**Quality information checklist for imported Specials**

This checklist is provided to assist with obtaining information to support quality assessments for imported Specials.

It is available in an edited Word format to facilitate copying and editing in local documentation.

For guidance on how to interpret the information please refer to our article about [evaluating the quality of imported Specials.](https://www.sps.nhs.uk/articles/evaluating-the-quality-of-imported-specials)

A separate checklist for imported Specials can be found in our article about [evaluating the quality of UK manufactured Specials.](https://www.sps.nhs.uk/articles/evaluating-the-quality-of-uk-manufactured-specials)

**Quality information checklist for Imported Specials**

* Country where licensed
* Marketing authorisation holder
* Marketing authorisation (or equivalent) number
* Importer into the UK, and supplier in the UK if different
* Wholesale distribution authorisation (Import licence) number of wholesaler (for EEA medicines)
* Specials manufacturing licence number of importer (for medicines from all other countries)
* Name of product as printed on pack
* Generic name, strength, quantity/volume per container and presentation
* Photographs or artwork of all faces of carton and primary container
* Language(s) used on pack (if images not yet available)
* MHRA no objection letter (or extract/details of any imposed conditions)

***If original labelling is not in English***

* Sample English overlabel, if overlabelling offered
* Translated PIL or SPC if available
* Original PIL or SPC if translation not available

***If the medicine is an International/Emergency pack with no MA number but identical to an EEA licensed medicine***

* Manufacturer name & address
* Evidence that the product is identical e.g. QP statement confirming the site and method of manufacture are identical

***If the medicine is not licensed in the EEA (or identical to a EEA licensed medicine, as above) and is not covered by a Mutual Recognition Agreement***

* Manufacturer name & address
* Certificate of GMP compliance for the manufacturer from an EU member state
* QP Certificate for the batch to be imported, or other certification e.g. Certificate of Pharmaceutical Product
* Certificate of compliance of the finished medicine with the TSE Regulations