FOI 23/618

Dear

I must explain that, because you've made a written request to the MHRA for data and information, we do need to deal with your email as a request under the Freedom of Information Act. This does mean that we will need to formally refuse your request under the FOI Act, but in doing so, I have also provided some advice and assistance below which I hope that you will find helpful

> *"I was looking to get the original fillings for Bacitracin and Daptomycin (antimicrobial peptides)*
>
> *I have looked online, but I cannot find a way to access these. Can you help me access these filings?*
>
> *I would be looking for the original papers and studies that were submitted that allowed the MHRA to approve its use.*

Section 12 of the Freedom of Information Act 2000 allows a public authority to refuse a request if the cost of providing the information to the applicant would exceed the 'appropriate limit' as defined by the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004.

The request in it's current condition would require us to retrieve physical archive boxes for a number of bacitracin products to establish the innovator products, each archive box may run to tens of 1000s of pages in length.

We would also need to consider variation applications of which there may be hundreds as these could fall within the descriptive term 'regulatory filings'.

The other point we need to mention is that if the entire regulatory filing is requested this will require a significant redaction exercise in order to remove information which may still carry commercial sensitivity or information that was submitted in confidence, equally we would need to consider redactions in relation to personal data. These activities are not subject to Section 12, but would be handled under Section 14 in terms of the burden on resource to complete these additional but necessary tasks in order to suitably prepare the information for release.

Further advice and assistance

Daptomycin
This product was first authorised in the EU, and the EMA website has a page dedicated to the innovator product which is named Cubicin. On this page you will find many iterations of public reports that have been published throughout the lifecycle of the product. The one of most interest is likely to be the main scientific

discussion, located here. The Introduction (page 1), clinical sections (page 11 onwards) may be of most relevance, including the mechanism of action (page 17).

Bacitracin
This is an older product, for example, this reference is from 1945 Bacitracin: A New Antibiotic Produced by a Member of the B. subtilis Group | Science, and according to our records there are no active marketing authorisations for this product/substance, only a drug allergy testing panel. Given the historic nature of the innovator products of Bacitracin, records will be held in paper format and will need to be requested from another site. We would suggest conducting Pub Med. based or other scientific literature searches to aid with your research question.

However, if you wish to pursue this topic with MHRA we can provide some advice for you to help narrow the scope of the request. Please note, it is unlikely that 'factors that made successful antimicrobial peptide therapies' is a topic which would be included in the regulatory dossier (filings) for a medicinal product, but we will likely hold information on the quality, safety and effectiveness of this medicine. The term regulatory filing we have presumed, as above, relates to the regulatory dossier of information which forms the main body of evidence to support the product licence, now known as a Marketing Authorisation. However, please note as mentioned above, 'regulatory filings' could also include variations and changes to product licences throughout the lifecycle of the product.

You could confirm which pharmaceutical form of the medicine you are particularly interested in; our electronic directory indicates that these medicines existed as a capsule, powder, cream, spray, ointment, ear drops, antimicrobial dressing, and soluble power for irrigation so it would help us to identify specific information that we may be able to retrieve within 24 hours if you could identify one of these. Some of these products also include a combination with other active ingredients e.g. bacitracin with hydrocortisone, polymyxin B sulphate, trypsin and others. Many of these products have two or three active substances, and any synergistic effects of these active ingredients may also be of use in relation to your research topic 'factors that made successful antimicrobial peptide therapies'. I have attached a list of products of the historical product licences, please note, 'data not held' does not indicate the data is omitted, but rather indicates instances where detail/s have not been indexed electronically.

I also noted that according to our electronic Directory Bacitracin Zinc/The Wellcome Foundation (PL 00003/5235R) is likely to include a full physical file and is perhaps the innovator product, in this file it is likely an expert report. This report may or may not be useful to your research topic, but unfortunately we will not know the content of the file unless a retrieval process is first undertaken.

Many thanks for you correspondence

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or
by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
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Yours sincerely
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