Part IX of the Drug Tariff enhanced assessment process Q&A

Version Updated 08 July 2026

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Eye Product Questions

[Eye product responses added 08 July 2026]

Q. Please can you explain within the new Eye Products classification how you are managing unit dose compared to multi dose bottles?

Unit of measure will continue to be taken into account when assessing price. Drug Tariff descriptors will continue to specify whether each product is single dose units or bottles.

Q. How is an 'active ingredient' being defined within the categorisation, is it being defined as an additional principal ingredient in the legal manufacturers license rather than a non-Polymers/small molecules such as a simple sugar?

This has now been amended from 'active ingredient' to additional 'key' ingredient. This is reflected now in the updated taxonomy.

For medical devices, principal or key ingredients are those which have a clinical claim and directly fulfil their intended medical action by physical or mechanical means. Other ingredients, such as simple sugars, which do not have clinical claims or direct medical action will be considered excipients.

Q. Please can you explain how you are allowing for products with more than 1 added ingredient?

If a product has a further declared key ingredient with evidence of clinical benefit, it will be considered for its own sub-category or value add points. If it is present as an excipient without clinical claims, it should not warrant a separate sub-category.

Q. How will molecular weights be validated, will company internal data be used?

Suppliers should state explicitly which method and testing conditions they used. Suppliers should provide a formal certificate of analysis or an independent laboratory technical data dossier stating:

- Weight-average molecular weight
- Method used
- Polydispersity index (where available)
- Measurement conditions – applicants should state the solvent, ionic strength and temperature used
- In-use stability (where available confirm that the polymer maintains its molecular weight band under standard storage conditions across the product's lifespan)

In addition, if your product's molecular weight has been evidenced in a peer reviewed paper then this can be used as evidence.

However, please note that it is **not mandatory** to provide molecular weight for the sodium hyaluronate category. Where a company cannot provide it at this stage they will not be removed from the tariff for this reason.

Q. How will molecular weight be defined, every lab has different tools and this can change over time on some products?

There are three established methods for determining hyaluronate molecular weight that NHS Prescriptions Services will accept (please see p.43 in guidance v2.4)

- SEC-MALS (size-exclusion chromatography with multi-angle light scattering)
- Conventional SEC/GPC – calibrated against hyaluronate-specific standards
- Intrinsic viscosity

Q. If a product contains two Polymers, will the molecular weight of the two polymers added together be considered for this product (particularly if it is a co-polymer)?

For products containing more than one polymer, the product's molecular weight banding is determined by the weight-average molecular weight (Mw) of the primary active polymer that has triggered its classification into the main-ingredient cluster. The molecular weights of separate polymers cannot be summed to determine the band, as this would misrepresent the product's clinical performance and would not be supported by analytical measurement. Secondary polymers or added ingredients are captured at the additional-ingredient level of the taxonomy. For true co-polymers, where two monomers are chemically linked into a single polymer chain, the co-polymer's directly measured molecular weight applies.

Q. Will the market for the market share assessment to evaluate the 5% and above share holders be defined as the whole Sodium Hyaluronate market (column H) as an example, the lowest level categorisation ie. molecular weight (column P) or any other level in between (columns J, L, N)? Similarly, which level will a benchmark product be defined at between columns H, P, J, L & N?

The minimum 5% market share policy for the benchmark will be at the lowest level cluster (column P). However, this still needs to be a reasonable price and if this generates many single product clusters then reasonableness will be judged in comparison to other clusters.

Q. In the new taxonomy, will each combination product have its own category or will all combination products be considered within a single category (eg. HA+ Carbomer, HA+Ectoin etc)? And will each combination category then be split into low medium high molecular weight?

The added ingredient will be clear in the descriptor but the products will be grouped together under added ingredient and then within molecular weight.

An exception would be made if clinical benefit could be proven which exceeds the standard within that cluster of products.

Q. Is the intention to compare all combination products within the range of 0.15-0.29%, rather than having 0.2% separated out as it was previously?

Yes. 0.2% solution sodium hyaluronate would be in this cluster- Medium concentration solutions: 0.15-0.29%

Q. How are you allowing for differences in shelf life from opening – for example some products are 3 months, others are 6 months? How are you allowing for products that contain 10ml of solution but deliver anywhere from 250 to 300 drops?

These factors can be used to gain value-add quality and social points under the enhanced assessment framework.

Questions on Timings

Q. What is the status of the patient survey publication?

- National Voices published the patient report on 15 January 2026. Patient views on medical devices prescribed to them outside of hospital in England – National Voices

  [This was updated 05 February 2026]

Q. I heard you say that all products in Part IX were in scope for the patients survey. Yet, Pen Needles were not studied. Can you elaborate? Can a company do an independent survey?

- Whilst all Part IX products were in scope for the patient report DHSC commissioned from National Voices, they were limited by what patients chose to respond on**.** The patient representatives appointed to the independent advisory panels for Part IX will also input and we have asked charities/patient organisations to provide any feedback they have gathered. If a company provided an independent survey to support a response to a value add quality question then the Panel would consider, if they choose to.
  [This was updated 05 February 2026]

Q. What is the latest status of the Categorisation?

- The latest version of wave 1 categorisation is available on the NHSBSA Part IX website and contains the updates to the eye products [7.2] and ear products [7.1.2].
- It is not our intention to only share categorisation at the time we initiate renewal, comments on other waves are currently being considered by the NHS England (NHSE) clinical panels and will be shared as soon as confirmed in the next couple of months. To be clear, the intention is not to wait until we're initiating each wave.

  [This was updated 08 July 2026]

Q. Can you confirm that if a company submits a product for Drug Tariff listing before the notice period (for their wave) starts guidance 1.7 will apply?

- (Para 13 in guidance) 2 months into the notice of renewal is the last opportunity to apply using v1.7, if the supplier chooses to do so.
- However, they will still need to apply for renewal ahead of the deadline under the new framework in addition (we just wouldn't hold the 'not prescribed' caveat against them as they will have been listed for less than 2 years).

Q. Can you also confirm that any notice of withdrawal/deletion will be a maximum of three months ahead of the month of tariff removal?

- For renewals - for those that choose not to apply for renewal or do not pass/withdraw then we committed to 6 month notice of deletion unless extensions may be needed to support patient switching for instance, at the discretion of NHSBSA. We are checking how best to do this so that prescribing systems do not remove products too early.

- The 3 months' notice of deletion still applies under normal circumstances where a company delists a product.

