

Outcome of the Process - Public Consultation on proposed Human and Veterinary Medicines, Medical Devices, and Compliance Fees for 2017

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 welcomed the ongoing freeze in fees, acknowledged the fact that fees had been reduced in certain areas and also acknowledged that given the increased regulatory activity it is possible that fees will need to rise in the longer term. The group have strongly urged that fees for clinical trials should not be increased in the future. They also appreciate that no fees are currently charged for Type IA notifications and asked that this would continue in the future. While they welcome the HPRA reduction in the fee caps for certain variations, they have reiterated their request that a single fee be charged for all related changes to the SmPC.

The manufacturing company also welcomed the ongoing freeze in fees and the addition of a pilot for scientific advice and related costs. The company have requested the HPRA to consider a number of amendments and changes to existing compliance variation fees.

3 HPRA RESPONSE

In relation to multiple changes to the same SmPC, these changes can relate to significant and different assessments, therefore the HPRA considers that the correct way of dealing with this is by capping the maximum fee which we reduced in 2016.

The request received from industry will be considered by the HPRA as part of the fees review in 2017.

4 CONCLUSION

There was a broadly positive response to the HPRA fee proposal for 2017. We note the comments received in the submission and will consider them further in 2017.

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

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

Finance, Corporate and International Department
16th November 2016