

# Outcome of the Process - Public Consultation on proposed Human and Veterinary Medicines and Compliance Fees for 2018

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## 1 NUMBER OF RESPONSES

The HPRA received one response from an industry representative group and one response from a manufacturing company. In advance of the public consultation, as part of developing the fee proposal, a number of submissions were received, which were dealt with in the fee proposal.

The HPRA welcomes all the suggestions and contributions made and, while we are not always able to take on board the proposals, we would hope that this document provides an explanation for our approach.

## 2 SUMMARY OF RESPONSES RECEIVED

The response received from an industry representative group related to human medicines fees. The response acknowledged that the HPRA has not increased fees since 2010, that fees were reduced in 2011 and 2012 and that from 2013 to 2017 the HPRA froze many fees and also implemented reductions in certain areas. The response also recognised that the HPRA faces increased responsibilities, an increase in staff numbers and an increase in payroll costs due to the reversal of the Haddington Road Agreement which will require a general fee increase of 2%. However, the group is disappointed with the proposed increase in the Drug Safety Update Report (DSUR) fee and the fee for amendments to include a new IMPD but recognises that the HPRA do not charge fees for academic trials.

A manufacturing company has requested the HPRA to consider a number of amendments and changes to existing compliance variation fees.

## 3 HPRA RESPONSE

The HPRA has reviewed the proposed increase to the DSUR fee, and in response to the submission received, has agreed to reduce the proposed fee of €500 to a fee of €200. In relation to the fee for amendments to include a new IMPD, the HPRA has decided to leave this fee at the proposed €800 as the work involved in the assessment of these amendments is significant and it is similar to reviewing a new clinical trial application.

In respect of the comments raised by a manufacturing company, we have responded directly to the company but are not proposing any changes for the 2018 fees but will keep the matter under review for 2019.

#### **4 CONCLUSION**

There was a broadly positive response to the HPRA fee proposal for 2018. We note the comments received in the submission and will consider them further in 2018.

Consequently, we propose to submit the revised fee structure as outlined in the original consultation document to the Minister for Health and the Minister for Agriculture, Food and the Marine for approval.

We would like to thank all those that contributed to the consultation process.

HPRA  
Finance, Corporate and International Department  
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