HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Outcome of the Process - Public Consultation on proposed Human and Veterinary Medicines and Compliance Fees for 2019

1 NUMBER OF RESPONSES

The HPRA received three responses from industry representative groups and five responses from human pharmaceutical companies.

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

Human Medicine fees

Two responses were received from human medicines industry representative groups. It was acknowledged that while the HPRA had increased fees by 2% in 2018, this had followed a general fee freeze and specific reductions from 2013 to 2017 and significant reductions in fees in 2011 and 2012. It also acknowledged the challenging healthcare environment and recognises that the HPRA faces increased responsibilities and increased costs. However, the groups were disappointed with the proposed fee increases which would only place additional burden on their members. They noted that their members already face increased costs due to the compliance and implementation of the Falsified Medicines Directive, Brexit and staffing costs. One submission stated that key factors such as the costs and resource burden on companies due to the Falsified Medicines Directive, Brexit, Pharmacovigilance, recruitment and market pricing should be considered in moderating HPRA's decision on the level of fee increases. It was also stated that the proposed increase exceeded the current inflation rate which could make Ireland a less attractive state for future applications. Both groups recommended restraint in relation to increasing fees.

It was also proposed not to increase fees for clinical trials and it was suggested that the annual maintenance fees for certain licences be increased, to make up this shortfall.

The responses received from human medicine companies again raised concern over the fee increases to new marketing authorisations and the general increase. The companies reiterated the above issues raised by the industry representatives, especially that the fee increase would add to their already high cost burden due to the FMD, staffing costs and Brexit. In addition, it was suggested that an increase in fees would hamper "access to medicines" and that the high volume of withdrawals and the reduction in new applications is a clear signal that Ireland is ceasing to be of interest to large pharmaceutical players. It was also suggested that shortages

and lack of supply for older medicines should have some element of a fee waiver or incentive to MA holders to apply for licences.

A manufacturing company has requested the HPRA to consider a cap on technical variation fees and requested a clarification of the proposed fee for an expedited IMP variation.

An organisation requested to consider waiving the inspection fee for non-profit legal entities.

Veterinary Medicine Fees

One response was received from the Veterinary medicines industry representative group. The group recognises the role of the HPRA, the professionalism of its employees and efficiency of the service provided to industry. However, the cost of regulation on the Animal Health Industry is too high and the industry finds the scale of proposed general increase of 8% difficult to accept in one phase. The industry expected costs to reduce based on the EU commission objective and the implementation of the new regulations which was used as justification for the increase is a reversal of their expectation. Also, the increase of 8% is the worst possible timing due to the challenges that Brexit will bring to the industry. The submission also highlights the difficulties experienced by the agricultural sector which are equally threats for the Veterinary medicines sector. The representative group requests HPRA to re-consider the proposed increases, however, if increases must be passed on, they ask that consideration be given to phasing these increases over a three year period to allow industry to get through the inevitable challenges of the coming year.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. While we appreciate and understand the points raised, as previously outlined, the HPRA cost base will increase significantly from increased payroll costs due to; the requirement to pay significant pension contributions to DPER, the reinstatement of Haddington Road pay cuts, the reinstatement of cost of living pay increases and increased payroll numbers. In order for the HPRA to cover these increased costs and to continue to deliver the service industry requires, the HPRA will need to increase the fees as per the fee consultation. The HPRA commits to review the fees during the cycle in 2019, and further amend the fee structure, if required for 2020.

In relation to essential medicines with very small markets the HPRA will be very happy to engage with companies over the level of fees charged. In addition, the HPRA is committed to considering any issues including fees, arising from Brexit which may prevent market access, and we would encourage companies with any Brexit related issue to engage with the HPRA.

4 CONCLUSION

Overall, while there was support expressed for the role and performance of the HPRA, companies and their representative bodies expressed concerns about the level of fee increases. 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 revised 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
27 November 2018