it may also support equity of access for patients, improve self-management of conditions and encourage innovation;
- 65% (49 of 75 respondents) selected 'approved apps being listed in one place';
- 59% (44 of 75 respondents) selected 'increased confidence in people using the apps';
- 55% (41 of 75 respondents) selected 'central assessment of apps';
- 51% (38 of 75 respondents) selected 'central pricing';
- 47% (35 of 75 respondents) selected 'enabling wider provision of apps'; and
- Three respondents disagreed that medical apps should be prescribed, with one suggesting that they didn't consider it to be a high priority.

Respondents outlined many challenges and disadvantages of prescribing apps:

- Many respondents noted that digital apps would be difficult to validate, assess and check and that listing apps in this way may create administrative burden for suppliers and NHSBSA. A few respondents suggested that to address difficulties in validating apps, the process could be aligned with other countries, e.g. DiGa in Germany, and existing processes, e.g. NHS Digital Technology Assessment Criteria (DTAC). One respondent suggested that approved apps form part of the NHS App.
- Several respondents argued that there is a need for thorough and regular assessment given the frequency of developments and updates in apps and the innate differences compared to physical products. Some respondents suggested that this could be addressed by local systems being responsible for assessment, whereas others argued that central assessment would reduce burden on local systems. One respondent suggested that the existing NICE framework should be used to evaluate medical apps.
- Challenges around pricing and reimbursement were raised by many respondents. Some responses suggested reimbursement and pricing could be done locally rather than on a Part IX type model, while others noted that reimbursing centrally could result in higher prices. A few respondents noted that it may not be possible for apps to work under the dispensing reimbursement model that Part IX is based upon. One respondent suggested that patients are given individual annual budgets.
- A few respondents noted practical concerns, such as the scale of the apps market and the possibility that patients may lose their phone. Several respondents suggested that consideration was needed around how apps would integrate into existing systems, e.g. prescribing systems.
- Several responses noted challenges around data protection. One respondent highlighted an issue of ownership of the data gathered by the apps. Others noted that observational data is a useful source of evidence for companies that are designing products.
- A few respondents suggested that clinicians may need support to encourage provision of apps, especially if their knowledge of apps is limited. One respondent noted that there are also opportunities for apps to be used by clinicians too, which wouldn’t be provided on a Part IX type model.
- Two respondents argued that potential for conflicts of interest should be considered if digital apps were prescribed, as it may result in patient choice being more easily influenced by vertically integrated manufacturers.
- One respondent argued that there is a risk that some patients may be excluded, such as those who are less comfortable with technology, and that patients may need support to use apps. There was a suggestion that community pharmacies may be able to support patients to address this.

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 2025/26 forecast figure so they will receive an increase of 0.6% (1.35% minus 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.

Appendix B: Target audience for the consultation

The consultation was targeted rather than public. This appendix outlines the groups that formed the target audience and their role in the Part IX.

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

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

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

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

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

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

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