Q. What is the deadline for wave 1 applications?

- Friday 27 March 2026.
- Except eye products only [7.2 in Part IX categorisation v1.2 (Wave 1 renewals) doc] where the deadline has been extended to 31 August 2026.
- ***[This was updated 08 July 2026 to reflect new deadline]***

Q. Can DHSC Confirm the timelines for all waves?

- Wave 1 the assessment period (the renewal period) will be end March – end July 2026.
- Wave 1 post action review will follow the wave 1 renewal period.
- There will be a review after each wave to ensure no unintended consequences. Between wave 1 and 2 we will pause before triggering wave 2 while we carry out the review. However, depending on the outcome of this we may not pause for every review moving forward.
- For wave 1, you will see the updates in the tariff around Nov 2026, and then for those products that are being delisted, they will remain on the tariff until around Feb 2027.
- See the indicative schedule on the NHSBSA website.
- ***[This was updated 08 July 2026 to update dates it will be reflected in the drug tariff.]***

Q. When will we receive the application form for new Part IX?

- The application forms are now available on the NHSBSA Part IX website.

Q. What is the expected timeframe for DHSC or NHSBSA to provide feedback, scoring results and benchmark price confirmation following the March 2026 submission window and will this be communicated to applicants in advance to support planning and appeal readiness?

- Currently, we are planning for scores to be shared with applicants from end of July 2026. There has been a slight delay to Point of Care Testing and hypodermic equipment so these suppliers will be informed of outcomes from end of August.

[This was updated 08 July 2026.]

Q. What is the window of time that applicants will receive scoring and feedback please? Conscious of managing resources over holiday period

- For wave 1, this is planned for end July 2026. If you think this will be difficult to manage please contact NHSBSA through partixrenewals@nhsbsa.org.uk and a solution will be found where possible.

[This was updated 08 July 2026]

Q. We are unsure which type of application some of our products fall into. Please indicate which 'Type of Application' these products fall into as the wording on 'Type of Application' neither fits a 'new application' nor a 'product already listed on Tariff'.

- If unsure please check by emailing partixrenewals@nhsbsa.nhs.uk
- As per Drug Tariff Guidance v2.4.pdf, the cut-off for submitting Part IX applications outside of the Enhanced Assessment Framework is two months into the notice of renewal. Therefore, if your application is for a product not yet listed on Part IX and the relevant product wave of renewals is approaching, you will need to submit a new product application using the new process.

  [This was updated 08 July 2026]

Questions on categorisation

Q. How can we find out/see what Cluster each of our products are in? Where is that published?

- The wave 1 categorisation is available on the NHSBSA Part IX website.
- We have previously shared the latest versions for the taxonomy for wave 2, 3 and 4 with industry on 31 March 2025, if you have not seen these please let us know. An updated version of wave 3 taxonomy was shared end of May 2026 and comments from that are still being considered.
- The comparable clusters are at the lowest level.
- For future waves, once the taxonomy is final it will be on the NHSBSA Part IX website. In the meantime, or if a supplier is struggling to find the relevant cluster, you can email NHSBSA (partixrenewals@nhsbsa.nhs.uk) and ask for clarification.

  [This was updated 08 July 2026]

Q. What products are granted new clusters?

- New categories and clusters can be created when different products come to market that are not comparable with existing listings, and therefore new clusters are more applicable to new listings rather than at renewal.
- However, the taxonomy was developed from 2023/24 data so it's possible we are missing a cluster for some products added since then. If you think this is the case, please state it in your application.
- New clusters are not created for every distinguishing feature but may be created for those features which add value to the NHS. This at the discretion of NHSBSA and the independent advisory panels which consider clinical comparability.
- We are not expecting many new clusters to be created during renewals, as further cluster creation is really for new innovative product applications.

  [This was updated 05 February 2026]

Q. What is the process for requesting a new cluster?

- New clusters can be created:
  1. Either based on the judgement of NHSBSA and the Independent Advisory Panel,
  2. or as requested by a supplier - which is then reviewed by NHSBSA and the panel where required.

- If you decide to request a new cluster for your product, you should include this and the rationale in "further product info" tab in the application form under the category you are applying for and also in the cover email for your application.
- During renewals, NHSBSA, and the panels where required will review and confirm cluster placement. This will then be shared with relevant suppliers and there will be the opportunity to appeal your cluster placement.
- Suppliers have 5 working days to respond with the rationale where they disagree.

  [This was updated 05 February 2026]

Q. Is it possible to move a product to another category at a later date?

- It is possible, in so far as if you are put in the wrong cluster you can appeal your cluster, which is then reviewed by NHSBSA and may result in your product moving. Once the clusters are confirmed, we do not expect products to move between clusters.
  [This was updated 05 February 2026]

Q. Can you please consider the following clusters be agreed for the Sharp bins segment categories to allow both suppliers to submit our current sizes which will support clinical choice and patient needs.

- At this stage for wave 1 it is for the panel along with BSA to say where a cluster does not work, however the supplier should still submit the size of the sharps bin as that information would still be seen in the tariff.

  [This was updated 05 February 2026]

Q. How are products in categories being reviewed with price ranges, is it by GM, CM and how are shapes reviewed?

- The wound and skin care categorisation is currently under further review. Sizes and shapes of dressings are being considered as part of this. We will share the updated version as soon as possible.
  [This was updated 05 February 2026]

Q. Will emollients become part of this and if so when?

- Yes, emollients are included under wound and skin care. This section is currently under review and the updated version will be shared as soon as possible.
- ***[This was updated 05 February 2026]***

Questions on applications

Suppliers should review the updated guidance for detailed information, which is available on the NHSBSA website.

Q. Where do I apply?

- The application form can be found on the NHS BSA website. Once completed this should be emailed to partixrenewals@nhsbsa.nhs.uk alongside any attachments.

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

- Please check on the NHSBSA website, in the first instance including the wave 1 categorisation. If unsure, you can email partixrenewals@nhsbsa.nhs.uk to check if you should apply for renewal of your products in wave 1. Please provide your products listed name identical to the name published in the latest version of Part IX of the Drug Tariff.

Q. What do I do if my product is in wave 2?

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

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

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

Q. What if my product is newly listed, is my application exempt from the prescribing checks?

- If a product has been listed for under 2 years and not yet prescribed we won't count it as not having been prescribed during the previous 24 months. However, if it's been listed for under 2 years it does still need to apply for renewal.

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

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

Q. Do the questions in the application form need to be answered at every SKU level?

- We need the SKU level information for the basic info (e.g. product info, size, SNOMED). But you do not need to complete the quality and social answers multiple times for different SKUs if no change. To avoid any misunderstandings, please state where your answer applies to multiple SKUs.

