HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Outcome of the Process - Public Consultation on proposed fees for Human Medicines, Compliance, Medical Devices and Veterinary Medicines for 2025

1 RESPONSE TO THE CONSULTATION

The HPRA received two responses on the Human Medicines, Compliance and Medical Devices 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 a human medicines industry representative group and one from a marketing authorisation holder.

The response from the human medicines industry representative group stated that the proposed fee for the decentralised application where IE is a reference member state – first additional strength (existing form) was inconsistent with other fees for subsequent extensions.

The response received from a human medicines marketing authorisation holder expressed concerns regarding the general increase of 5% and the increase in clinical trial fees by 15%. The company noted that these increases would further strain their resources and would hinder their ability to introduce new treatments and conduct essential clinical trials in Ireland.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. In relation to the comment from the medicines industry representative, the HPRA has made the appropriate change to the fee.

Regarding the comments received from the human medicines marketing authorisation holder, the HPRA acknowledges the company's concerns on the proposed increase to the clinical trial fees and recognise the importance of supporting clinical trials in Ireland. The basis for the increase was to reflect the impact of the clinical trials regulation (CTR) and to bring HPRA fees in line with similar agencies in Europe. However, in recognition of the concerns expressed, we have revisited the fee proposal and consequently have reduced the proposed increase from 15% to 10%.

In relation to the comment on the proposed general increase, the HPRA increased the fees in 2024 by 1.5% which combined with the proposed 5% for 2025 equates to 3.25% over the two

years which is significantly less than the combined payroll and inflationary increases. The HPRA funds the authorisation of medicines without exchequer funding and is therefore required to cover its costs. While we appreciate that increased fees impact stakeholders, the HPRA needs to cover the increases to its costs so that it can continue to deliver both its public service remit and the service industry requires. Consequently the HPRA will be maintaining the proposed increase to the fees of 5%.

Although not identified as part of the consultation process, in light of the end of the Brexit exemptions and the introduction of the Windsor Framework, and based on comments received from industry, the HPRA have proposed not to add any increase to the annual fee for dormant authorisations to help maintain those authorisations.

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.

In managing the fee consultation, we have sought to ensure that the proposals are reasonable and reflective of the economic framework that we all operate within. We have reflected on the comments received and taken on board those comments where appropriate.

Consequently, as we are required to cover our costs with fee income, we propose to submit the fee structure amended as outlined above to the Minister for Health for approval.

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

HPRA
Finance, Corporate and International Department
06 November 2024