Part IX 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.