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By email 3<sup>rd</sup> September 2020

### **Re Freedom of Information Request**

Dear Dr [REDACTED]

Thank you for your FOI enquiry requesting information on the process for release and distribution of Erwinase<sup>®</sup> which we received on 11<sup>th</sup> August 2020.

Your request has been handled under the Freedom of Information Act 2000 (FOI). The information you requested and our response is detailed below:

*Dear Sir/Madam I notice from your website you clearly state "Batch available for collection" regarding Erwinase whilst I understand Jazz are your distribution partner, what does this exactly mean, ie what condition is it in and has it been reviewed by the relevant Qualified People?*

As manufacturer Porton Biopharma Limited (PBL) are responsible for producing the product, filling, testing and ensuring that it meets specification.

All Erwinase<sup>®</sup> batches are released by a Qualified Person in accordance with EU pharmaceutical regulation, as well as being independently reviewed by regulatory consultants from an international global company.

The product is supplied as a freeze-dried power in a capped and sealed glass vial along with a Certificate of Analysis to the specification required by the intended market, for example the UK, the EU, the USA, Germany or Canada.

The product is then released and made available for collection by Jazz Pharmaceuticals who are responsible for its labelling, packaging and release to those different markets. Whilst PBL are producing consistent high-quality batches of Erwinase<sup>®</sup> on schedule, we are unable to influence the time taken for collection and the subsequent release to market.



Information disclosed in response to this FOI request is releasable to the public. In keeping with the spirit and effect of the FOI, this letter and the information disclosed to you may be placed on our website, together with any related information that will provide a key to its wider context. No information identifying you will be placed on the website. If you have any queries regarding this information, please refer your request to me in writing in the first instance.

Yours sincerely

Dr [REDACTED]  
Porton Biopharma Limited