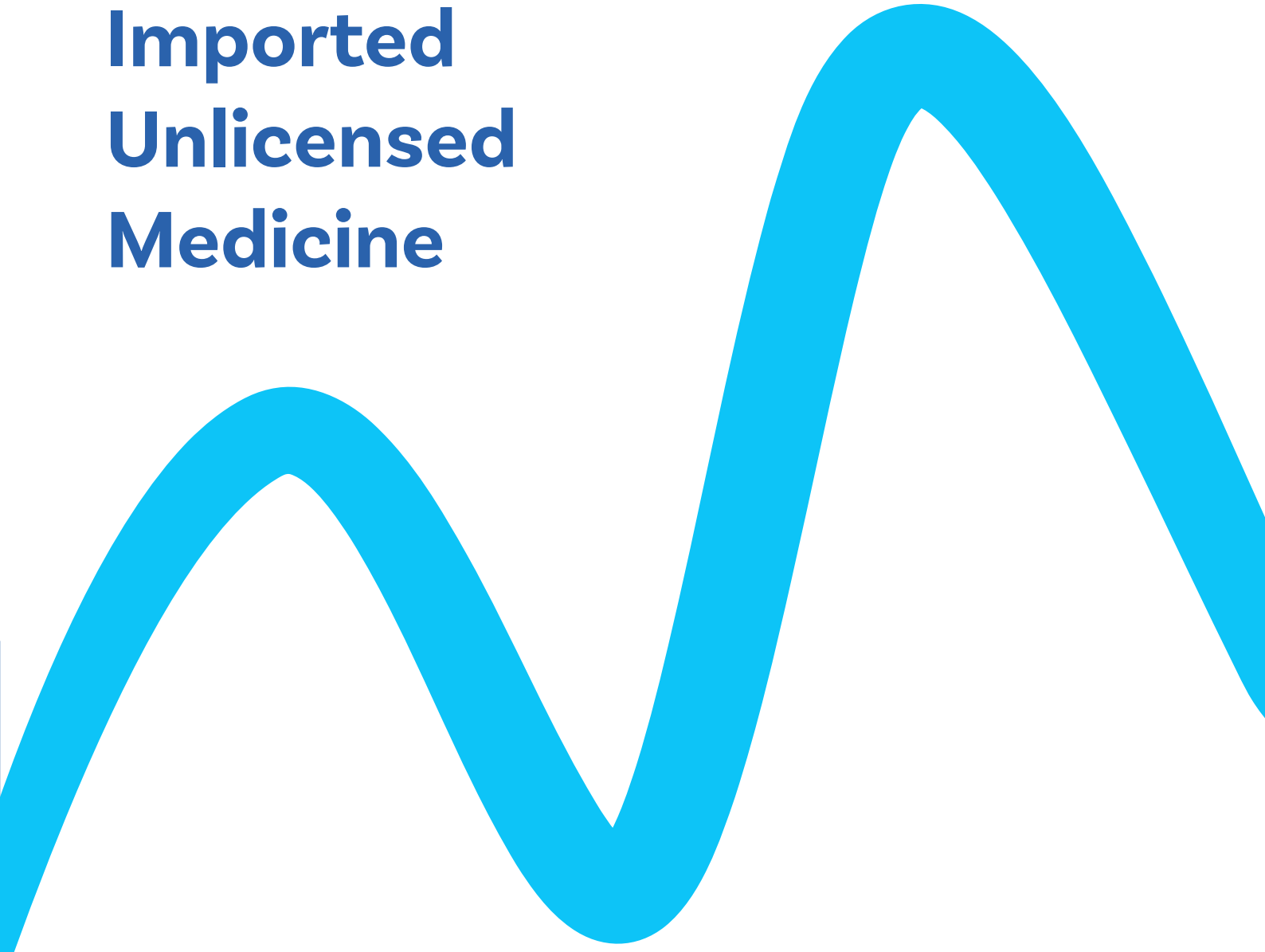
Mawdsleys

Sourcing an Imported Unlicensed Medicine



Step 1.
Healthcare professional identifies the need for an Unlicensed Imported Medicine

MHRA guidelines state that the preferred choice is for a patient to have a UK or EU licensed medicine. However there are many instances where it is necessary to seek alternatives.

There is a strict hierarchy to be followed when selecting the medicine to be used:

1. UK or EU licensed medicine
2. Off Label use of a UK or EU licensed medicine
3. An imported product licensed in another country
4. A Special product manufactured in the UK by an approved Specials manufacturer or facility
5. An extemporaneously dispensed medicine
6. An imported product not licensed in source country
7. Non-UK made unlicensed medicine or food supplement

Any medicinal product without a Marketing Authorisation in the UK (granted by MHRA) or Europe (granted by EMEA) is classed as an unlicensed medicine in the UK. An unlicensed medicine could be required in one of the following situations:

- If the medications which are licensed in the UK are unsuitable e.g. patient is allergic to an ingredient or cannot tolerate the licensed form
- If the patient's condition is rare and there are no licensed medications available in the UK
- If the UK licensed stock is temporarily MCS (Manufacturer Cannot Supply) or permanently discontinued
- If clinicians have used the medicine in a different country and wish to use it in the UK
- If new clinical trials show the medicine to be effective in other conditions, so clinicians wish to use the unlicensed medicine Off Label in the UK

Licence Requirements

To import unlicensed medicines from within the EU, a Wholesaler Dealers Authorisation (WDA) is required. To import products from outside the EU, a Manufacturer Specials (MS) licence is required (the same licence as required to manufacture and assemble specials).