Q. Can multiple products and product types be submitted under 1 form, or will they need to be completed individually?

- Multiple product SKUs can be included on the same form however if there is a different product type please submit that on a separate form. For example, if you

supply lancets and blood glucose testing strips we would expect to see them on 2 different forms.

- We need the SKU level information for the basic info (e.g. product info, size, SNOMED). But you do not need to complete the quality and social answers multiple times for different SKUs if they are the same. To avoid any misunderstandings, please state where your answer applies to multiple SKUs.

  [This was updated 05 February 2026]

Q. Will there be a minimum/maximum amount of evidence that can be sent in with the application form?

- No there is not. You should email your application form and supporting documents together in one email to partixrenewals@nhsbsa.nhs.uk. Please make it clear in your responses in the application form which document the response refers to.

Q. Will the renewal form be submitted via a portal

- No. The applicant should email to partixrenewals@nhsbsa.nhs.uk

Q. The Government's response to the consultation recognised some products may not be suitable for this assessment. What methodology will be used to determine such cases?

- We have said in the policy paper that we will not include the requirement to renew neonatal and paediatric stoma bags and products that are listed in the Part IX technical specifications. We recognise that the volumes of sales are not there for companies in the neonatal and paediatric group, however these are very important products. Similarly, we may on a case-by-case basis identify other categories that we exempt from renewal for similar reasons. We suggested in the policy paper this might include certain bespoke or highly personalised products.

Q. On the form, for the question on the change in manufacturer since the original listing - does this apply if we've since submitted updates for amends? And this is therefore just capturing any updates to the current Drug Tariff listing?

- Yes you only have to notify of changes to the current DT listing, if you have already updated these details previously and they are still correct then write 'no'.
- We will clarify the wording in the form to: "Is the supplier different from the current listing?"

  [This was updated 05 February 2026]

Q. What forms need to be completed for an application?

- Either the renewal or new application form, depending on whether you are applying for a new listing or renewing an existing listing. These can be found on the NHSBSA website. See the introduction tab which includes a checklist to help you check what other attachments to include.
  [This was updated 05 February 2026]

Q. The application form states one product range per spreadsheet. What is classed as a range? For example, would two different sizes of one brand of lancets would be classed as a range? And would two different and non-interchangeable brands of glucose testing strip be classed as a range?

- Yes. Two different sizes of one brand of lancets would be classed as part of the same range. But two different and non-interchangeable brands of glucose testing strip would not be classed as a range. If unsure email BSA at partixrenewals@nhsbsa.org.uk.
  [This was updated 05 February 2026]

Q. Is there an easy way to check which SKUs are already listed?

- Go to the Drug Tariff page on BSA site, click on 'Drug Tariff Part IX', you can see the drug tariff in excel form under the year and most recent month – you can filter to your supplier name and then you can copy the information into the application form. If there are SKUs you can't see in the excel then email partixrenewals@nhsbsa.org.uk.
  [This was updated 05 February 2026]

Questions on the enhanced assessment framework

Q. Do we need to submit the Carbon Net Zero plan/offset and Modern Slavery statement with the application, or are these to also be published somewhere?

- Carbon reduction plan/ net zero commitment and the modern slavery statement – developed by supplier and published on their website and provides a link in their application. For organisations with no website, a copy of the documents is to be provided alongside the application.
- We've had a question as to whether there is a £5 million threshold on contract value under procurement rules between providing a Net Zero Commitment or Carbon reduction plan. There is for procurement, but our position for Part IX applications is that suppliers can choose to do either. This is not strictly procurement however we have used the thresholds as a guide. If you have a carbon reduction plan already you can submit that (see page 13, para 37 of guidance v2.4).
  [This was updated 05 February 2026]

Q. Can you provide model answers for the assessment process?

- We are not providing sample answers as that can be misleading - there is not a right way to answer and we don't wish to limit what companies might provide for this. Each application is unique and will be considered on its own merits. Following wave 1, we will share any further high-level tips for applications where relevant particularly if there are any common themes emerging from the process.
  [This was updated 05 February 2026]

Q. On the additional minimum requirements for continuous glucose monitor sensors, it was asked 'Is the user able to delete readings from the meter memory? Which scenario does this refer to -

- **Is the user able to delete readings which the CGM has measured and recorded in the associated App?**
- **Is the user able to delete blood glucose readings taken by a separate blood glucose monitor and recorded in the CGM App either through manual upload or Bluetooth?**
- **Is the user able to delete blood glucose readings taken by a separate blood glucose monitor for calibration purposes, and recorded in the CGM App either through manual upload or Bluetooth**

- We think that ideally the user should not be able to delete any readings recorded into the associated App. However, for the assessment it will be treated as the first bullet, the user should not be able to delete readings which the CGM has measured and recorded in the associated App.

  [This question was added 27 October 2025]

Q. We have seen the entry requirements for Wave 1 – (the annexes, very detailed for some categories). Will other categories have these requirements. Can DHSC confirm these are layered on top of basic CE mark in an effort to stop cheap products with no quality or social value scores flooding market?

- To ensure we are listing products suitable for prescribing on the NHS, we have additional minimum requirements for certain diabetes products because they have been identified with appropriate specialist input. Where we identify that further minimum requirements need to be set we will do so. These additional requirements are in addition to the pre-requirements, which include a CE and or UKCA mark.

Q. Is there an argument that quality is being sidelined in favour of cost alone?

- No, the products applying to renew have already been previously assessed under the existing framework and as mentioned new applications have to demonstrate that they are as effective as the current standard of care.
- The higher quality products, can have a higher price as per the framework. So that in itself ensures quality is not sidelined in favour of cost.
- To ensure adequate quality, we have additional minimum requirements for certain diabetes products because they have been identified. Where we identify that further minimum requirements need to be set we will do so.
- If a product is not comparable other products on Part IX it can have a separate cluster, but it must demonstrate its cost is reasonable.

Q. What do you specifically mean by "alternatives"? (Found in the Quality evaluation framework)

- In the framework "compared to alternatives" means how does your product compare to the nearest alternative treatment or device.

Evidence

Q. Does the scoring have a sliding scale?

- Quality and social do not have a sliding scale- a sliding scale makes the scoring less objective.
- Pricing has a sliding scale as it is based on a numerical calculation.

Q. Is there a preference for clinical vs real-world evidence, is company authored evidence acceptable and what about the age/cohort etc?

- Yes, company authored evidence is acceptable. The important components of good evidence are using the right population cohort and selecting a suitable comparator.
- The NICE Late Stage Assessments (LSAs) identified that some of the problems with studies were that they were predominantly non-comparative with small sample sizes, did not often report statistical significance, were largely considered at high risk of bias and varied in their populations, outcome definitions and timepoints of measurement.
- There would be a preference for real world evidence, however we recognise that isn't always achievable so therefore we also value clinical evidence.
- In addition, there is a preference for evidence in primary care.

