

Outcome of the Process - Public Consultation on proposed Human Medicines, Compliance fees, Medical Device fees and Veterinary Medicines for 2023

1 RESPONSE TO THE CONSULTATION

The HPRA received two responses on the Human Medicines, Compliance fees and Medical Device fee consultation and no responses on the Veterinary Medicines consultation.

The HPRA welcomes all the suggestions and contributions made as part of our fee consultation. This document is a summary of the outcome of the consultation.

2 SUMMARY OF RESPONSES RECEIVED

One response was received from human medicines industry representative group and one from a medical device company.

The response from the human medicines industry representative group stated that the fee increase raises concerns for industry regarding the impact on access to medicines in a market environment where the price of medicines is reducing and the costs are increasing. They noted that their members had a challenging year with the ongoing FMD, Brexit, Covid related changes and by the war in Europe. It was also stated that the proposed fee increase may result in the withdrawal of Marketing Authorisations. The industry representative requested a suspension or at minimum a deferral of any fee increases.

The response from the medical device company raised some comments in respect to the fee proposed for a "letter confirming that a device or list of devices are registered with the HPRA" and the fee proposed for a re-assessment of a notified body.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. In relation to the comments from the medicines industry representative, HPRA appreciates and understand the points raised about costs increasing in an inflationary environment. However, the HPRA funds the authorisation of medicines without recourse to exchequer funding, like industry, the HPRA cost base will continue to increase significantly in 2023. The cumulative payroll increases agreed by Government amount to increases of 8.5% over 2022/2023 (5% in 2022 and 3.5% in 2023). In addition, the HPRA is also experiencing some significant increased other costs due to the current high inflation. In order for the HPRA to cover these increased costs and to continue to protect public health and to deliver the service industry requires, the HPRA will need to increase the fees as per the fee consultation.

In relation to specific potential medicine shortages, that are related to the regulatory costs, the HPRA are happy to engage with those companies on the specific fees.

In respect to the comments raised by the medical device company, we have responded directly to the company to clarify the queries raised.

4 CONCLUSION

The HPRA's primary objective is the protection of public health but in delivering this we are committed to providing a first class service to the industry we regulate. We will continue to review the cost base of the HPRA and related fees. As always, we commit to reviewing our fees annually to ensure that the fee levels are appropriate to the functions and costs of the HPRA.

Consequently, as we are required to cover our costs with fee income, we propose to submit the 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
24 November 2022