NHS
Business Services Authority

Department of Health & Social Care

AN INTRODUCTION TO PART IX OF THE DRUG TARIFF

Produced by the Department of Health and Social Care and the Part IX Drug Tariff Industry Forum

CONTENTS

Version	Date	Amendment History
1.6	May 2022	Updated by DHSC and NHSBSA to include guidance on promotional policy, changes in regulations, signposting for further information and update to process following COVID.
1.7	September 2023	Update to paragraph 5 to reference the change to the DT1A form to include a question about the applicant's intent regarding supply to Northern Ireland during the agreed transitional period.

Executive Summary

‘The Drug Tariff – National Health Service England and Wales’ [from hereon – the Drug Tariff,] is a monthly publication issued by NHS Prescription Services of the NHS Business Services Authority (NHSBSA) on behalf of the Secretary of State for Health and Social Care. The Drug Tariff outlines what contractors will be paid for providing NHS services i.e. for reimbursement of the costs of drugs, appliances etc and remuneration [as part of a dispensing contract].

This guidance refers to Part IX of the Drug Tariff. Part IX contains a list of appliances and chemical reagents approved by NHS Prescription Services on behalf of the Secretary of State for Health and Social Care for prescribing at NHS expense by an appropriate practitioner.

Manufacturers and distributers wishing to supply an appliance or chemical reagent for NHS prescribing must first seek approval from NHS Prescription Services for inclusion of that product in Part IX of the Drug Tariff. This guidance aims to assist manufacturers submitting products for inclusion into Part IX of the Drug Tariff. NHS Prescription Services compiled this guidance for manufacturers and suppliers of medical devices on behalf of the Department of Health and Social Care in conjunction with the Part IX Drug Tariff Industry Forum.

Description of Part IX of the Drug Tariff

1. Regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 provides that the Secretary of State must compile and publish a statement, referred to as the Drug Tariff; which must include, among other things, the list of appliances and chemical reagents dispensed, or expected to be dispensed, in accordance with NHS prescriptions. NHS Prescription Services deals with applications on behalf of the Secretary of State. Part IX of the Drug Tariff – this list – contains the appliances and chemical reagents, which can be prescribed by prescribing practitioners at NHS expense.

2. Part IX has four sections:

   A. Dressings, bandages and certain other appliances;

   B. Incontinence appliances;

   C. Stoma appliances;

   R. Chemical reagents.

3. The Drug Tariff is published monthly and is available electronically from NHS Prescription Services' website http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx

4. Manufacturers wishing to supply appliances and chemical reagents for the primary care market must seek approval from NHS Prescription Services (on behalf of the Department of Health and Social Care) for inclusion of a product in Part IX. The aforementioned Regulations provide that the Drug Tariff must state the prices at which the dispenser's reimbursement for appliances is to be calculated.

Geographical Basis and Devolution

5. The Department of Health and Social Care's responsibilities in relation to Part IX of the Drug Tariff extend only to England. The National Assembly for Wales operates a common policy with the Department of Health and Social Care and therefore the Drug Tariff currently covers both England and Wales. Scotland and Northern Ireland maintain and publish separate Drug Tariffs, and manufacturers are advised to check their individual arrangements[1].
   Further information on inclusion in the Northern Ireland and Scottish Drug Tariffs can be obtained from their websites:

   eVadis Team, Edinburgh:
   https://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/

   Business Services Organisation, Northern Ireland:
   http://www.hscbusiness.hscni.net/index.htm

[1] Since 26 May 2021, the EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) has applied in EU Member States and Northern Ireland, and these will also apply for a transition period in Great Britain. For the purposes of collaboration and transparency, the DT1A application form currently includes a question about the applicant's intent regarding supply to Northern Ireland.

Appropriate Practitioners and Supplementary Prescribing

6. A listing in Part IX enables products to be prescribed on the NHS by GPs, dentists (if they are also listed in the Dental Formulary), appropriate practitioner prescribers, provided this this is done within their competency, supplementary prescribers (where this is part of an agreed clinical management plan), and community practitioners (Part IXA only).

7. An Appropriate Practitioner is a non-medical prescriber and includes a range of professions including doctors, nurses, pharmacists and a number of allied health professionals (AHPs). More information on which AHPs can prescribe is available here. Some qualified Supplementary Prescribers can also prescribe under agreed Clinical Management Plans. Dentists can prescribe medical devices on the NHS if they are listed in the Dental Formulary. Similarly, Community Practitioner Nurse Prescribers can prescribe any medical devices on the NHS if they are listed in the Nurse Prescribers' Formulary (all Part IX devices are included in the formulary).

Medical Devices

8. The regulation of medical devices/appliances is changing due to the UK leaving the EU. Applicants are advised to visit the Medicines and Healthcare Regulatory Authority (MHRA) website for the latest advice.

Criteria for Inclusion of Products in Part IX

9. Applications must meet the following three criteria for inclusion in Part IX of the Drug Tariff:

    - The products are safe and of good quality;
    - They are appropriate for GP and, if relevant, prescribing by appropriate practitioners;
    - They are cost effective.

10. In the comparatively rare situation that NHS Prescription Services seeks independent advice on these issues; responsibility for the final decision will remain with NHS Prescription Services. For example, for applications of an innovative product, NHS Prescription Services may seek external expert advice.

Safety and quality

11. Manufacturers and suppliers have a responsibility to ensure the medical devices they supply comply with the relevant UK legislation, and to supply copies of the appropriate certificates as evidence. Manufacturers and suppliers are also responsible for the currency of the listings in the Drug Tariff and must inform NHS Prescriptions of any changes to the original certification submitted which will affect the listing.

12. The following should be noted.

- From 1 January 2021, all medical devices, including in vitro diagnostic medical devices (IVDs), placed on the UK market, must be registered with the MHRA. There will be a grace period for registering, these dates are different for Northern Ireland - please refer to MHRA guidance https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk
    - Class IIIs and Class IIb implantable, and all active implantable medical devices and IVD List A products must be registered from 1 May 2021;
    - Other Class IIb and all Class IIa devices and IVD List B products and Self-Test IVDs must be registered from 1 September 2021;
    - Class I devices, custom-made devices and general IVDs (that do not currently need to be registered) must be registered from 1 January 2022.

Appropriateness for GP and other prescribers

13. Appliances may be supplied for community use by means other than on an FP10, and some appliances may be appropriate for use in the community but not appropriate for prescribing on an FP10. An example of this is when it would be more appropriate to loan a medical device to a patient rather than prescribing it – when it becomes their property. The supply on prescription may not be the most cost-effective route of making the appliance available in the NHS, and NHS Prescription Services may challenge this proposed route of supply, if they think this route of supply would be too costly. Similar considerations may apply where products which are supplied in pack sizes are not appropriate for individual use.

