HTF ASSOCIATES LTD

Supply Chain Process Specialists

Import of Licenced Products from within the EEA*

The UK Parallel Import Licensing scheme allows medicinal products authorised in other EU member states to be marketed in the UK provided the imported products have no therapeutic difference from the equivalent UK products. If a licensed product for which you are not the MAH is imported from within the EEA* into the UK you need the following:

- **A Wholesale Dealer's Licence (WL) on which the parallel import option has been selected**
- **Marketing Authorisation- Parallel Importing for that particular product (using MHRA form MLA201[PI])**
- **To have informed the UK Marketing Authorisation Holder (MAH) of the product, which you are about to import, that you plan to parallel import that product.**

When applying for the Parallel Import Licence for a product you will need to submit mock-ups of the Patient Information Leaflet (PIL) and carton (or label) you plan to re-pack into - as the imported one will not be in English - as well as a report on "user testing" of the PIL (a recent requirement for PILs).

We have regulatory consultants who are experienced in this and would recommend that you use them for this on an ongoing basis.

If the MAH varies the product at all (e.g. changes the PIL wording, adds a safety comment, etc.) you are required to implement the same change.

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* European Economic Area – EC plus Norway, Iceland and Lichtenstein

HTF Associates specialises in the Supply Chain operation in the Pharma Industry. This includes outsourced supply chain management, obtaining a Wholesaler Dealer's Licence (WL) from the MHRA, selecting pre-wholesalers and advice on all aspects of Supply Chain Management in the pharmaceutical industry.

For further information and help on this topic contact HTF Associates at enquiry@htfassociates.co.uk

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