Important information for Applicants

Below is some useful information to help when making an application

Please read the Guidance to Manufacturers thoroughly before you make an application

- We require an electronic signature which should be provided as a scanned handwritten signature. We will not accept a cursive font or other electronically generated signatures which do not originate from a handwritten script. Please contact nhsbsa.pixie@nhs.net if you do not know how to do this.

- Please separate the application forms, certificates, labels, photographs etc and send as separate email attachments. Please do not send them as one PDF.

- Please do not make speculative applications. When you sign the declaration, the product you are applying to list MUST be ready for supply on the UK market. This adds to our workload and pushes back applications for products which are ready for the market. In exceptional and unforeseen circumstances affecting the supply chain we will consider delaying a listing for up to 3 months, but this is considered on a case-by-case basis. If this is not deemed appropriate, applicants will need to re-apply.

- The final decision regarding the category under which a device is listed will be decided by the NHSBSA. If you are unsure about proposing a category, this field can be left blank. Please remember that the Drug Tariff is not intended to be used by prescribers to guide clinical decision making. It is a *tariff* of prices.

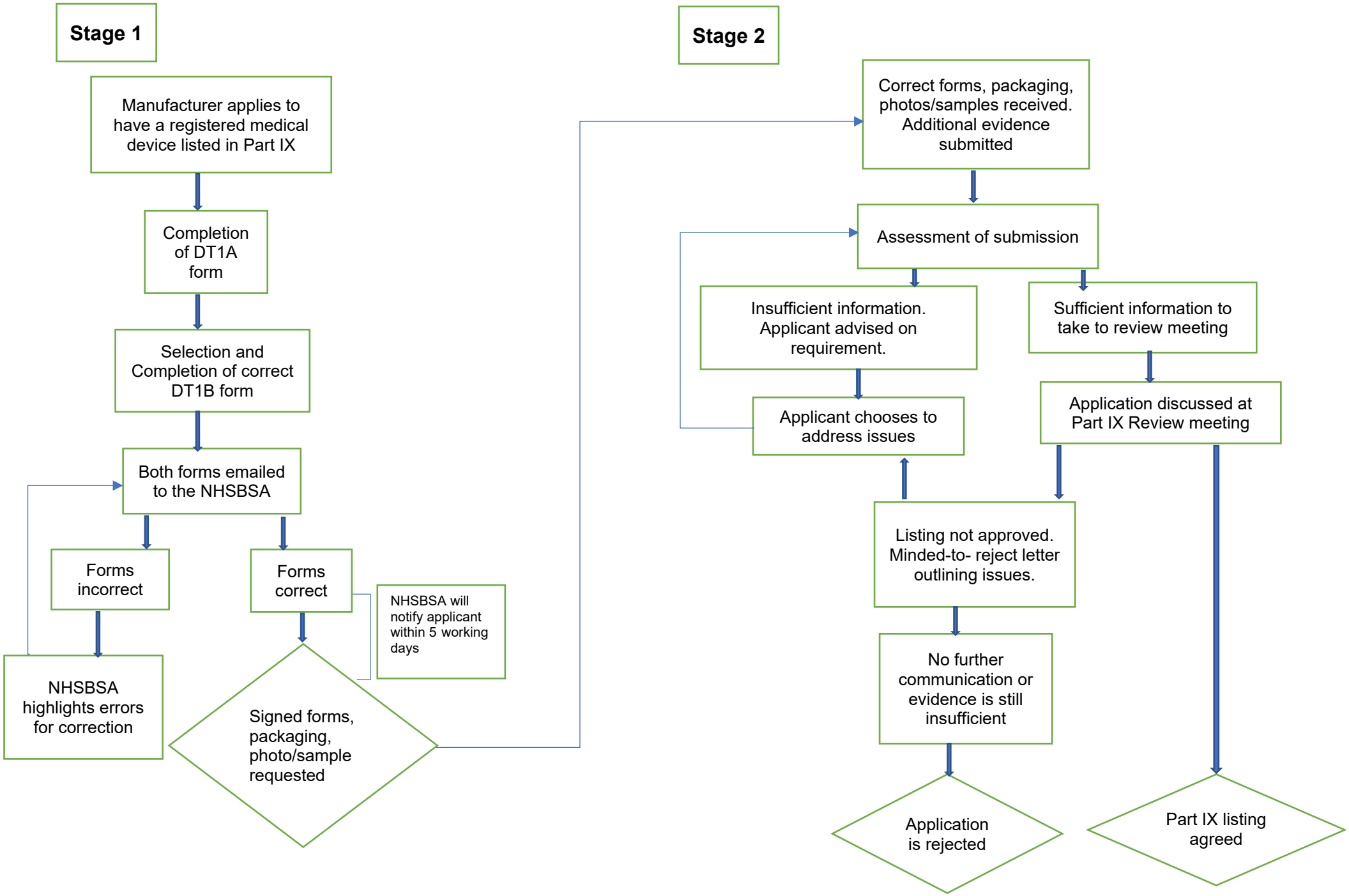
- We require good quality original photographs of the device which clearly show the product from all angles, as well as the labelling and registration marks. The photographs should include one of the device itself out of its packaging and should be taken by the applicant and not be promotional shots or taken from websites. If we are not satisfied with the quality or authenticity of the photographs, we will request a sample of the device to be sent to the NHSBSA office.

- The application form should not include all the background evidence. The application form should contain only the information specifically requested at this stage. Evidence should be supplied once the information on the DT1A form is confirmed to be correct.

- The evidence should be supplied at the second stage. It should be laid out in a logical format, ideally in a report. Tables and graphs should be clearly labelled, and key references should be included in full. Failure to do so will result in these being requested later and this will inevitably delay the assessment. If there is too much evidence to supply in an email attachment, we have a document upload facility and can supply the instructions on request.

- Supplying evidence can be an iterative process, depending on several factors including for example, i) whether there are similar products already listed ii) the price of the product iii) the strength of the evidence provided. Once assessment starts you may be asked for further information. If possible, it is our preference that this is sent in one email as this won't be re-assessed until everything we have asked for has been received.

- Please send each application on one clearly named email. This should include all the documentation pertaining to that application.


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
Forms correct
NHSBSA will notify applicant within 5 working days
NHSBSA highlights errors for correction
Signed forms, packaging, photo/sample requested
Stage 2
Correct forms, packaging, photos/samples received. Additional evidence submitted
Assessment of submission
Insufficient information. Applicant advised on requirement.
Sufficient information to take to review meeting
Applicant chooses to address issues
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