14. Appliances considered appropriate for prescribing by GPs and other prescribers will usually be for self-administration by the patient, perhaps with the help of a carer. Some appliances may need to be administered by a doctor or other health professional. These products should not require enhanced training of the doctor or health professional specifically in their use. Some medical devices are only suitable to be used by a doctor or healthcare professional in a clinical setting.

15. If a product can be prescribed by a GP or appropriate practitioner and can be used in the community, it would satisfy the above criteria. If however, a product was only suitable for use in a hospital setting it would not satisfy the criteria. The above criteria are likely only to be necessary when similar products have not previously been listed in Part IX. If a similar product is already listed in Part IX, the criteria would generally be extended to a similar product.

16. Some medical devices may not be considered appropriate for prescribing. Prescribed items allowable on an FP10 should be for the treatment of a medical condition – which can include diagnosis and prevention. This does not include items that could be considered more appropriate for the social care of an individual e.g. incontinence and sanitary pads, modified cutlery or crockery, or drinking vessels, wheelchairs and walking sticks etc. This list is not intended to be exhaustive, and NHS Prescription Services will advise on suitability, and inform the applicant of the final decision.

17. The above consideration is only likely to be necessary when similar products have not been previously listed in Part IX. If a similar product is already listed in Part IX, the criterion would generally be extended to a similar product.

Cost Effectiveness

18. Issues of cost effectiveness centre around whether it would be sensible for the NHS to pay for the device to be used. The two main considerations are:

    i. Whether the product should be reimbursed at all i.e.

    - It may be more cost effective to lend it to a patient, or to treat a patient in a clinic with the appliance.

    ii. Cost. There are two aspects:

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

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

The following paragraphs discuss these points in detail.

Whether the NHS should reimburse at all

19. This issue may arise if similar products have not been listed before. Not all appliances registered as a medical device would be considered suitable for reimbursement by the NHS if, for example, the product is for a purpose which does not form part of NHS services or if provision of the product via prescribing would be unaffordable.

Cost compared with alternative treatments

20. This issue may also arise if similar products have not been listed before. NHS Prescription Services' consideration will centre on the question of whether other products/treatment regimens are available which deal with the condition in question at less cost and/or more effectively, which translates to a similar or reduced total cost.

Cost compared with similar products

21. This question may arise if similar products have previously been listed. See Annex A.

Negotiation

22. There may be a degree of negotiation in the agreeing of a price between the applicant and NHS Prescription Services. This will tend to be a more necessary feature if information enabling acceptable comparisons to be made is unavailable.

Evidence Required

23. The type of supporting evidence required will depend on the circumstances of each application. All applications for inclusion of a product onto Part IX of the Drug Tariff must demonstrate patient benefit as well as appropriateness for NHS prescribing by GPs or other prescribers.

24. NHS Prescription Services and the DHSC welcome applications from manufacturers producing innovative devices and appliances. Applicants will need to be aware that evidence supporting innovative products is likely to need to be more robust with proven demonstrable clinical benefits for patient care. Further discussions with external agencies may also be necessary which may extend the expected and usual timelines for the application processes.

25. All applicants will need to be aware that the need for evidence is likely to be greater if Part IX does not already contain similar products. In addition, applicants may need to support their case with evidence if they are asking for a higher price than apparently similar products, which have been listed in Part IX of the Drug Tariff before. Where questions arise over the appropriateness of a listing, NHS Prescription Services will explain their concerns and clarify to the applicant what evidence might allay those concerns. Applicants are referred to Annex A for further information and guidance.

26. NHS Prescription Services will accept different levels of evidence appropriate to the device being considered. Applicants are advised that NHS Prescription Services cannot provide detailed advice with regard to the type of evidence appropriate to their submission product.

27. As NHS prescription Services are acting in the role of assessor, no face-to-face meetings / telephone conversations will be held with applicants and correspondence must be conducted via e-mail. This is to ensure transparency, a clear audit trail and impartiality. If it is felt that a verbal conversation would be easier for the sake of clarity, NHS Prescription Services will initiate the appointment.

28. If questions arise over cost-effectiveness, NHS Prescription Services will email to explain to the applicant 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.

29. When a manufacturer submits a chemical reagent for consideration, they must make an annual declaration of the free services that they will provide in order to support the use of their product e.g. the supply of educational material, meters and the provision of helplines. This is done using the CRSDF01 form available on the NHS Prescription

Services' website. If the reagent is listed, it is the responsibility of the listing holder to update this information on an annual basis.

Promotional Policy

30. Any appliances approved for listing must comply with current UK legislation regarding clinical claims. Reference can be made in plain text to the availability of the product on NHS prescription on non-promotional material and should only be made in the technical information specifically designed for the advice of healthcare professionals. This includes:
    • entries in the BNF, MIMS, Chemist and Druggist
    • articles in peer reviewed journals
    • the standard company data sheet
    • product data sheets on company websites (which must be password protected)

    Suppliers must not use terminology on any packaging, websites or promotional material which implies further involvement with the NHS or Drug Tariff, such as approved, supported, endorsed, authorised or certified.

31. Any "direct to patient" marketing or advertising material (in either hard copy or electronic format, including social media websites) promoting an appliance listed in Part IX must not make reference (express or implied) to (a) NHS approved listing; or (b) the product being available on prescription. Any breach of this provision may result in the product being recommended for de-listing. It is also important to remember that these products may require amendments to be made to their packaging to make them suitable for supply on prescription. The language and context of the packaging should be appropriate to the supply of the device on prescription.

The Freedom of Information Act

32. The Freedom of Information Act 2000 came into force in January 2005 and gives any person legal rights of access to information, which is held by a public authority. The Freedom of Information Act 2000 contains 23 exemptions under which a request for information may be refused. Submissions from manufacturers may fall under a number of exemptions from the Freedom of Information Act 2000. Manufacturers are recommended to ensure that all submissions for inclusion onto Part IX of the Drug Tariff are marked "Commercial – in Confidence" if they wish information on their applications to be withheld.

