Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

Mr [redacted]
[redacted]

9th February 2024

FOI 24/068
FOI 24/069
FOI 24/070

Dear [redacted]

Thank you for your three Freedom of Information (FOI) requests dated 15th January 2024.

Please see below your requested information in **bold** with our response to each of the questions raised within each of the three FOI requests.

Please note, we have only provided a response to the questions that have been directed to us in each of the three FOI requests provided to you by the Department of Health and Social Care (DHSC).

FOI 24/068

How many adverse reactions to PENCILIN V were recorded at Scarborough Hospital from 1992-1997.

I would like all data and documents available on the person's involved in these adverse reactions, including all public and private data and information recording these events at Scarborough Hospital from 1992-1997.

In response to the above requests, we have conducted a search of our Adverse Drug Reaction (ADR) database for reports in which the reporter postcode is given as 'YO12 6QL' or the postal address contains 'Scarborough Hospital', alongside a reported suspect medication of phenoxymethylpenicillin.

I can therefore confirm that the Medicines and Healthcare products Regulatory Agency (MHRA) has not received any UK spontaneous suspected ADR reports submitted from Scarborough Hospital between 1992-1997 where phenoxymethylpenicillin has been included as a suspect drug.

When considering the information provided above, it is important to be aware of the following points:

- Despite Yellow Card reporting being considered a professional responsibility for healthcare professionals, it is still voluntary and therefore some adverse reactions to phenoxymethylpenicillin may not have been reported.

- The accuracy of this data relies on the postcode and address being correctly provided by the reporter in the original Yellow Card.
- The provision of postal addresses is not required to submit a report; reporters are required only to provide a contactable address which can be either an email address or postal address.
- If reporters only provide an email address, these will not have been included in this analysis and therefore the true number of reports received could be greater.

What procedures and protocols were in place from 1992-1997 for those who had adverse reaction to medication and or Stevens Johnson Syndrome and what testing, be it genetic, HLA, blood or DNA was in place at Scarborough Hospital.

What was the medical guidance at Scarborough Hospital from 1992-1997 for those with suspected adverse reaction and for children with Stevens Johnson Syndrome diagnosis.

With regards to these two requests, the MHRA does not hold this information. However, as directed by the DHSC, you may wish to contact Scarborough Hospital, which may hold information relevant to these requests. The contact details are:

Website: https://www.yorkhospitals.nhs.uk/our-hospitals/scarborough-hospital/
Email: yhs-tr.FOIRequests@nhs.net

FOI 24/069

How many Stevens Johnson Syndrome diagnosis' were made between 1985 and 1998 in the UK

- **Which hospitals were these diagnosis made at?**
- **How many of these diagnosed patients have had any type of medical testing to determine the cause of their disease?**

Unfortunately, the MHRA does not hold information relating to Stevens-Johnson Syndrome (SJS) diagnosis data. We are sorry for the confusion and the inconvenience caused by the misinformation that led you to contact us. I would advise you to contact the Office for National Statistics, where you may find the information, you need. They can be contacted at Contact us - Office for National Statistics (ons.gov.uk)

FOI 24/070

I would like to know which departments of the UK government permitted the licence and use of PENCILIN V from 1983- 1993.

The MHRA are the regulator of medicines, medical devices and blood components for transfusion in the UK. MHRA was formed in 2003, following the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency. In 1983-1993, medicines were regulated by the MCA, the predecessor of the MHRA.

I would like to know who were the UK manufacturers of PENCILIN V in the UK from 1983- 1993.

Please find attached a list of licences for Penicillin V (Phenoxymethylpenicillin) that were active (granted) in the above time period. We are unable to confirm the manufacturers of the products as this information is exempt from release according to Section 41 (Information provided in confidence) and Section 43 (Commercial Interests) of the FOI Act.

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Please note that Section 43 is a conditional exemption, conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity). However, we do consider that there is a likely/definite commercial harm caused in releasing the names/addresses of the manufacturers of these products, as to divulge this would reveal the business arrangements that a marketing authorisation has with others with regards to the manufacture of their product, which could be useful to rival companies. Therefore, on consideration of the public interest, our decision is to withhold the information.

I would like to know who were the healthcare companies which sold these products of PENCILIN V.

Please refer to the attached list, which includes the name of the Marketing Authorisation Holder for each of the products.

I would like to know what brands of PENCILIN V were supplied to the North East of England from 1991-1992.

MHRA does not hold this information. The MHRA grants Marketing Authorisations for medicinal products, allowing them to be marketed, based on an assessment of their safety, quality and efficacy. The MHRA carries out inspections to check if manufacturing and distribution sites comply with the Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). However, it is not within our remit to track or record the location of supply of specific authorised medicines.

I would like to know what the guidance was relating to adverse reactions and penicillin V in the UK from 1985-1993.

You may be interested to know that you can find the product information for phenoxymethylpenicillin/ phenoxymethylpenicillin potassium products here and here. You will find Summary of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) and Public Assessment Reports (PARs) which may be of interest to you.

However, you may wish to contact NHS Trusts and NHS Foundation Trusts, which may hold information regarding the relevant clinical guidance that was available for healthcare professions to use in the UK from 1985-1993. Please see this link for the NHS provider directory.

I would like to know what were the procedures of immune, genetic or blood disorder testing and or guidance relating to Stevens Johnson Syndrome and drug allergies in the UK from 1990 – 1995.

MHRA does not hold the information you have requested. Please contact the FOI team at NHS England (NHSE) which may hold information relevant to your request. Contact details can be found here: https://www.england.nhs.uk/contact-us/foi/

The MHRA continues to monitor the safety of all authorised medicines and vaccines, including penicillin, to rapidly detect, confirm, and quantify any new risks and weigh these against the expected benefits.

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We can then take any necessary action to minimise risks to individuals, which can include updates to product information or recommendations to healthcare professionals.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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