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 2026

1 RESPONSE TO THE CONSULTATION

The HPRA received three responses on the Human Medicines, Compliance and Medical Devices fee consultation and two 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

Two responses were received from human medicines industry representative groups and one from a marketing authorisation holder.

The response from one human medicines industry representative group did not request any changes to the fees outlined in the consultation but asked for clarification on the clinical trial fees. The other industry representative group conveyed their opposition to the proposed 2.5% increase, reflecting difficult financial constraints on the generics industry, and also opposed the restructuring of fees for new product applications.

The response received from an individual human medicines company also expressed concerns regarding the general increase of 2.5% and the increase in clinical trial fees. The company noted that the cumulative increases of 2024 and 2025, within a short timeframe, presents significant challenges for industry stakeholders and the cost of maintaining licences, introducing innovative medicines to the Irish market and conducting clinical trials is already substantial.

There was one response received from a veterinary medicines industry representative group and one from a marketing authorisation holder.

The response from the veterinary medicines industry representative group acknowledged that the general increase of 2.5% seemed reasonable and proportionate to the national inflation rate. They also welcomed the simplification of the fees for new applications but required clarification on other fee supplements for new product applications.

The response from the veterinary marketing authorisation holder valued the role the HPRA plays and recognised the importance of having a robust, functional and well-resourced regulator. However, the company expressed concerns regarding the increase in the annual maintenance fees and the fees for SPC harmonisation.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. In relation to the clarifications requested from the medicines industry representative, we have responded directly to the representative.

Restructuring of new product application fees.
While the generic industry group objected to the restructuring of the fees, no reason was given. These fees are intended to be cost neutral when taken as a whole, and the HPRA commits to ensuring that this is the impact of the change. In the event that it is not cost neutral, we will readjust the fees in 2026 for 2027. The proposed structure reflects an approach seen in other agencies, including the EMA, and will bring a welcome simplification to the fee and application process.

Annual increase for inflation.
It was noted that three of the five responses were satisfied with or did not object to the 2.5% increase. In relation to the comments received from the generics industry representative body and the human medicines marketing authorisation holder objecting to the proposed general increase of 2.5%, the HPRA acknowledges the budgetary pressures for industry stakeholders. However, the HPRA is also subject to inflation and is required to meet its costs from fees.

Clinical trial fees
The human medicines company also objected to the increase in the new clinical trial application fees for mono-nationals and applications where Ireland is the CMS. The HPRA acknowledges the company's concerns, however HPRA fees were significantly less than both the cost of providing the service and the fees in other Member States. The new fees are designed to align with other Member States and to ensure clinical trials are sufficiently resourced.

Supplemental fees for new veterinary applications
In the context of the new amalgamated new application fees, there was a request to clarify whether some of the supplements for new veterinary applications would still apply. It is confirmed that, where applicable, these will apply. The supplements relate to fees charged for additional target species (fee codes 522, 542 and 562) and the mutual recognition/decentralised outgoing supplement per CMS (fee codes 528,548 and 568). These fees will be charged in addition to the new product application fee.

Increase in veterinary annual maintenance fees
Regarding the concerns relating to the proposed increases in relation to the veterinary annual dormant fees, the HPRA did not propose to increase that fee by €100 but to leave this fee at the 2025 level. In relation to the other two proposed annual fee increases, the fee increase was intended to reflect the greater costs of maintaining veterinary authorisations under the NVR; however, the HPRA has reflected on the concerns raised. Consequently, we have taken the decision to reduce the proposed increase from €100 to €50 per PA.

Increase in the veterinary fee for SPC harmonisation
The increase in the fees for SPC harmonisation is required to cover the resourcing costs in assessing these applications, which are 180 day procedures and require two assessors and administrative support. To cover the time and cost of the required resources it was deemed necessary to increase these fees, however, on reflection the HPRA will reduce the increase in these fees from 100% to a 30% increase for 2026 but, because of the potential resources involved, we will keep these fees under review in 2026 for 2027.

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 within which we all operate. 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
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