33. Section 41 of the Freedom of Information Act provides an exemption of the right of access under the Freedom of Information Act if release would be an actionable breach of confidence. This exemption qualifies the right of access under the Freedom of Information Act 2000 by reference to the common law action for 'breach of confidence'. According to that action, if a person who holds information is under a duty to keep that information confidential (a 'duty of confidence'), there will be a breach of confidence if that person makes an unauthorised disclosure of the information. The concept of 'breach of confidence' recognises that unauthorised disclosure of confidential information may cause substantial harm. For example, the disclosure of a person's medical records could result in a serious invasion of that person's privacy, or the disclosure of commercially

sensitive information could result in substantial financial loss. The law protects these interests by requiring the information to be kept confidential: if information is disclosed in breach of a duty of confidence, the courts may award damages (or another remedy) to the person whose interests were protected by the duty.

34. Section 43 (2) of the Freedom of Information Act 2000 exempts information, disclosure of which would be likely to prejudice the commercial interests of any person. It also includes a specific exemption for trade secrets. It protects not only the commercial interests of third parties but also the commercial interests of the public authority that holds the information. Under the terms of the Act, 'Commercial' can be taken to mean relating to an activity in the way of a business, trade or profession.

Further information on the Freedom of Information Act 2000 is available from https://www.gov.uk/make-a-freedom-of-information-request/the-freedom-of-information-act .

NHS Prescription Services' Decisions on Part IX listing

35. Two types of listing decision are available:

i. Acceptance – a GP or other prescriber may prescribe on the NHS for any patient or condition for which, he/she considers the appliance appropriate.

ii. Rejection – the appliance may not be prescribed by a GP or other prescriber on the NHS. Prior to a formal rejection decision, NHS Prescription Services will issue a "minded to reject" letter outlining why the application does not meet the selection criteria. The applicant should respond in writing, within a period of 28 days, either providing the additional supporting evidence required or setting out proposals to collect the additional evidence in support of the application. NHS Prescription Services will make a final decision within 28 days of the applicant submitting the additional evidence.

36. An applicant may submit a request for a review of a rejection decision by NHS Prescription Services. Applications for review are limited to:

i) NHS Prescription Services not having acted fairly and in accordance with this guidance document;
ii) NHS Prescription Services' decision is perverse in the light of the evidence submitted;
iii) Did NHS Prescription Services take into account all the relevant information available at the time?

The Review Panel cannot reverse the decision made by NHS Prescription Services; the Review Panel can only overturn it and refer it back to NHS Prescription Services for reconsideration. The application to request a review must be made in writing no longer than 15 working days following notification by NHS Prescription Services of the rejection. The Review Panel will consist of at least one Non-Executive Director of the NHS Business Services Authority who will chair the panel, an officer or nominee of an appropriate trade association and a third (neutral, with neither NHS Prescription Services nor trade association interests) member to be agreed between the two parties and

chosen from a list of appropriately qualified people held by NHS Prescription Services. NHS Prescription Services provides the Review Panel secretariat. Review panel members will have had no prior involvement with the application under review.

The place and time of meetings will be agreed with Panel members. The Review Panel will consider only the written documentation and evidence obtained by NHS Prescription Services in connection with the application and will not consider any new evidence. The Panel will have access to all the documentation, including correspondence and reviews of the decision-making process. This documentation could be made available to the Part IX applicant on request within 3 working days. The applicant will not be present and there will be no oral presentations. There will be no correspondence between the Review Panel and the applicant.

In the initial meeting the Review Panel will allocate roles and scope the format of the review. The Panel will be expected to organise suitable meetings which will be recorded and culminate in a final meeting after which the decision will be made known to NHS Prescription Services and the applicant. The Panel's final decision, specifying the reasons, should be notified in writing within 10 working days. The applicant will be kept fully informed and the final decision will be expected to be made within 3 months of the applicant requesting a review, unless an extension is requested by the Panel. The review mechanism is not intended to affect other legal rights of challenge.

Pricing

37. The DHSC has reached agreement with industry representatives on a number of issues in connection with Part IX. Two are of direct relevance to the costs/pricing question. Attached are:

    - Annex B: a statement by the DHSC on settling the entry price of products.

    - Annex C: an agreement reached between DHSC, NHS Prescription Services and the Part IX Drug Tariff Industry Forum on price rises. In reaching this agreement the Part IX Drug Tariff Industry Forum represented all relevant manufacturers.

38. For arrangements for the reimbursement and remuneration of services relating to appliances within Part IX of the Drug Tariff, please see https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff

39. If a manufacturer wants to align the anniversary dates for price increases across a product range, NHS Prescription Services can manage this request by applying the procedure outlined in Annex C.

The Application Procedure

40. Manufacturers or suppliers should complete the application forms (DT1A and DT1B) for each product or product range they seek to include in Part IX. One copy of each form, and a copy of the relevant CE documents should be sent via email to pixie@nhsbsa.nhs.uk.

41. All applications should be submitted electronically to NHS Prescription Services. The process to be followed is outlined in Annex D. Initially the forms, together with the relevant CE documents are checked for accuracy. If any information is missing, the information will be requested from the applicant and the forms submitted by the applicant will be deleted from the system. This process will continue until all of the forms that are submitted as part of the application are all correct. No amendments to forms will be made by NHS Prescription Services. NHS Prescription Services will acknowledge each form within 5 working days of receipt.

42. Once the initial application process has been completed, further instructions will be sent by NHS Prescription Services to the applicants outlining the type of digital photographs or samples that are required, and whether PDF copies of the packaging are required. If product samples are required, they should be identical to the final product, though not necessarily from a production run if this is impractical. The text of the proposed labelling should be final though it may be presented in mock-up form if the finally produced version is not available. The final electronic copy of the forms must have a digital handwritten signature applied by a Responsible person in the company. Clinical data may be attached to an email or, if this exceeds 20MB, there is a document upload facility that may be used, and NHS Prescription Services can share details on request.

Note to manufacturers – check that your application form is fully completed before sending it to NHS Prescription Services.

43. Once all the information is present the application can be formally logged. An indication of the current timeline for the application process can be found here. A number of factors may cause this timeline to be extended e.g. missing documentation, complexity of information to be evaluated and applicants requesting additional time to provide further information.

44. Manufacturers or suppliers should inform NHS Prescription Services if any changes are made to their products that affect the entry within the Drug Tariff or NHS dictionary of medicines and devices (dm+d), for example: a name change, a change in manufacturer/distributor of the product, a change in the packaging, a change to the product specification, a code change, or if the product has been discontinued. In the first instance, NHS Prescription Services should be notified of changes/discontinuations using the DT3 form available on the NHSBSA website. A new application may need to be submitted if certain details of the original product specifications change. Such changes may include change of pack size (only where the pack size is listed in the Drug Tariff) or change in size, for example a change in dimensions of a dressing. If an application is being made for an additional colour to be added to an existing lymphoedema product range at the same price, a full application is not necessary, however the manufacturer/supplier must notify NHS Prescription Services of the full product details including order code to

enable population of the dm+d. NHS Prescription Services does not require a DT1 form, certificates or a product sample in this instance.