Step 2.
Unlicensed Medicines Supplier Identifies Sources of Product

Mawdsleys stock over 500 imported medicines and have access to over 2,000 imported medicines. If a product is not already stocked by us, or has not been recently sourced by us, we have robust processes in place to ensure we can support hospitals in sourcing the medicines they need for their patients.

The diagram below shows the processes Mawdsleys follow when a request comes in from a hospital for a new unlicensed medicine:

Request submitted to Mawdsleys Unlicensed Customer Services

Mawdsleys Medicine Research team search global databases to identify markets the required product is licensed in. The list of identified products is passed to the Mawdsleys Buying Team

Mawdsleys Buying team contact global supply base of over 40 countries and identify suitable sources of products, requesting prices

Information is collated by Mawdsleys Medicine Research Team to assess product suitability and produce a shortlist of options based on key considerations

The key considerations taken into account by Mawdsleys when sourcing are product quality, availability, continuity of supply, product literature and cost.

Establishing the Suitability of the Product

When the shortlist of products has been produced, further work is required to ensure the products are the most appropriate for importation and use. Products should be chosen based on the MHRA Hierarchy of Preference:

1. Products licensed in EU are the preferred choice for importation

2. Products from a Mutually Recognised Country (MRC) are the next preference

3. Thirdly, products can be imported from other countries, which are not mutually recognised

Other considerations must then be taken into account:

- Is the product a Controlled Drug (CD) and will therefore require a CD import licence?
- Is a PIL and SPC available, and if so will they require translating?
- Will TSE (Transmissible Spongiform Encephalopathy) certification be required? (Requirement for importation from Non EU or Non MRC countries)

Validation of the Supply Source

Once the product is deemed appropriate for the request, checks must be carried out on the suitability of the supply source. All suppliers used by Mawdsleys Unlicensed Medicines go through a standard checking process that includes:

- Provision of documentation demonstrating compliance to GDP (Good Distribution Practice) / GMP (Good Manufacturing Practice)
- Provision of appropriate WDA or equivalent licences, plus any necessary Export and CD licences
- Confirmation that required documentation is available for all products for hospitals (where available) such as PIL and SPC
- Completion of Quality Audit to check: Adequate AE (Adverse Event) reporting process, counterfeit drug detection processes and recall notification system

Step 3.
Unlicensed Medicines Supplier Imports the Product

Once a product and supplier are approved,
the process of planning the importation can begin.

Product Set Up

The following process is followed by Mawdsleys:

Completion of New Line Form

Product set up on system

Creation of Product Summary Sheets. Photographs taken.

Product added to Mawdsleys Online for customers to view

Import Approvals

Simultaneously, Mawdsleys will apply for import approvals from the MHRA. These are required for all products that are to be sold within the UK. There are times when the MHRA will object to an unlicensed import for reasons such as there is already a centrally licensed or UK licensed equivalent product. The processes are as follows:

Need	Process
Non Critical Import	28 days from receipt of acknowledgment letter from MHRA
Urgent Clinical Import	A “Letter of Clinical Need” can be submitted to reduce waiting period

Other considerations prior to importation are:

- Is the product hazardous and therefore will it be subject to special handling or shipping requirements?
- Does the product have any specific storage requirements outside the norm?

Order Placement and Stock Delivery

If import approval has been granted, the product can be ordered and arrangements made for shipping as per the process below:

To maintain the stability of the product it is critical that, throughout the supply process, the product is stored and transported as per the label conditions. Therefore Mawdsleys ensure the temperature is monitored for all products from the start of the journey to their final destination. All temperature data from the shipment is reviewed on arrival at Mawdsleys as part of the Quality Assurance release checks that take place.

1. Mawdsleys place order with supplier
2. Supplier confirms approximate lead time
3. Product shipped to Mawdsleys as per GDP guidelines

Quality Checks

On arrival, all stock must go through quality checks resulting in acceptance or rejection of the stock by Mawdsleys QA team. Checks include temperature data check, physical product check, and checks to ensure correct and up-to-date product documentation and importation documentation are available. If the product passes checks, it will either move into stock, or move to the production booths for over-labelling if required.

Over-labelling and Translation

85% of all unlicensed products Mawdsleys supply are either in English or will have an English over-label added by Mawdsleys on to the package, as well as a translated PIL or SPC. If a product requires a label, PIL or SPC translation, Mawdsleys use a specialist translation company trained to understand medical terminology. This way we can be sure that the translation is 100% accurate. When translations are returned they are thoroughly checked by Mawdsleys' quality team before being signed off for final release.

Product Dispatch

When all parts of the sourcing and procurement process have been completed the product is ready to be dispatched. All products are transported to hospitals using fully approved GDP compliant transport. A free next-day delivery service is provided for all ambient and cold chain products to mainland UK. There are also late cut-off times to help hospitals, and no minimum order values. Mawdsleys can accept orders by EDI as well as by email and fax.

Full and translated documentation (e.g. Product Summary Sheet, PIL, SPC) is available for unlicensed medicines – these can be included with the product, or are emailed or available on Mawdsleys Online, the dedicated customer portal.

Summary

The process to identify the need for an unlicensed product, source it, import it and conduct all the necessary checks before it is dispatched to hospitals is a complex process, but Mawdsleys have everything in place to manage this as safely and efficiently as possible on behalf of our customers.

This information could be used for your Continuing Professional Development (CPD).

For Unlicensed Medicines Enquiries please contact us:

0161 742 3482 **unlicensed@mawdsleys.co.uk** **mawdsleys.co.uk**

Mawdsleys