

## Unlicensed Products – “Specials”

The manufacture, importation, distribution and supply of an unlicensed relevant medicinal product for human use in the UK is termed a “special”. There is a specific category on a Wholesale Dealer’s Licence for handling specials that needs to be selected when applying.

All products must normally have a Marketing Authorisation (MA) before being placed on the market in the UK. There are some very specific exemptions in the UK to allow unlicensed products.

A special can only be supplied if:

- **There is a bona fide unsolicited order**
- **Formulated by a doctor/dentist registered in the UK**
- **Used by a patient under the doctor/dentist personal supervision (named patient)**
- **Certain supply chain conditions are met (too detailed to specify here)**

If the medical need can be met by an existing licensed product you are very unlikely to be granted permission to use a special.

The manufacturer of “specials” must hold a “specials” manufacturing licence from the MHRA

For importing unlicensed products you must notify the MHRA of your intention to import, using the standard form available on-line.

Advertising of “specials” is usually not allowed, with only the service you provide being allowable advertising. You may, however, respond to requests for information on specific products.

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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](mailto:enquiry@htfassociates.co.uk)**