45. Manufacturers and suppliers are responsible for the accuracy of the listing, and this includes any changes to the CE or UKCA certification which will affect the validity of the listing.

46. If the supplier of the device is a distributer and there is a change of distributer NHS Prescription Services must be informed immediately. Evidence will need to be provided by both parties showing that the responsibility for distribution has been transferred. NHS Prescription Services will not attempt to resolve any disputes relating to such changes and will refer the matter to the DHSC.

Procedure to Remove Products from Part IX

47. This procedure applies to products listed in Part IX – Appliances. Those products, which have not been prescribed during the previous twelve calendar months – using data from NHS Prescription Services' database – will be eligible for removal from Part IX. The criteria and procedure to be applied are set out in Annex E. It may also be necessary for NHS Prescription Services to remove products listed in the Drug Tariff without the agreement of the manufacturer. Although this is very rare it may occur when a permanent (i.e. not only affiliated to a certain batch) significant risk to patient safety has been identified and a safety alert issued as a result, or in cases where a legal challenge has occurred over a product which has been listed. In these situations, NHS Prescription Services will contact the owner of the listing and explain why the item is being removed from the Drug Tariff.

48. ***Contact Details***

For further details please contact:

The Drug Tariff Team
NHS Prescription Services
NHS Business Services Authority
2nd Floor Annexe
Bridge House
152 Pilgrim Street
Newcastle Upon Tyne
NE1 6SE
Telephone: 0191 2293652
Email: pixie@nhsbsa.nhs.uk

Contact details for the appliance trade associations are in Annex F, some commonly asked questions are answered in Annex G.

ANNEX A

GENERAL GUIDANCE ON THE TYPE OF TRIAL DATA AND COST-EFFECTIVENESS DATA THAT SHOULD BE PROVIDED TO SUPPORT AN APPLICATION

The economic evidence should compare the costs and health benefits/consequences of the medical device with those of the most relevant comparative intervention(s) for a UK NHS setting.
Comparative analyses such as cost-effectiveness analysis, cost-benefit analysis and cost-consequences analysis are all acceptable methods of economic evaluation.

Comparators

The most appropriate comparator(s) will represent current standard practice within the NHS.
If the new technology is being introduced as an alternative to existing products and therapies, the appropriate comparator(s) will represent the costs and health benefits of the current practices using the existing products and therapies.
If this is a new technology for which no current alternative product or therapy exists a “do nothing” approach may be appropriate which will represent the disease/care pathway without intervention.
If the new technology is associated with a number of different applications, for therapeutic areas or patient subgroups, the analysis should represent this. There may be different comparators for the different applications, therefore the economic analysis will need to represent them all.
The choice of comparator(s) will need to be justified within the evidence submitted.

Data

The effectiveness and resource use data can be collected alongside clinical trials or taken from existing published evidence or based on observational data. All are accepted methods of data collection as long as data sources are clearly stated and limitations and uncertainties of the data and methods are addressed in the evidence.
All data sources and methods will need to be explained and referenced.
The relevant costs of the alternative interventions should at least represent the associated healthcare costs (the inclusion of societal costs should be presented as a separate analysis).
The range of costs to include in the analysis may depend on the nature of the comparison.
Justification should be given for the exclusion of any cost categories.
When measuring the costs and consequences of the interventions being evaluated different methods can be used. Data can be used from clinical trials and also estimated from alternative data sources. Useful databases and information sources include:

The National Institute for Health and Care Excellence (NICE) Evidence Series incorporating the National Library for Health, providing links to clinical guidance, journals and databases, and the Cochrane Library
https://www.evidence.nhs.uk/about-evidence-services/journals-and-databases

PubMed/ MEDLINE http://www.ncbi.nlm.nih.gov/pubmed/

CINAHL http ://www.cinahl.com/

ISI Web of knowledge http://www.isiwebofknowledge.com/
The Cochrane Collaboration

http://www.cochrane.org/

National Institute for Health Research, Centre for Reviews and Dissemination (CRD), York University https://www.crd.york.ac.uk/CRDWeb/

Google Scholar http://scholar.google.co.uk/

SIGN guidelines http://www.sign.ac.uk

TRIP database https://www.tripdatabase.com/

Department of Health hospital episode statistics at https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics

Personal Social Services Research Unit. Unit costs of health and social care http://www.pssru.ac.uk/

Center for the evaluation of value and risk in Health https://cevr.tuftsmedicalcenter.org/

Sensitivity Analysis

Sensitivity analysis should be undertaken as part of the economic analysis to address uncertainty surrounding parameters, model structure and methodology, where applicable, and the impact on outcome measures and the cost-effectiveness of the new technology.

One approach to sensitivity analysis is scenario analysis. This is where a series of scenarios are created that represent a combination of alternative parameter values to those of the best representation using published data (the reference case). This will usually at least include a scenario that represents the best case and worst case scenarios, plus any other scenarios that require investigation.

Another approach is threshold analysis. Threshold values of key parameters or outcomes are identified and combinations of alternative parameter values are assessed to determine what would cause these thresholds to be exceeded and whether these are realistic scenarios.

Types of clinical evidence

Clinical evidence is not generally required if a similar product is already included in the Drug Tariff. Clinical evidence should be included where the product claims to demonstrate clinical benefits or where the product's physical characteristics claim clinical significance. Table 1 outlines the levels and types of clinical evidence.

Table 1 – levels and types of evidence. [Level 1++ providing the most robust evidence]

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++	High quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies (for example, case report, case series)
4	Expert opinion

NICE, Reviewing and Grading Evidence, National Institute for Health and Clinical Evidence (April 2006)

ANNEX B

STATEMENT BY THE DEPARTMENT OF HEALTH AND SOCIAL CARE ON THE ENTRY PRICING OF PRODUCTS

1. In the case of products similar to products already listed, the NHS Prescription Services of the NHS Business Services Authority will generally aim to ensure that the price of the new product is broadly in line with those already listed. If applicant companies want, at the time of application, to suggest factors supporting the price they are seeking they are free to do so.

2. NHS Prescription Services will take applicants' suggestions into account in reaching their views. There is no obligation on companies to volunteer suggestions if they do not wish to, though it may save time if it means NHS Prescription Services does not have to ask. Whether they do or not NHS Prescription Services will reach provisional decisions on entry pricing and will tell the applicant company, with an explanation of their reasoning. It will then be open to the company to make any points, or further points, it wishes. Listing will not go ahead until NHS Prescription Services and the company are agreed, among other things, on the entry price.