Q. What evidence scores 10 and what scores 5? What is the difference between good and satisfactory?

- Where possible we have clarified the language for the scoring, but ultimately we require the expertise and judgement of the panel to decide on the individual strengths and evidence of the application.

- The scoring is not based on the hierarchy of evidence but on demonstration of the criteria.

Q. If a product has been assessed by NICE then it has to be available, how are you treating those and shouldn't they have their own category?

- The specific recommendations on individual technologies assessed under medical technologies guidance by NICE are not intended to limit use of other relevant technologies which may offer similar advantages.
- Therefore, having a NICE assessment does not necessarily mean the product needs its own category.

Q. The evidence levels required in the framework are too high for full points for product effectiveness, most medtech products do not have this type of evidence.

- We have made changes to the scoring language to clarify evidence level 2 minus and 3 evidence are accepted, but the panel reserve the right not to accept this evidence if they deem it inadequate. Whether 2- and 3 evidence are accepted is dependent on the product and the claims of increased product effectiveness.

Q. NICE are reviewing the evidence requirements for Medtech products, how will this be taken into consideration for Part IX?

- National Institute for Health and Care Excellence (NICE) are considering the evidence requirements, following the late-stage assessments on Part IX products. Therefore, DHSC reserves the right to change the Part IX evidence requirement as appropriate. If so, we will communicate this in a timely way,

Q. Can you provide more detail on the methods and processes on how the panels will assess quality submissions from companies.

- The panels will assess the value add quality responses where submitted. The quality evaluation framework should be used as a guide. The panels will receive training from DHSC and BSA on applying the quality evaluation framework.
- We're not giving 10 marks for better evidence, and 5 for poorer. It's about whether the criteria of the framework is backed up by evidence.

Q. How will real-world evidence generated in NHS settings — for example through ICBs or health innovation networks — be incorporated into renewal decisions, particularly for high-volume categories like wound care and diabetes monitoring?

- Where real world evidence is available, we would expect the panel to consider this in their assessment.

Q. Is it possible to ask for any further detail around the application process for a product currently used in the Hospital setting to be available in the community setting?

- If you believe the product is appropriate for prescribing outside of hospitals and meets the minimum requirements, you should apply to the Drug Tariff for a listing. If the team determine that the product meets the criteria for a listing, it may be offered a permanent or temporary listing.

Quality - *Value add*

Q. Why can applicants only submit 3 value add criteria out of 4, will there be opportunity to submit a 4th?

- There will be no further opportunity to submit an additional value add criteria, applicants can only submit 3. Suppliers will likely submit answers for their strongest value add areas, allowing an additional 4th response creates an unnecessary resourcing burden on independent panels.

Q. Some of the content under the quality value add criteria prompts are not relevant to my product, so why is it in the framework?

- Not all of the example prompts will be relevant to all products on Part IX of the Drug Tariff. If the supplier can issue other credible evidence to support contribution to this theme this will be evaluated if a clear rationale is provided. We will consider on a case by case basis.

Q. The scoring “good/satisfactory” should be more clearly distinguished.

- Where possible we have clarified the language for the scoring, but ultimately we require the expertise and judgement of the panel to decide on the individual strengths and evidence of the application.

Q. Product Effectiveness Scoring. The EAF states that to achieve 10 points for a “Good demonstration” of product effectiveness, “the evidence robustly demonstrates product effectiveness beyond minimum requirements and clear, measurable benefits.” However, the EAF also defines the minimum requirements for renewals as “Not applicable – the requirements are the pre-qualification criteria”, which include holding a valid CE/UKCA mark, MHRA registration, confirmation of supply, and appropriateness for prescribing in primary care. Could you please clarify how “minimum requirements” are defined in the context of product effectiveness, and, given the pre-qualification criteria are regulatory rather than clinical, how companies are expected to demonstrate effectiveness and consistent, measurable outcomes beyond these minimum requirements?

- The minimum requirements are used to demonstrate that a product is effective and functions as stated. We do not require evidence of minimum requirements to be provided for products applying for renewal because they have already been assessed by NHS BSA who have deemed them to meet their requirements for listing.
- Therefore, the product effectiveness section is about demonstrating that the product has some additional benefit with regards to effectiveness compared to alternatives listed on Part IX.
  [This question was added 19 November 2025]

Q. Does evidence have to be specific to that variant of device or can evidence for previous generations be considered?

- Generally, the evidence should be on the specific product the application is for, but it is looked at on a case-by-case basis. If it’s a model upgrade it’s potentially fine, but we can’t comment without seeing the detail.
  [This was updated 05 February 2026]

Social

Q. With renewals being at product SKU level yet many measures for social value being at Brand level, how do we best represent ourselves.

- To be clear, this is not social value that you have in procurement as this process is to list a product onto Part IX. This is the social criteria outlined in the enhanced assessment framework. This social criteria is at the product level.
  [This was updated 05 February 2026]

Q. Who will score the three social submissions from companies?

- BSA will be scoring the social responses- they are receiving training on this.

Q. As stated previously we have concerns that companies will find it challenging to score the 4 points but may be able to get 2 for secondary packaging evidence. Can you give some further examples of how a company would score 4 please

- To a large degree this is relative to those products most similar to it, so we can't share a definitive example of what would score a 4.

Circular Economy

Q. The circular economy questions are not relevant to my products.

- We are building circular economy principles into MedTech assessments in line with the Department's Design for Life roadmap.
- We recognise that circular solutions will pose varied technical challenges across the range of products on the Part IX tariff and this may impact ability to score in this section of the criteria. This is reflective of the scale of change needed to deliver a circular economy, and the purpose of this criteria is therefore to incentivise innovation wherever possible, to deliver on the Design for Life Vision as well as NHS Net Zero.
- To reflect the unique challenges of circularity for each product the assessment considers a range of circular economy practices (reduce/ reuse/ recycle/ remanufacture) and compare each product's circular economy support with other equivalent products on the market to account for maturity of innovation in that product area.

Q. What does gold standard look like for Circular economy?

- We wanted to emphasise the point that your product doesn't have to be reusable or have the best circular functionality to get full marks.
- We're taking into account the state of the art for each product area so it's also about whether your product is innovating in this area and supporting a circular economy by pushing boundaries.
- Submit what you can, because you might think it's not enough to get good marks but if you compare well against equivalent products, you could.

  [This was updated 05 February 2026]

Q. Re circular economy - you said is at product level - but a lot of the efforts and good work are at company, not product level – so for us for instance we have Eco Design

principles baked into our process. So therefore curious how this then gets considered at product level only in an application / how best to present this information? Would you advise we state these principles or approach in each product application? As they are super important.

