Part IX Frequently asked questions

DT1A Form

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. As both CE marked and UKCA marked products are accepted in the UK until June 2023, 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.

The Assessment Process

Q6. ***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.

Q7. ***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 nhsbsa.pixie@nhs.net for details of our own system.

Q8. ***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.

Q9. ***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. Generally, we will require photographs of the product if it is similar to other products and will possibly need to see a sample if a new category is being requested, and we agree in principle to this request.

Q10. ***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 help them understand the product, 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.

Q11. ***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.

Q12. ***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.

Q13. ***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

Q14. ***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.

Q15. ***I am a manufacturer of a medical device and use a distributer of my medical device who ‘owns’ the listing. I want to change my distributer 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.

Q16*. 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.

Q17. *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.

Q18. 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.

Q19. *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.

Q20. *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.

Q21. I have a device with an App component, can I apply for a listing in Part IX?
Stand-alone Apps registered as a medical device are not listed in Part IX. We will assess medical devices which have an App but this must be an optional feature and it will not be considered as part of any price premium requested. More information explaining how the NHS is using Digital Technology Assessment Criteria (DTAC) to assess digital technology at the point of procurement is available.