3. It is open to companies to say, with reasons, which product or products it would be appropriate to compare their new product with. If the entry price sought by the applicant is different from similar products it is open to companies to say why. The following may be relevant:

- Any anticipated difference in cash costs to the NHS arising from use of the new product (because, for example, of different product durability or different quantities required);

- Any anticipated differences in patient benefits arising from use of the new product (eg, comfort, ease of patient application, speed of recovery);

- Any other anticipated impacts within the NHS (eg savings of staff time, greater ease of disposal). Note that it would be difficult for us to reflect such factors in the entry price unless any savings are actually realisable.

4. It is recognised that considerable investment in research and development costs might be incurred in developing new products or treatment regimes. In some instances applicants might be seeking higher prices to reflect the investment they have incurred. However, DHSC and NHS Prescription Services have a duty to ensure that the NHS gets value for money. Therefore, applicants requesting a listing for new products or treatment regimes for which there are no listed comparators should provide satisfactory evidence of improved outcomes/savings/patient benefits commensurate with the requested price. NHS Prescription Services, having accepted that a product is suitable for listing, will negotiate a price on the evidence submitted by the applicant.

ANNEX C

PART IX OF THE DRUG TARIFF: AGREEMENT ON ANNUAL INCREASES

1. The agreement is between the Department of Health and Social Care (DHSC), the NHS Business Services Authority (NHS Prescription Services), which administers the arrangements on behalf of the Secretary of State, and the Part IX Drug Tariff Forum deemed for this purpose to represent companies marketing products listed in Part IX of the Drug Tariff.

2. The agreement is not intended to be legally binding on DHSC, NHS Business Services Authority (Prescription Services), the Part IX Drug Tariff Forum or the company's marketing listed products. Neither is the agreement intended to create legal rights or obligations in respect of any person. The Part IX Drug Tariff Forum will use its best endeavours to ensure that the companies adhere to the agreement.

3. NHS Prescription Services will ensure that any companies which apply for a Part IX listing, are informed that price rises will be determined in accordance with this agreement.

4. This agreement applies to price rises for which NHS Prescription Services' agreement may be sought periodically in respect of listed products. The agreement applies to branded products. Generic products receive an automatic annual price increase in June.

5. Companies may seek price rises for a particular product once a year or any longer period which they may determine. If price rises are sought at intervals longer than one year, the amount will not be greater than if they were sought at annual intervals. However, this will not prevent NHS Prescription Services from considering financially neutral applications from companies wishing, for example, to change the dates of their pricing year.

6. The maximum price rise will be calculated as being the forecast of the gross domestic product (GDP) deflator for the next financial year minus Factor X where X is currently 0.75. Factor X is subject to review. For applications made in accordance with this agreement the maximum so calculated will apply to individual products and NHS Prescription Services will grant the maximum amount unless the company applies for less. However, higher rises for some products will not be granted even if offset by lower increases for other products.

7. The forecast of the GDP deflator to be applicable will be the Treasury forecast for the following financial year current on the date the written application for a price rise is received by NHS Prescription Services. Information relating to the latest forecast on the GDP for the following financial year can be found at www.hm-treasury.gov.uk/data_gdp_index.htm. The current GDP deflator is shown here. Please note this is for the **following financial** year and **not** the calendar year.

   Companies should send applications for price rises to NHS Prescription Services two months before the publication deadline of the Drug Tariff in which the price rise takes

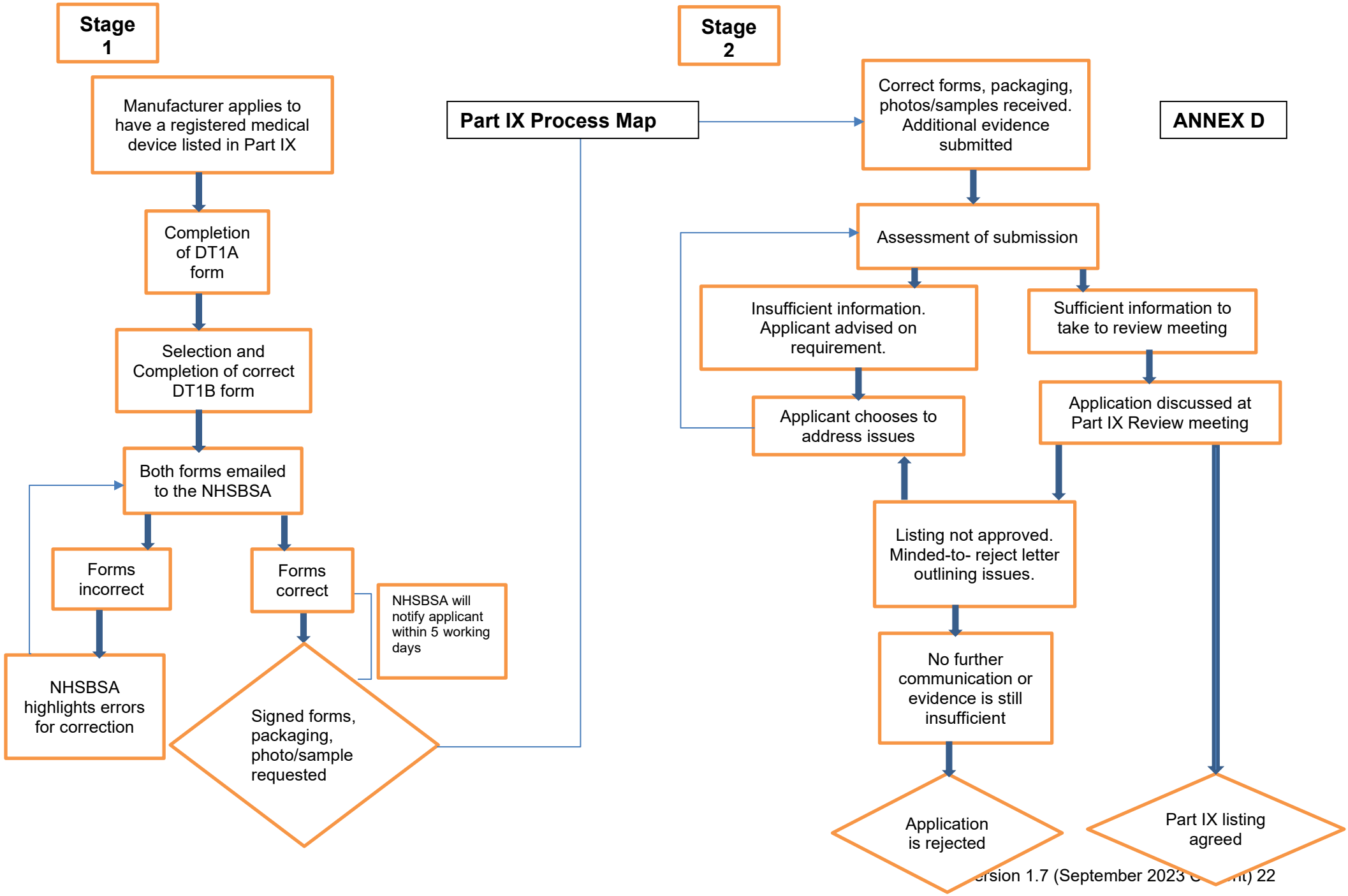
effect. A price increase request received in October 2019 would be effective for the January 2020 Drug Tariff. The price increase applied would be the **forecast GDP deflator for the following financial year**. The current GDP deflator being used for price adjustments is also shown on our website at www.nhsbsa.nhs.uk/PrescriptionServices/1818.aspx

