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

Version Updated 25 September 2025

Contents

Questions on Timings

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

- The patient report has been delayed as have had clinicians checking it with comments to action. We are not changing any of the quotes used as that is the patient's perspective but there are some clarifications needed to be provided to aid understanding amongst prescribers and patients. We are aiming to publish in October now.

Q. What is the latest status of the Categorisation?

- Categorisation was last shared on 31 March this year. The wave 1 categorisation is now available on the NHSBSA Part IX website. There are some small changes from the 31 March version following feedback. These include:
- In POCT –
    - Amendment to 6.4.1 - it previously incorrectly mentioned a brand name
    - Amendment to 6.9 - Renaming the 'apomorphine delivery' subcategory
- It is not our intention to only share categorisation at the time we initiate renewal, however we haven't been able to work through all the feedback from April yet. Comments on other waves are currently being considered by the NHSE Subject Matter Experts and clinical input panels and will be shared as soon as confirmed. The intention is not to wait until we're initiating each wave.

Q. Can you confirm that if a company within Wave 1 submits a product for Drug Tariff listing before the notice period starts in September/October 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. 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.

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 be August – October 2026

- There will be a post action 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.
- So for wave 1, you will see the updates in the tariff in Oct 2026, and then for those products that are being delisted, they will remain on the tariff until Jan 2027.
- We are not sharing detailed timings for wave 3 and 4 given the potential for change in the post action review. But broadly following the same logic if nothing changes in the post action review we anticipate the wave 3 assessment would be in early 2028 and the wave 4 assessment would be in early 2029.

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

- The application form is now available on the NHSBSA Part IX website.

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 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. 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.

Questions on the enhanced assessment framework

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. 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.

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.

Social

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.

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.

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.

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 the 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 Oct 2026 Drug Tariff. This is the case whether the renewal application results in an increase or a decrease in price.

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 impossible 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 2.1).

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.

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. We will be seeking panel members around November and the chair will be involved in final appointments of panel members.

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 accurate, 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.

- 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 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.

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.

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.

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.
- 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 man 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 the applicants 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:
    - 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.
    - 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.
    - Introduce temporary listings process – to support the adoption of innovative products into the NHS to benefit patients, including where innovation is happening at pace.