

# Outcome of the Process - Public Consultation on Proposed Human and Veterinary Medicines, Medical Devices, and Compliance Fees for 2016

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## 1 NUMBER OF RESPONSES

The HPRA received one response from an industry representative group and one response from a parallel importer. 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 may need to rise in the longer term. The group have strongly urged that fees for clinical trials should not be increased now or in the future. They have also re-iterated their request that a single fee be charged for all related changes to the SmPC and proposed a reduced fee for work sharing variations where Ireland is the CMS. The parallel importer asked for further clarification on the proposed changes and subsequent reduction in fees for parallel import variations.

## 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 and we have reduced those caps for 2016. We note the comment on referrals and will review to ensure that the fee is appropriate. Minor editorial changes arising from a referral should not normally attach separate fees per section of the SmPC.

In relation to reduced fees for work-sharing variations where Ireland is the CMS, these procedures are still relatively new and we will be reviewing the fees further. While we charge the same fees for incoming work-sharing variations as for national variations, we do not charge any additional fees for outgoing and on that basis, with the limited numbers received, consider the overall fees to be fair. We will, however, consider separate fees in next year's review.

## **4 CONCLUSION**

There was a broadly positive response to the HPRA fee proposal for 2016. We note the comments received in the submission and will consider them further in 2016.

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  
24 November 2015