The calculation of price rises shall be to one tenth of one penny (the unrounded sum). The price rise will be granted to the nearest penny (the rounded sum), sums of 0.5 of a penny being rounded up. The next periodic calculation shall be from the unrounded sum. No price rise will be granted where the calculation of the unrounded sum does not produce a new rounded sum. NHS Prescription Services will notify companies of both the unrounded and rounded sums.

8. NHS Prescription Services will consider applications for additional price rises for a category or categories of products where cost pressures are being incurred in exceptional circumstances. The only criteria agreed with the DHSC currently are raw material shortages where suitable alternatives are not available or the imposition of statutory duties with a recognised cost impact. If a company considers that an exceptional price increase is warranted because of an unforeseeable shortage of a key raw material, they should contact NHS Prescription Services for advice on how to proceed. Upon receipt of a request in writing a formal acknowledgement of receipt will be sent to the sender within 5 working days. NHS Prescription Services will determine the period, not less than three months, for which successful applications will be applied.

9. The parties to this agreement will attempt to resolve any disputes in good faith. Any changes or additions to the agreement will only take effect if expressed in writing.

10. There will be no formal appeal procedure if a price increase has been refused.


Stage 1
Manufacturer applies to have a registered medical device listed in Part IX
Completion of DT1A form
Selection and Completion of correct DT1B form
Both forms emailed to the NHSBSA
Forms incorrect
NHSBSA highlights errors for correction
Forms correct
NHSBSA will notify applicant within 5 working days
Signed forms, packaging, photo/sample requested
Part IX Process Map
Stage 2
Correct forms, packaging, photos/samples received. Additional evidence submitted
ANNEX D
Assessment of submission
Insufficient information. Applicant advised on requirement.
Applicant chooses to address issues
Sufficient information to take to review meeting
Application discussed at Part IX Review meeting
Listing not approved. Minded-to- reject letter outlining issues.
No further communication or evidence is still insufficient
Application is rejected
Part IX listing agreed

ANNEX E

MECHANISM FOR REMOVING ITEMS FROM DRUG TARIFF PART IX

1.1 **Discontinued Drug Tariff Part IX Medical Devices**

On notification or confirmation in writing that a Medical Device listed in Part IX has been discontinued, the appliances in question will be marked with a three-month notice of deletion and removed from the Drug Tariff once this period has expired.

The notice of deletion will also be included in the preface to the Drug Tariff one month prior to the removal of the product from Part IX.

1.2 **Review for continued listing of Medical Devices in Part IX**

The NHSBSA will request that a manufacturer/supplier confirms the following with regard to all their product listings in the Drug Tariff -

- The product(s) is/are still available under the terms agreed when it/they was/were first listed and there have been no changes to these.
- All certification is up to date.
- In the event of any changes to the above, NHSBSA will be notified immediately in writing.

The manufacturer will be offered three options:

1) Do nothing and in the following month a three-month notice of deletion will be published in the Drug Tariff for all of the listed products,

2) Write to the NHSBSA within 28 days confirming that:

(i) The product(s) is still available under the terms agreed when it was first listed and there have been no changes to these.,(ii) All certification is up to date, and
(iii) In the event of any changes to the above, the NHSBSA will be notified immediately in writing.

3) Write to the NHSBSA confirming that the product should be removed from the Drug Tariff.

The NHSBSA will provide manufacturers with a list of products they have listed in the Drug Tariff; those products with a low level of prescribing will be highlighted for particular attention. A standard form is available on the NHSBSA website for download and completion as declaration that continued listing is required.

In the event of the manufacturer being either -

a) unable to comply with the conditions of listing in Part IX of the Drug Tariff, or

b) failing to return a completed declaration form within the specified time period,

the affected product(s) will be marked with a three-month notice of deletion and once this period is completed, future listing of the products will require submission and approval of a new application for Part IX of the Drug Tariff.

1.3 Medical Devices included under a generic category

Some medical devices can be prescribed if they meet the technical specification for a generic category and these products are not listed by their brand name e.g. Absorbent Cotton BP 1988 and Gauze Swab Type 13 Light BP 1988, Sterile. NHS Prescription Services will inform the DHSC if no medical devices have been prescribed under the generic category on prescription form FP10 in the previous twelve calendar months.

Following a period of 28 days the generic category will be marked in the next edition of the Drug Tariff with three months' notice of deletion. The notice of deletion will also be included in the preface one month prior to removal from the Drug Tariff.

1.4 Appeal procedure

There will be no formal appeal procedure. Manufacturers and suppliers will use the application procedure to reapply for a product to be listed in the Drug Tariff Part IX if this is appropriate.

ANNEX F

TRADE ORGANISATIONS

ABHI
Association of British Healthcare Industries
www.abhi.org.uk
Tel: +44 (0)20 7960 4360
Email: enquiries@abhi.org.uk

BHTA
The British Healthcare Trades Association
www.bhta.com
Tel: +44 (0)20 7702 2141
Email: info@bhta.com

BIVDA
British In Vitro Diagnostics Association
www.bivda.org.uk
tel: 44 (0)8456 188 224
email:enquiries@bivda.co.uk

SDMA
www.dressings.org.uk/
E-mail : sdma@dressings.org.uk

UTA
Urology Trade Association
https://urologytradeassociation.com
Email: uta@whitehouseconsulting.co.uk

ANNEX G

Frequently asked questions

The Application DT1A and DT1B Forms

Q1*. What information is required for the general description of the product?*
We require a brief description of the main indicated uses for the device. If it is a cream, ointment, eye or ear drop we need to know the main ingredients and whether the product complies with any standards (e.g British Pharmacopoeia).

