HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Outcome of the Process - Public Consultation on proposed Medical Devices Fees for 2021

1 OUTCOME OF THE CONSULATION

The HPRA received two response from manufacturing companies, one response from a regulatory consultant and one response from a member of the public.

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

Medical Device Fees

Two responses received related to the current environment in which we are operating, with Covid 19. One response expressed disappointment the fees were being adjusted at this time, while the second response suggested that a new reduced fee to encourage the development of essential tools for public health purposes (such as rapid tests for Sars CoV 2) should be introduced. It was suggested that this reduced fee should in turn be passed on by manufacturers for tests to government and the public.

Two responses received sought clarification on how the Fees relating to Manufacturers are calculated and applied. One of which welcomed the lower fee of €250 for small manufacturers and suggested the idea of a slightly higher fee for small manufacturers with a larger turnover. One manufacturer expressed concerns regarding the potential additional fee for those entities who are both a legal entity and have a manufacturing facility.

One response recommended that the fee for Authorised Representatives, representing low risk devices should be capped at €1,100.

One response recommended that an alternative method of calculating the Importer / Distributor fees, in place of the link to turnover, should be considered.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. The HPRA acknowledges that it is a difficult year for the medical device industry with Covid, Brexit and the preparation for the new Regulations. While the HPRA has restructured some of the fees and introduced new fees to accommodate the requirements of the Regulations the HPRA has made every effort to ensure

that the fees charged are equitable, reflective of the responsibility and activities of the organisations involved.

To address the clarification sought in relation to the Manufacturer Fees the HPRA will ensure that the guidance document that outlines the medical devices fees clearly explains the application of the manufacturer fee.

The HPRA recognise the importance of innovation and provides regulatory support and advice to individuals, academics, small and medium enterprises, pharmaceutical and medical device companies, and other groups who are developing innovative health products or technologies. https://www.hpra.ie/homepage/about-us/stakeholders/innovation-office

The HPRA does not propose to change the cap for Authorised Representatives, representing low risk devices. The Authorised Representatives role is a significant role in ensuring regulatory compliance of medical devices. Particularly in the context of the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), the obligations of the Authorised Representatives are specific and require suitable resource and competence in order to meet those obligations.

In relation to calculating the Importer / Distributor fees, the HPRA does not propose to change the method of calculation at this time. Before introducing these fees in 2017 considerable consultation was held with stakeholders and the majority of the feedback supported this model, The HPRA will continue to monitor and assess feedback in relation to this fee.

4 CONCLUSION

The HPRA proposes to progress the revised fee model following this consultation process. We will strive to support and work with entities in the implementation of these fees; this includes publication of a comprehensive guidance document and our availability for dialogue on specific circumstances.

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 for approval.

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

HPRA
Medical Devices Department
01 December 2020