Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]

10 May 2024

MHRA reference: FOI2024/00037

Dear [redacted]

Thank you for your information request, which we received on 12 April. You asked for:

> *1/ is MHRA aware that there are no suitable topical iodine based antiseptic products available to UK consumers – by which I mean available in high street pharmacies? [Of course they are available for use in hospital on a daily basis]*
>
> *(I am aware that EU regulations advised against it for water sterilising…but that is not the same as usage for topical purposes).*
>
> *2/ Is it acceptable for a licensee i.e "Market Authorisation Holder" to have a license for a product and have apparently no desire to supply it to the market? The product is readily available in other countries as far as I am aware.*
>
> *3/ Does the MHRA have the power to investigate non-supply of medicines that are licensed? Can it remove licenses from those companies not willing to supply? Should it do so in this case (Ecolab).*
>
> *4/ Does the MHRA have any remit to regulate the market for medicines and ensure there are no distortions and obstructions to access and availability of medicines? If it does, can it please investigate. If not, which organisation would cover that?*

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5/ Is it acceptable to the MHRA that a product that appears on the WHO list of essential products (under antiseptics and disinfectants) is not available to the general public when there are no obvious safety concerns?

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

Concerning your specific questions:

1. Is MHRA aware that there are no suitable topical iodine based antiseptic products available to UK consumers – by which I mean available in high street pharmacies?

There is one marketing authorisation granted for a topical iodine-based antiseptic - Alcoholic Iodine Solution BP, Iodine Tincture BP (PL 12965/0019). It is available through the General Sales List (GSL). The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are published on the MHRA website, please see link below:
https://mhraproducts4853.blob.core.windows.net/docs/2199a3f5216236921928f58e7be4ed38fc889bcc
https://mhraproducts4853.blob.core.windows.net/docs/fc91aac8de1d4e8c29d737e250ed6c350e283d43

This product currently has an exemption granted under the Sunset Clause until 03 October 2024 (see response to Q2 below).

2. Is it acceptable for a licensee i.e "Market Authorisation Holder" to have a license for a product and have apparently no desire to supply it to the market?

MHRA operates a Sunset Clause provision under Regulation 67 of the Human Medicines Regulations 2012 SI No 1916, as amended. This means that a marketing authorisation for a medicinal product will cease to be valid if the medicinal product is not placed on the market for three consecutive years.

3. Does the MHRA have the power to investigate non-supply of medicines that are licensed? Can it remove licenses from those companies not willing to supply?

MHRA does cancel marketing authorisations for medicinal products that have not been placed on the market for three consecutive years, under the Sunset Clause (see response to Q2 above).

4. Does the MHRA have any remit to regulate the market for medicines and ensure there are no distortions and obstructions to access and availability of medicines? If it does, can it please investigate. If not, which organisation would cover that?

5. Is it acceptable to the MHRA that a product that appears on the WHO list of essential products (under antiseptics and disinfectants) is not available to the general public when there are no obvious safety concerns?

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By way of background, it may be helpful if I explain the respective roles of the Department of Health and Social Care (DHSC) and Medicines and Healthcare products Regulatory Agency (MHRA) with respect to medicines shortages. The DHSC has overall responsibility for ensuring the continuity of the supply of medicines in the UK. It has a Medicines Supply Team (MST), which works closely with the Commercial Medicines Unit in NHS England who have specific responsibilities relating to many medicines procured for hospital use. Together these teams work closely with the MHRA, the pharmaceutical industry, the devolved administrations and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do arise. When notified of an impending issue, the team will conduct a thorough risk assessment and determine what action should be taken. The team will escalate the shortage issue, where appropriate to the Medicines Shortages Response Group (MSRG); a multi-disciplinary advisory body who provide oversight and support with management and communication plans. Further information on MSRG can be found here: https://www.england.nhs.uk/wp-content/uploads/2019/11/a-guide-to-managing-medicines-supply-and-shortages-2.pdf

MHRA is responsible for the regulation of medicines and works very closely with both the MST and the MSRG, receiving information about potential shortages and attending MSRG meetings. For some shortage issues, MHRA may support the manufacturer by utilising regulatory processes, if appropriate.

We have provided a list of suitable alternative topical antiseptics that are currently licensed, a link to the PILs and SmpCs for these are provided below: https://products.mhra.gov.uk/search/?search=topical+antiseptic&page=1

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

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Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information