Q2. *What price and order codes should be provided?*
The prices listed in the Drug Tariff are the trade price excluding VAT. The price applied for should not be the retail price or greater because this would not meet the requirement of being good value for the NHS to fund. Pharmacists are reimbursed the Drug Tariff listed price by NHS Prescription Services when they supply the device. When the price in the Drug Tariff is for a single unit but the product comes in larger packs e.g., dressings, the unit price should be provided. The pack size for these products should also be provided. The code numbers should be the manufacturer's code for the product if it has one.
These are not always listed in the Drug Tariff, please refer to the category you are applying for. We will also require the GTIN (barcode) of the product(s) if it is not custom made.
We don't require you to provide us with the PIP codes for the products. If you require a PIP code, please contact the Chemist & Druggist.

Q3. *Does my price have to include postage and packaging?*
If the medical device is suitable for listing in Part IXA (and is not a catheter) or Part IXR, the price must include any postage costs. The listed price is the price that the dispensing contractor is reimbursed for providing the product to the patient. Unlike for medicines, pharmacy contractors do not have to provide a medical device if to do so is not part of their usual business. This means that if they are likely to be out of pocket because of supplying the device, they could refuse to provide it to the patient thus resulting in some inconvenience. If however, the product is to be listed in Part IX A Catheters, Part IX B or C, the contractor is able to claim out of pocket expenses.

Q4. *What information is needed regarding the CE/UKCA marking?*
The DT1A form must be completed for all applications, and then the appropriate DT1B form should be chosen depending on how the medical device has been registered. Both forms need to be signed with a handwritten digitally uploaded signature from an identified senior person in the company. We require copies of the relevant certificates as detailed in the DT1B form. We are aware of the extended transition periods in place for complying with both the CE and UKCA marks, including the acceptance of expired CE certificates providing certain criteria have been met. It is the responsibility of the applicant to ensure they are meeting the

transitional provisions for medical devices and in vitro diagnostic medical devices according to EU 2023/607, and the signature on the DT1A form will be indicative of this. You should take care to ensure you use the form which correctly relates to your product. Please refer to the MHRA website for the latest advice.

Q5. ***What details are required to fulfil the information required for 'Clinical demand'?***
We require you to state the estimated patient population for the type of product you are applying for e.g. if your product is an insulin pen you need to give an estimate of how many diabetic patients are likely to need to use the pen. We also require you to provide what your current or estimated sales figures will be for your product and what percentage of the market you expect to gain.

Q6. ***I am applying for a procedure pack. What application forms/certificates etc do I need to include?***
This will depend on whether a CE/UKCA mark is applied to the whole pack. Applying an overarching CE/UKCA mark to the whole pack and having the certificates applicable to the whole pack is the simplest option as you will only need to make one application. The pack will attract one prescription charge unless it comprises components which are listed separately in the Drug Tariff, in which case each of these would also attract a charge.
If you are assembling a procedure pack which does not carry an overarching CE/UKCA mark, you will need to include one DT1A form, and a DT1B form and the relevant certificates for each component. If these components are also to be separately listed in the Drug Tariff, we will require a DT1A form for the pack, and full applications for each component. You will need to make it clear in the covering email what the application is intended to cover. It should be noted that in this instance, the procedure pack would attract a prescription charge for each component listed separately in the Drug Tariff.

Q7. ***Do all the products I am applying for need to be named individually on the Declaration of Conformity?***
It is preferable that the Declaration of Conformity uses overarching descriptions of the products you are applying for. If individual products are itemised, there is a risk that products are missed off or misnamed and any product codes, if listed are incorrect.

Q8. ***I have a device which uses software or has an App component, can I apply for a listing in Part IX?***
At the moment the DHSC has directed NHSBSA that stand-alone Apps registered as medical devices are outside the scope of Part IX. We will assess medical devices which use an App as an *optional* feature, but it will not be considered as part of any price premium requested. The NHSBSA cannot assess medical devices which store patient data or transmit data to third-party devices or which rely on the ownership of a personal electronic device such as a mobile phone or computer. More

information explaining how the NHS is using Digital Technology Assessment Criteria (DTAC) to assess digital technology at the point of procurement is available.

The Assessment Process

Q9. ***What happens in Stage 1 of the process?***
Stage 1 is all about getting the information on the forms correct and complete and sending in the correct certificates to fulfil the criterion of 'safety and quality'. If the forms are incorrect, you will be told what is wrong, and asked to resubmit the entire completed form and certificates again. Nothing will be kept on our systems in such circumstances, and information cannot be added to by the BSA or 'corrected'. We will reply to this submission within 5 working days. Please do not supply photographs or samples before being specifically asked to do so.

Q10. ***Why am I being asked to split my lymphoedema application?***
Applications for lymphoedema garments which consist of multiple garment types, classes, sizes, lengths, widths, and other varying features within a single application take much longer to process and assess than other types of Part IX application. In some cases, single applications have consisted of thousands of lines of products needing to be assessed and added. In one particular case, the authoring alone for a single application took nearly 3 weeks to complete.

Requesting the splitting of these larger applications allows us to process and assess them more efficiently, speeding up overall approval timelines for these products. Splitting these applications into smaller parts also allows us to offer applicants the option of progressing some parts of the range more quickly, where no further information is required, if a significant amount of additional information is still outstanding for other parts of the same range.

We therefore request separate applications for each class and garment type (by body area), as listed in the table below. Please note that this list is not exhaustive, and this splitting process is subject to change.

LYMPHOEDEMA GARMENT APPLICATIONS (Split By:)	
Class	ONE class of garment per application
Garment Type/Body Area	ONE garment type/body area per application, for example: *Below Knee / Calf* *Thigh High* *Tights / Panty / Leggings* *Capri Pants / 3/4 Length* *Bermuda Pants / Shorts* *One legged panty* *Body Bandage* *Ankle sock* *Armsleeve* *Glove* *Toe Cap*

Q11. ***What happens in Stage 2 of the process?***
Once we are happy that the information is complete and correct you will be asked to send in the digitally signed forms, and also advised on the photographs and PDFs of packaging we require. At this point you should also send in any supporting evidence for clinical and cost effectiveness. If your submission is particularly large, you can request to upload the application on our secure file share site. For security reasons, we cannot download from a third-party site but please email PIXIE@nhsbsa.nhs.uk for details of our own system.