- This is not something that is considered as part of the Part IX assessment process. However, ICBs take this type of thing into consideration when deciding what to recommend for prescribing.
  [This was updated 05 February 2026]

Q. For circular economy, will the evaluation panels be able to assess the maturity of circularity for a whole category of products – e.g. does the timing of the assessment process allow for products to not just be assessed on an individual basis?

- Yes. For circular economy, you will see in the scoring column of the assessment framework that these products are compared with equivalent products on the market.

Supply Chain Resilience

Q. The supply chain resilience questions should include companywide initiatives rather than brand specific

- The aim of this criteria is to demonstrate that the health system can rely on the supply of this specific product. This could be as a result of company wide initiatives but must relate to the specific product.

Q. Please give more detail on what kind of evidence you require – historical? On file?

- The evidence should be up to date, for example you would send in your most recent business continuity plan. A case study could be historical, but demonstrating that your current plans would result in similar positive outcomes.

Packaging

Q. Packaging for sterile products are unable to be made from recycled materials (ISO 11607)

- We have updated the language in the scoring guidance to move away from specific levels of recycled content, in line with feedback received and clarified that secondary packaging is included in the assessment.

Q. What type of Life Cycle assessment are you looking for? Carbon Footprint or full LCA report?

- Ultimately, this section is in comparison to equivalent products on the market – so the more comprehensive analysis demonstrating the criteria is more likely to get maximum points. And a full life cycle assessment is more comprehensive than carbon footprint.

Q. How many points can you get for reducing secondary packaging?

- In most cases it will be 1 point but a large reduction would potentially be scored 2 points if adequately evidenced.

Q. Do you have any further information on the type of evidence you require?

- In terms of the type of evidence, this could include Life Cycle Assessment, use of a packaging impact calculator, demonstration of how packaging has been reduced as much as possible and evidence of recyclable material etc.

Pass score

Q. You have stated that a product cannot achieve a pass even if they score 55 from quality, minimum requirements, and social value, they must get a score from price as well. Can you also confirm that a product cannot pass on price and minimum requirements alone, they must get a quality score as well. We are concerned that low-price low-quality products could score 60 and pass.

- At renewal, a product already listed on the tariff with a CE/UKCA mark that has not submitted value added quality or social responses can still pass if the price allows them to pass. This is intentional so that a company can submit this for certain products where they don't need to spend much time on renewal. The product will have had to meet the criteria for a new application when it first applied so we do not agree this means low quality products are being listed.

Pricing

Q. The current 32% and above criteria which means companies will score zero points for price needs further discussion. We need to have commitment from DHSC that this % cannot change as we move through the waves and that any proposal to amend for the next round of renewals needs sign off with the DTC before any changes are implemented.

- We are letting companies propose prices on renewal so this criteria acts as a safeguard on pricing. We have committed to pause for review following wave 1 to assess the process and outcomes. We hope that we do not need to change anything as a result but we are open to admitting any unintended consequences which you may also be keen to change? We would discuss any proposals to amend for wave 2 with you and state this in the guidance (para 16).

Q. Will Companies have more than one opportunity to reduce price to maintain their listing? And how long will companies have to reduce their price?

- (Para 65) If a product initially fails on price, the applicant will have one opportunity to lower its price below the maximum pass price. A company does not need more than one opportunity to do this. Any decisions on listings must be final by the end of the renewal period, therefore once a company has been notified they haven't passed on price we recommend you come back within 5 days.

Q. Can you also confirm when any price changes will be amended in the tariff, will it be the same as today, only in the month the change takes affect either as an increase or decrease.

- Updated prices for wave 1 will be reflected in the November (oral, dental, ear, nasal products) and December (point of care testing and hypodermic equipment) 2026 Drug Tariff. This is the case whether the renewal application results in an increase or a decrease in price.
  [This was updated 08 July 2026]

Q. We had comments from some suppliers around how the pricing framework means that they might have to lower their price or they would fail.

- Your product would only be able to price above the benchmark if it demonstrates superior quality or social scoring. This is because we are committed to delivering the best value medical devices for patients and the NHS.
- However, if the product with the lowest price is deemed artificially low for the category, NHSBSA will not make that price the benchmark. This ensures that the pricing is not undercut.

[This was updated 05 February 2026]

Q. Each year, we have the opportunity to increase some prices within our portfolio. Does this process still stand independently of the renewal process?

- As you may be aware, each year suppliers have the opportunity to increase prices as outlined in the guidance v2.4 annex D.
- This process still exists. If you are due an annual price increase during the renewal period you can still apply for this.
- In order to see 1 month's uplift before the new prices take effect the price increase request needs to be completed a month before the end of the renewal period to allow enough time for the changes to be reflected on the tariff before the new prices take effect.
- This price is then superseded by the renewal process, where each applicant submits a new application with a proposed price – which the scoring is then based off.
- Going forward, the annual price increase can be granted a year after the renewed prices are published. Applications for an annual price increase will be closed for the following 10 months (from the date of listing). A company can then apply 2 months in advance for an annual increase, with increases applied from month 12. (see annex D of the guidance).

[This was updated 05 February 2026]

Q. If a product receives points for pricing but not enough to garner a PASS overall. Is adjustment in price still possible in review section of the timeline or does the pricing section need to FAIL (+32%) for pricing to be resubmitted?

- If you fail on price you have the opportunity to lower your price without having to resubmit.

[This was updated 05 February 2026]

Benchmarking process

Q. How is the benchmark determined?

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

5% of prescription volumes, the product with the highest prescription volumes will be considered as the benchmark.

- NHS Prescription Services will conduct a manual review of each benchmark to ensure that it is appropriate.
- See the “Price Evaluation” section in the guidance, paragraph 59 – 70 for further information.

Q. Is the 5% prescription volume threshold for benchmarks determined at the SKU level or at the (product? brand?) level?

- Where the function of the SKU is the same, we expect the SKU prices to be the same and benchmarking would be at the product level.
- Where the SKU’s are across different clusters it will be done at the SKU level, i.e. they are not clinically comparable. For example, dressings will be clustered into size bandings.
- We appreciate there may need to be exceptions to this rule and BSA will discuss with affected suppliers where this applies.

Q. We understand the benchmark is still not going to be visible – can DHSC explain why?

- It is not possible to share the benchmark before companies submit their applications, because the benchmark is dependent on the proposed prices from the companies submitted in those applications. In addition, clusters need to be confirmed in order to work out the benchmark – which is not possible until all the applications are in. Once updated the Drug Tariff will be publicly available.

