HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Outcome of the Process - Public Consultation on proposed Medical Device Fees for 2018

1 INTRODUCTION

The HPRA following a three year period of engagement with the industry and a public consultation, introduced fees for medical devices for the first time in 2017. Prior to the introduction of the fees, HPRA recognised that the fees would need to be reviewed following the first year of application. We received significant feedback on the fees and revised the fee model to reflect that feedback. This outcome document is the result of the consultation and the revised model which already incorporates much of the feedback received.

2 NUMBER OF RESPONSES

The HPRA received two responses from industry representative groups and twenty two responses from medical device companies. The majority of the responses came from manufacturing companies with the remainder received from authorised representatives and distributors.

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.

3 SUMMARY OF RESPONSES RECEIVED

In general all respondents welcomed the review by HPRA and the proposed reduction in fees while some respondents requested further reductions or commented on the proposed fee structure.

The responses received from the industry representatives group welcomed the proposed reduction in fees for financial year 2018.

The responses received from manufacturers came from all size categories. Broadly there was a positive response with some commenting that the fees were still excessive. Many companies considered that the previous fee model was not appropriate. A request was made for a consideration of a reduced fee for "virtual manufacturer" and for micro enterprises.

Some companies remain concerned that the fees levied on EU authorised representatives based in Ireland are still higher than other member state competent authority fees and the fees should be bench marked against other EU countries. One company made the point that the proposed fee model will not be enforceable on distributors or manufacturers in other EU countries

supplying directly to Ireland, thereby putting Irish economic operators at a financial and potentially a regulatory disadvantage.

The HPRA also received a number of queries specific to the companies commenting on the consultation.

4 HPRA RESPONSE

The HPRA notes the request for further fee reductions but in the context of the significant reductions proposed for 2018 this is not possible. In relation to legal manufacturers who have no physical activity in Ireland ("virtual manufacturers"), we acknowledge that the consultation document was unclear and in fact these companies are charged the authorised representative fee and not the full manufacturing fee as suggested in the consultation. In relation to specific companies where the fee structure may result in a penal fee due to a different operating model not envisaged by the fee model, the HPRA is happy to engage with those companies on a one on one basis. The HPRA recognises that we are still learning about the structure and business models that exist within medical devices and are happy to engage with companies who believe that their activities are not appropriately reflected in the fee model. We will continue to engage with the industry in relation to medical device fees and we will consider the fee structure in future consultations. In relation to manufacturers and wholesalers who supply the Irish market but have no physical presence on the Irish market, we acknowledge that these companies are not under the current fee regime. This reflects the fact that the HPRA does not have a legal basis to charge fees to companies not present in our market although where they use an Irish distributor or an authorised representative they come under the HPRA fee regime. In relation to the fees for authorised representatives, these fees have been significantly reduced. The HPRA has noted the points raised by individual medical device companies specific to them and will address the general questions raised on categorisation and devices individually.

Conclusion

There was a broadly positive response to the HPRA fee proposal for 2018 /2019. We note the comments received in the submission and will consider them further when reviewing future fee models.

Consequently, 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
Finance, Corporate and International Department
12 June 2018