FOI 23/580

Dear

Thank you for your email.

> *"we would like to understand if there is an NHS / Public access list for information on all current businesses with a specials (MS) licence?*
>
> *Further to this, we understand that specials tariffs are adjusted quarterly based on reported manufacturing volumes. is this information managed by the MHRA and if so, is there a coalesced repository of this information breaking down the products made and by which manufacturers?*
>
> *If this doesn't fall within the MHRA's remit, we would appreciate being signposted to the relevant area."*

Unlicensed medicines, commonly referred to as "specials", can be manufactured in the UK or imported from abroad. In order to manufacture unlicensed medicines in the UK, the licensed manufacturer will require a Manufacturer's Special Licence (MSL). If the unlicensed medicines are to be imported into the UK then, depending on the country of origin a different type of licence may be required.

The importer of an unlicensed medicinal product (a "special") into the UK must hold:
(a) a Wholesale Dealer's Licence (WDA (H)) if the product is to be imported from an EEA member state i.e. the EU plus Norway, Iceland and Liechtenstein, or
(b) a Manufacturer's "Specials" Licence (MSL) if the product is to be imported from a third country i.e. a non-EEA country, for example the USA, Canada or Australia.

- The list of WDA holders can be found here: https://www.gov.uk/government/publications/human-and-veterinary-medicines-register-of-licensed-wholesale-distribution-sites
- The list of MSL holders can be found here: https://www.gov.uk/government/publications/human-and-veterinary-medicines-register-of-licensed-manufacturing-sites

However please note that not all MSL holders can import unlicensed medicines nor can all WDA holders. You will need to engage with them directly to confirm if they are suitably licensed to do so or not.

The MHRA does not oversee the costing or funding of any medicine, we do not set tariffs, the price of medicines or whether these are funded by NHS, Clinical Commissioning Groups (CCGs) or individual trusts. Therefore we do not hold this information.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
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