Q. What does the Manual BSA benchmark check involve?

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

Q. Can you use value instead of volume to select the benchmark? We request that the benchmark price product/sku has at least 5% market share in both value and volume.

- Whichever approach you take between using value or volume to set the benchmark, in 89% of clusters you still get the same benchmark. So for the vast majority of clusters it does not make a difference.
- Where it does make a difference, using value puts more expensive products at an advantage over comparable products with a lower listed price that are prescribed at the same rate.

Q. What data source will be used for checking which products haven’t been prescribed?

- The most recent Prescribing data available for the past two years will be checked for wave 1. Prescribing in Northern Ireland and Wales will also be checked.

Q. How will different sizing be accounted for in the pricing?

- Products put in the same cluster will be products that are clinically comparable. Each cluster will have a standard Unit of Measurement (UOM) which reflects the way products in the cluster are interchangeable. The original price and quantity / volume of each product will be converted to reflect the UOM of the cluster. This allows the price and quantity / volume of product in a cluster to be fairly compared according to how they are interchangeable from a clinical perspective.
- These principles will be followed when deciding how to cluster products and selecting an appropriate UOM for each cluster.
- When NHS Prescription Services apply these principles to wound care dressings, we would expect that dressings will be grouped into different sizes, reflecting the fact that different sized dressings meet different clinical needs. Once products are grouped, we would expect the UOM to be one dressing, rather than cm^2, because dressings within each cluster are interchangeable on a one-to-one basis. The benchmark price in these clusters would therefore be set against the dressing with the lowest unit price, given that the dressing represents 5% of total dressings prescriptions in the cluster.
- Note that whilst the principles in which products are grouped and compared will not change, the way in which BSA interprets this cluster to cluster can.

Q. DHSC will have the discretion to select the benchmark product if the lowest price point product wasn't suitable. Can we gain clarification on how this would be formalised or detailed.

- NHS Prescription Services, NHSBSA have this discretion. DHSC are still keeping an arm's length from this aspect.
- NHS Prescription Services will work within a rough set of parameters such as identifying if the company is undercutting the market, but this is a common sense review.

Q. What if a company has a range of sizes and one passes but another doesn't?

- If the products are in different clusters they are assessed separately, one product size in a range could fail, but another could pass. This is the same as how the process currently works.

Q. How will you assess single product clusters on price?

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

concerns, such evidence may need to include data to demonstrate clinical benefits. (Paragraph 70 of the guidance v2.4).

Q. Products have to have at least 5% share of prescription volumes to be in a cluster. Invariably, these products may well have taken several years to get to this position by the very conservative nature of product uptake in the NHS. The existing price increase mechanism over that time may have allowed a price increase perhaps of 5-10% over 7-8 years (this is a calculation you can make) which means that the cluster baseline price may well be biased towards lower priced products. New products might not be able to compete due to increases in clinical development, evidence development, manufacturing, labour costs, energy prices etc that may well have increased hugely since a cluster product was introduced several years ago. It must be possible to factor this into your reference pricing to avoid biasing the process for new and innovative devices as ultimately it will be the patient that is denied more modern and perhaps more effective medical devices in primary care?

- If the product is innovative and more effective then the application should score higher points in quality which would justify a higher price point. Or the product could potentially be put in a different cluster and not compared on price.

Q. As there is currently no explicit resubmission pathway post-deadline for taxonomy changes, what is the process if the taxonomy changes after the submission deadline for suppliers to resubmit if they believe they belong to a different cluster?

- Once the cluster placement has been decided by NHS Business Services Authority (NHSBSA), and the panels where required, these will be shared with industry and there will be the opportunity to appeal your cluster placement.
  [This question was added 19 November 2025.]

Annual Price Increases

Q. I am concerned my product will be at a disadvantage depending when their current annual price increase is due, so will potentially miss out on their increase for a year.

- No product is at a disadvantage with regards to timings for annual price increases as products can freely propose a price, with the knowledge that prices will be fixed for a year. The last deadline for applying for an annual increase is a minimum of 3 months before the renewals starts.

Q. Can you please clarify how the annual price increase mechanism works under the new process?

- If you are due an annual price increase during the renewal period you can still apply for this – however in order for this uplift to be reflected in the tariff this needs to be completed a month before the end of the renewal period in order to see 1 months uplift before the new prices take effect.
- This price is then superseded by the renewal process, where each applicant submits a new application with a proposed price – which the scoring is then based off.

Exceptional Price Increases

Q. How will EPIs fit into the updated process?

- The Exceptional Price Increase (EPI) process will remain in place, however, if the cluster includes ongoing EPIs at the point of review, NHSBSA reserve the right to postpone the renewal period until the point at which the EPI expires if they deem it appropriate. Renewal periods, once commenced, supersede any ongoing Annual or Exceptional Price Increases, with the date at which the new price is listed becoming the new anniversary date for the product. See the Part IX application guidance for further information.

Related key topics

Independent Advisory Panels

Q. Concerns around impartiality of panels and how it can be ensured there is no unconscious bias – particularly around the distinction between satisfactory vs good

- The Independent Advisory Panels will have diverse membership to ensure that different perspectives are accounted for and reduce the potential for bias, including clinicians, patients, NHS Commissioners involved in formulary production and independent experts (e.g. from academia). Any panel members' conflicts of interest will need to be declared up front. Panel members will also take part in training ahead of sitting on the panels to mitigate against this. Panel members will be aware suppliers are able to appeal against scores, and therefore they must be able to justify decisions taken.
- There will also be review points (including engagement with stakeholders, e.g. industry) and opportunities to amend the process to ensure an objective assessment, with the first review point being after the first wave of products are assessed.

Q. Concerns around the volume of products the panels need to assess

- We will share further details on the panels in due course but we are working to ensure we have robust panels with the necessary diverse expertise.

Q. Can you also provide information on how you will recruit the panel members and the level of experience you will require.

- The chairs will be formally appointed by the public appointments team. The chairs will be involved in final appointments of panel members. The opportunity is advertised on gov.uk.

[Updated 08 July 2026]

Q. Can you also confirm how long you anticipate the assessments will take bearing in mind there are over 2000 brands on Part IX. How many reviews do you anticipate being undertaken each day?

- We don't expect 2000 unique applications for wave 1. It is closer to 400 and split between 2 panels.

- We recognise this is a significant assessment and are recruiting up to 26 panel members to cover it. The chair will ensure consistency of scoring and moderation meetings will cover the cluster.

Q. We heard that DHSC may be thinking of having some sort of reduced information for the panels – will the panels be able to read all the evidence? Will summarising the evidence be robust enough?