Q12. ***How do I provide a signature?***
We need the handwritten signature of an identified, responsible person in the company, and this should be scanned or digitally uploaded onto the forms and be duplicated as printed text.

Q13. ***What photographs/samples do I need to provide?***
You will be advised at the time of application, but usually photographs will be sufficient. These should show the device from all angles, both packaged and unpackaged with CE/UKCA markings clearly shown. These should not be stock images from websites and should be taken on a desk next to a ruler or pen so we can see the scale. We may request to see an actual sample if it is a new type of device, or a new category is being requested.

Q14. ***I don't understand what is being asked of me, and I am being asked for further evidence, can I phone or email and ask for advice?***
NHS Prescription Services cannot provide a high level of support to applicants because they are acting in the role of assessors and so must remain impartial and independent of the applicant and their submission. The Drug Tariff Part IX Forum can provide advice, please email drugtariff@bhta.com. Alternatively, there are consultants in the field who

may be able to help. If NHS Prescription Services feel that a meeting is necessary, they will contact the applicant. All correspondence is conducted using email so that files contain a complete audit trail of the application. There may be several email exchanges to this effect until the assessor considers they have all the information to take to a review meeting.

Q15. ***How long does the application process take?***
We acknowledge receipt of your initial application form within 5 working days of receiving it, and the signed form with photographs/samples and any further evidence within 15 working days. The progress of the application can be tracked using the date on the confirmation email and visiting our website. Once the assessment has started, the applicant will receive email updates on progress. The timeline to final preparation for formal review is dependent on overall workload, and turnaround time by the applicant.

Q16. ***How will I be told of the outcome of a review meeting?***
You will be notified by email of the outcome of a review meeting. If this review meeting has been successful an email will be sent to you from the PIXIE email box and will contain a PDF mock-up of the Drug Tariff entry, and the offer of a month for listing. You will be asked to confirm that the product is available and ready for distribution, for the GTIN codes, and to check the PDF. Please check the PDF mock-up *very carefully* – this is how the entry will appear in the Drug Tariff, and on the Dictionary of Medicines and Devices (dm+d) which feeds into prescribing and dispensing systems. The applicant is responsible for the accuracy of this.

Q17. ***What happens if I am unable to provide the information?***
You will usually be given the option of withdrawing the product from the process if the assessor indicates that they will be recommending to the reviewers that it does not fully satisfy the three criteria for listing. If however, you prefer for it to be reviewed, and the reviewers agree with the assessor, you will receive a minded-to-reject letter which will outline the reasons for refusal. These will have already been highlighted as deficiencies by the assessor, and you will have been given the opportunity to provide the missing information. You will have an option to provide the information within 28 days or to say how you will address the requirements and the expected timescale (which will usually be within 3 months). If neither of these can be met, you will receive a letter rejecting the application. You are free to make another application when the information is available.

After Approval

Q18. ***Can I hold an application back after it has been approved if supplies are not available?***
An application should not be made in ‘anticipation’ of supplies being available because you have signed to say that they are available. This is

also unfair on applicants who have products ready to be made available on prescription. However, we recognise that sometimes there are other unforeseen problems with distribution and we will hold an approved application open for up to 6 months but during this time no changes can be made to the agreed terms of listing.

Q19. ***I am a manufacturer of a medical device and use a distributor of my medical device who 'owns' the listing. I want to change my distributor but do not want to lose the Part IX listing, what do I need to do?***

You need to send the NHSBSA a letter from the original distributor to say they are no longer going to be distributing the medical device in the UK from a stated date. We also need a letter from the new distributor to say that they will be taking the distribution over from a stated date (which should leave no 'gap' between the two dates). If the manufacturer is the 'owner' of the listing and made the original application, there is no need to inform the NHSBSA of a change of distributor.

Q20*. What do I do if I have supply problems with a Part IX listed device?*

If you are aware that there are supply issues with a medical device listed in Part IX, you must notify the NHSBSA about this as soon as possible. If this is a temporary issue, this can be indicated in the Drug Tariff, and dispensing contractors will be asked to contact you directly for updates. If the supply is likely to last many months we will discuss the options with you.

Q21. *My Part IX listed device has been improved with different features, but I do not want to change the price of it, do I need to let the NHSBSA know?*

You should let us know of any changes to your product on the DT3 form. Staff will assess what, if any, changes need to be made to the listing. If the changes are deemed to be 'substantial' enough that it should be considered a new product, you will be asked to submit a new application. You will need to allow time for this to be assessed and will need to build this into your plans.

Q22. What do I do if the product codes are changing but my product is not changing?

If the product codes are not listed in the Drug Tariff you do not need to do anything.

If product codes are listed, you need to notify us as soon as possible and at least 4 months before the new product codes are available in the supply chain. We will need to annotate products with the old codes with a notice of code change and list the new product codes in the Tariff once the old codes have been removed. If products are not listed, they will not be reimbursed on FP10 prescription.

Q23. ***I no longer want to supply a product I have listed in Part IXA, what do I need to do?***

Please let us know as soon as possible if a medical device is no longer going to be available to patients. We will mark the entry with a 3-month notice of deletion which will inform prescribers and dispensers that it will be removed from the Drug Tariff in 3 months' time and will no longer be available on prescription. The DT3 form can also be used for this purpose.

Q24. ***I have secured a listing for a product which is to replace an existing product, what should I do?***

To manage the changeover period between the old and new listings we require receipt of the application in good time, allowing time for assessment and the minimum time to listing as outlined in the guidance. As a rough guide this will be at least 5 months. We will mark the entry with a 3-month notice of deletion, but once the device is removed from the tariff it cannot be reimbursed on FP10, so old stock should be depleted from the supply chain. The acceptance letter for the new product will offer a listing date, and this is usually the soonest date available. *Very* occasionally and, depending on where we are in the cycle for preparing the Drug Tariff, we can bring this forward a month. It is possible to have the two products listed simultaneously provided they are named differently, have different product codes (if applicable) and different GTINs.

We recognise that it is difficult to coordinate such changeovers and will work with manufacturers wherever possible to accommodate the transition. However, our processes are far-reaching and therefore relatively inflexible.

Q25. I need to increase the prices on devices which are listed in Part IX, what should I do?

There is a price increase mechanism which is outlined in Annex C of An Introduction to Part IX of the Drug Tariff, and of which you are informed when the listing is offered to you. You cannot increase the price outside this agreement. If NHS Prescription services is made aware that dispensing contractors are unable to obtain the device at the Drug Tariff listed price, and are left out of pocket as a result, we will contact you and ask you to follow the agreed process.