

Response Document - Public Consultation on Proposed Fees Consultation 2015 – Human Products and Veterinary Medicines

1 NUMBER OF RESPONSES

The HPRA received one response from an industry representative group, one joint response from two generic companies and four responses from parallel importers. 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.

1.1 Summary of response 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 the fee cap on multiple variations had been reduced by 16% to 23% previously, acknowledged the increased workload of the HPRA and welcomes that any future increase to maintenance fees (which should be minimal) would be to active marketing authorisations only. The group however re-iterated their request that the cap on multiple variations be further reduced. The generic companies' proposals also related to human medicines and recommended a significant restructuring and reduction to the annual maintenance fees, queried the level of fees for being placed on the interchangeable list, the repeat use fee and, while welcoming the resubmission fee for name changes, asked that the fee be offset against subsequent variation fees. The parallel importers all asked that the change to the requirements in relation to updating the SmPC, are reflected in a reduced variation fee.

2 HPRA RESPONSE

In relation to the proposal to further reduce the fees for multiple variations to the same SmPC; as noted the cap was reduced in previous years by between 16% and 23% in response to industry representations. We do not propose to reduce this fee category this year but we are committed to reviewing the maintenance fee structure in 2015 and will incorporate a review of variation caps at that point. This review is also relevant to the response from the generic industry and we will consider their proposal in respect of maintenance fees and how the proposal impacts on the total fee structure in this review. In response to the criticism of the fee for inclusion on an interchangeable list, it should be noted that all the current lists are being generated for free by the HPRA and the fee only arises where a company is requesting the creation of a new list or to add a product to an existing list. This approach is being followed despite the considerable resources that the HPRA is utilising in generating the lists. We accept

the point in relation to the repeat use fee in the case of medicines shortages in the country of destination and we are happy to review the fee on a case-by-case basis. The pre-submission fee for name changes will be offset against the variation fee, where the name initially submitted is accepted.

In relation to parallel importers, the new procedure will hopefully simplify the process for parallel importers and where the changes have no impact on the approved SmPC, package information leaflet (PIL) or labels for a PPA no variation need be submitted thus generating savings for the PPA holders. In other cases the changes to the product information will still need to be updated and assessed by the HPRA. It is proposed to review the impact of this new system after 6 months of operation and consider the fee level on the basis of that review.

3 CONCLUSION

There was a broadly positive response to the HPRA fee proposal for 2015. We note the comments received in the submission and will consider them further in 2015.

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 the Marine for approval.

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

Rita Purcell
Director of Finance, Corporate & International
26 November 2014