- This is not true, the panels will be passed all of the evidence for the section they are assessing.

Q. Please can DHSC explain their thinking behind having only half of the panel reviewing some applications and half reviewing others. We understand there will be a lot of work, which we have warned DHSC about numerous times – we are concerned having variation of panels will bring inconsistency to the process? Can DHSC show us the methodology for ensuring consistent decision making and transparency by panels?

- Ahead of the renewal period the independent panel members will receive comprehensive training in order to apply the assessment framework consistently across all categories.

- While specific experts with the most relevant clinical experience will review the applications initially, these scores will be brought to the Panel meetings for discussion and agreement. This entire panel will be provided with the documentation ahead of the meeting in order to provide any comments on the assessment outcome. The chair will oversee the entire process to ensure a fair and consistent process.

Q. Can DHSC tell us the process and membership for the new group looking at Wave 3 taxonomy? Will this process be repeated for Wave 4?

- The work is ongoing and is being supported by panels within the NHS England Medicines Value and Access Directorate, that have been established as part of a separate piece of work looking at prescribing models for stoma, continence and wound care.
- Given this group have the relevant expertise they have been passed the draft taxonomy that was shared on 31 March 2025 with additional questions for them to consider based on further feedback from industry. In addition to this if at the time of renewals there are additional changes to the taxonomy that the independent panel decide are required these will be implemented. For example, this could be due to further products being listed that require new clusters.

Q. What is the background of the patient representatives, and how many will there be?

- The appointed patient representatives are people with lived experience but we have also reached out to charities/patient organisations in case they have anything to share to support, for example patient surveys or reports.
- Patients are not assessing products, but act as support and provide information that helps inform panel discussions. For wave 1 we have 9 patient representatives in total.

  [This was updated 08 July 2026]

Q. How many members will be on each panel and will there be transparency for industry on the expertise they bring to each of the product categories?

- The members and job titles of the panel members have been published on gov.uk [Drug Tariff Independent Advisory Panels: Part IX - GOV.UK]

[This was updated 08 July 2026]

Q. How does the process work for the panel scoring?

- Panels are responsible for scoring quality criteria. Where possible we have clarified the language for the scoring, but ultimately we require the expertise and judgement of the panel to decide on the individual strengths and evidence of the application.
- The scoring is not based on the hierarchy of evidence but on demonstration of the criteria relating to the product claims being made.
- The applications will be reviewed by multiple individuals, in addition to this prior to scoring there will be calibration meetings to ensure consistency.
- The chair will also ensure consistency of scoring and moderation meetings will cover the cluster following the independent scoring. NHSBSA will take a similar approach for social scoring.

[This was updated 05 February 2026]

Q. You have stated there will be c. 400 applications for wave 1, have you assessed the time it will take to review each application and score it?

- Yes we have. We have built in extra resource and the applications are split amongst the panels and BSA for scoring. We will also consider the operational experience and processes when we undertake the wave 1 review.
[This was updated 05 February 2026]

Temporary listings

Q. What documents will be used for a temporary listing application? Also, what will be the criteria to move from temporary to a permanent listing?

- There is not a separate application template for temporary listings. NHS Prescription Services, NHSBSA are already considering them. Companies should apply as per normal and if BSA thinks a temporary listing (rather than a rejection) is an option then it will be considered.

- On review if the company have the evidence they were previously missing, e.g. of use in the community/at home and assuming there is nothing adverse resulting from it then it would be granted permanent listing. We plan to seek feedback from ICB teams on these ones too.

Q. Will all new product listings from now until the 1st wave of review for Wound Care automatically be set to temporary listing until clinical evidence has been evaluated?

- No. We will continue to grant permanent listings. Until confirmed it is not certain which products will be renewed in wave 2.

Appeals process

Q. Can you confirm when a company appeals what information they would need to provide to be successful. We have agreed that they need to lodge an appeal within c. 5 days but how long will they have to put forward the additional information.

- An appeal does not require new information to be submitted. We assume the appeal is because they are not happy with the score and if it's a quality score BSA will check the consistency of scoring across similar products to check. And if it's social then another team in BSA (to the one who scored) will check the consistency.

Q. What is the timeline for complaints?

- Following disclosure of the scores (for new applications and renewals) the applicant should email partixrenewals@nhsbsa.nhs.uk within 5 working days with their intention to appeal, providing information on what is being appealed against. If any further information is required, applicants will be notified at this point. If the applicant wishes to provide further information they will be given a timetable for doing so. NHS Prescription Services and Independent Advisory Panels review appeals, and the score will be adjusted where applicable. NHS Prescription Services aim to complete any appeals within 20 working days. This timeframe is subject to review after the first wave.

Q. In current guidance a company can't challenge their score (appeal) on quality if they pass, only if they fail. Why is this?

- The aim of the applications and renewal process is ultimately to be listed on Part IX of the Drug Tariff. If you achieve a quality score, that enables you to be listed on the tariff then there is no material benefit to appealing your score. The scores are not shared so it would be an unnecessary burdensome addition to the process.
  [This was updated 05 February 2026]

Impact of the updates on the wider system

Q. How will the update of the Drug Tariff be trickled down to Formularies?

- Formularies are developed at the local level, Part IX is a list of the medical devices available for prescribing in primary care and in the community. Through increasing the comparable categories on Part IX we are making it easier for those developing formularies to see the comparable products that are available.
- As a separate piece of work DHSC are looking to develop guidance on the development of formularies for medical devices.

Q. How will changes effect downstream data e.g. upload to prescribing platforms?

- Once the changes have been made in the Drug Tariff these will be picked up and reflected in prescribing systems. We are engaging with prescribing systems to ensure this process is as smooth as possible.

Q. How long will deselected products remain in tariff i.e how long to clear stocks
Q. How will the DT handle a category where a very high proportion of patients are using products that fall outside the pricing restrictions of the scheme. Potentially hundreds of thousands of patients will need to now be given alternative products which is not conducive to a busy NHS.

- What we've learnt through this process so far is that there are a lot of products on Part IX where the company is no longer operating or supplying a particular product. Part of why we're doing this is to validate the list to what's actually available and so that pharmacists are reimbursed for what they dispense.
- If any products do not pass the process, 6 months' notice will be given for delisting. However, if it is identified that the system needs longer to adapt to alternative products then we reserve the right to extend the notice of deletion. This may be because of the need to allow for effective switching for patients. A list will be compiled and shared with ICBs so that patients can start to be switched onto other products where required.
  [This was updated 05 February 2026]

Q. How will the changes be communicated to prescribers and dispensers

- Products for deletion get a black dot next to them in the Drug Tariff;
- Products to be removed also get updated on dm+d to 'not prescribable on the NHS', so that this is reflected in prescribing systems.
- This will be complemented by regular comms which already go out on changes to the dm+d database and networks.
- A list of any products being removed will be compiled and shared with the ICBs so that patients can be gradually switched onto other products where required.
- The other changes to categorisation and pricing will feed through from the published Drug Tariff to prescribing systems.

  [This was updated 05 February 2026]

Wave 1 review

Q. Please can you explain what will happen during the post wave 1 review. Is this an opportunity for resubmission of any SKU where scoring was not met?

- This will take place following the renewals process.
- This review will enable us to understand if the new process operates in the way that is expected and to make any adjustments as needed. It will also review process steps to ensure its as optimal for us and industry as possible. There will be an opportunity to feedback and collaborate on any proposed changes during the wave 1 review.
- The wave 1 review is not an opportunity to resubmit where a product has failed. During the renewals process, once the scores are shared there will be an opportunity for suppliers to lower their price if they have failed on price, in order to remain listed. There will also be an opportunity to appeal if they have failed. After this, the suppliers cannot apply to relist the product until the product has been delisted and removed from Part IX of the Drug Tariff.

Other initiatives

Q. How do the Part IX reforms link in with other initiatives?

Value Based Procurement:

- DHSC have ensured that, where appropriate, there is consistency with Value Based Procurement principles. DHSC are developing standard guidance for MedTech Value

Based Procurement for application in secondary care procurement from early 2026. The enhanced assessment framework for Part IX of the Drug Tariff is relevant to setting the reimbursement price of products prescribed in primary care and allows the Tariff list to be produced, it does not however rank or advise on products for purchase.

Late Stage Assessments:

- The Late Stage Assessment outcomes do not directly impact the Part IX assessments, they are more relevant to those making the prescribing decisions.

Supporting SMEs

Q. How will you support Small to Medium sized Enterprises (SMEs) through the application process?

- Throughout the development DHSC has worked closely with industry to refine the updated process, including SMEs. In response to feedback, in order to support SMEs we made the following amendments:
    - introducing an updated application form to streamline the process,
    - extending the notice period to 6 months in order to allow longer to complete paperwork,
    - introducing temporary listings to support evidence generation – this is likely to particularly benefit SMEs, who may have less resource to meet all the criteria requirements on first application.

Q. Have DHSC undertaken any scenario planning on the risks to patient supply if market leader(s) in a category are delisted. We know that other suppliers cannot fill the void immediately, in fact supply chains can take months to react to any potential market shortage.

- We are giving 6 months notice of deletion, with scope to extend in exceptional circumstances, for instance, patients need longer be supported to switch product.

- This scenario already happens when companies decide to delist products.

- In para 114 it states that NHSBSA reserves the right to extend the notice period of removal if appropriate, for example reasons affecting supply.

Q. The estimated savings will be detrimental to the business environment and may encourage companies to withdraw from the UK market.

- The new policy may result in some products needing to reduce their prices to remain listed. The higher reductions in prices will more likely be experienced by products that are lower in quality and higher in proposed price. Comparison between products can increase awareness of different brands amongst prescribers, which can support small and medium sized businesses to enter the market.

- The proposals are designed to support innovation. The enhanced assessment process will allow comparison between products based on their merits. This should increase transparency and competition and by extension patient choice, therefore encouraging new products and small and medium sized businesses to enter the market.

Q. The projected savings may cause products to withdraw from the market – impacting patient and clinical choice, putting legacy products at risk, creating supply resilience issues and putting an extra burden on NHS staff to support with product switching.

- This is not a procurement - Part IX will remain a list of devices available to be prescribed in the community via the FP10 prescription route. NHS organisations involved in the creation of formularies and medicines optimisation teams and organisations responded very favourably to our proposals as it aids their understanding of comparable products.
- The enhanced assessment framework makes it possible for products to pass with only the required certification under regulations, if their price is appropriate. Where companies are claiming that their product achieves better results, if they can evidence this a higher quality score can be achieved and this may allow for a proportionately higher listing price.
- It is difficult to identify which devices are broadly comparable. The increase in understanding from these proposals is intended to increase meaningful choice, not to decrease choice for clinicians and patients. Comparison between products can increase awareness of different brands amongst prescribers, which can support small and medium sized businesses to enter the market.
- If any products are identified for removal, 6 months' notice will be given. A list will be compiled and shared so that patients can start to be switched onto other products where required. In most cases a removal would be because the product has been identified as discontinued or not prescribed in the past 24 months.

Risks

Q. Have DHSC calculated the hours needed by companies to complete renewals for every SKU?

- As per the Impact Assessment we have estimated the cost impact for businesses which included hours completing applications. We do not expect different answers for quality and social for every SKU, they would be the same across the product.

Q. How will BSA cope with the amount of information they will receive at renewals when they already have an average 6 month backlog on applications?

- The Prescription Services team at NHS BSA has recruited a significant amount of additional resource. In addition, the new process has an application form clearly setting out what information is required for each application. This has been designed with the aim of simplifying the process for both applicants and NHSBSA and should mean there is much less back and forth between NHSBSA and applicants. Further to this, currently NHSBSA are responsible for assessing all of each application, under the new process it will have the support of the Independent Advisory panel who will be assessing the quality criteria of applications.

Q. Are DHSC fully aware of the risks associated to impact on supply chain (and manufacturing complexities) if any large company has to remove a product from the market? Product lines / adjustments can take month / years. Capacity to fulfil another major companies orders would be unrealistic in timeframes outlined by DHSC

- DHSC recognises the potential risks associated with a product is removed from the tariff either through a delisting decision or a decision by a supplier to remove a product from the tariff. DHSC need to balance this risk with the need to ensure the products available on the tariff are of appropriate quality and are cost effective.

Q. Considering the levels of uncertainty for industry and the level of work in phase 1 of Part IX reform, would DHSC not reconsider just doing categorisation first, then testing the matrix before rolling this huge reform out?

- As outlined in the Impact Assessment this was considered as part of the options analysis as part of the policy development. In addition to the recategorization of Part IX, DHSC and NHSBSA are moving forward with the updates as outlined in the Part IX policy paper:
    1. Introducing a renewal process to Part IX - to keep the Part IX list up to date with clinical practice and ensure value to the NHS.
    2. Apply an enhanced assessment process for products to be listed on Part IX - in order to validate claimed product features and benefits with clinical experts or patient representatives when assessing the evidence, relative efficacy or patient benefit.
    3. Introduce temporary listings process – to support the adoption of innovative products into the NHS to benefit patients, including where innovation is happening at pace.