

# **Public Consultation on Proposed Human and Veterinary Medicines, Medical Devices, Precursor Chemicals and Controlled Drugs and Compliance Fees for 2012**

## **Outcome of the Process**

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### **Number of Responses**

The IMB received 2 responses from industry representative groups. In advance of the public consultation, as part of developing the fee proposal, a number of submissions were received which were dealt with in the fee proposal.

The IMB 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.

### **Summary of Responses Received**

Of the 2 responses received, 1 related to human medicines fees and 1 related to fees for precursor chemicals and controlled drugs. The response in relation to the human medicines fees welcomed the reduction in maintenance fees, acknowledged the fact that the controlled drugs fees were unchanged since 1988 and that the IMB had flagged the increases since 2009, it also contained a detailed proposal in relation to Article 63(1) fees. The response in relation to precursor chemical and controlled drugs strongly opposed the proposed increases. The response also acknowledged that the increases had been flagged in 2009 and delayed by two years following a public consultation in 2009 but they made the point that the economy has contracted further in that period and that their members are not in a position to pay the increased fees.

In relation to the fee proposal, other than the section on precursor chemicals and controlled drugs, there was a positive response to this, the sixth annual public consultation on fees.

### **IMB response**

Proposal in relation to Article 63(1)

For 2011 the IMB reduced the cost of this fee code by 50% and therefore has passed on significant savings to the industry and recognised the concerns in relation to this fee code. As the respondent is aware the IMB has in place a well established process for reviewing specific fee proposals received before the 10<sup>th</sup> of June each year. It is therefore proposed that the submission received in respect of Article 63(1) will be further reviewed in 2012.

### **Controlled Drugs**

The IMB is very aware of the extremely difficult economic climate within which our stakeholders are operating. However, it has not been suggested that the current fees (set 23 years ago) are adequate to fund the important function of licensing precursor

chemicals and controlled drugs nor has it been suggested that the proposed fees for 2012 are unfair. It therefore becomes a matter of the availability of exchequer funding. The Department of Health (DOH) has indicated that the funding received by the IMB for this function will be withdrawn over a four year period and thus there is no option but to increase the fees as outlined in the consultation document. It should be noted that the controlled drugs fees are at present payable to the DOH but it is hoped that the competency for the function will be legally transferred to the IMB in 2012 (currently the IMB carries out the licensing activity but the legal responsibility remains with the DOH).

## **Conclusion**

There was a positive response to the proposal to reduce the maintenance fees and as outlined above, a negative response to the proposal of increased fees for precursor and controlled drugs fees. The IMB is sympathetic to the concerns expressed but must also ensure that it has adequate fees to fund these necessary and important functions. Consequently, we propose to submit the revised fee structure as outlined in the original consultation document to the Minister for Health and Minister for Agriculture, Food and Marine for approval.

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

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**Rita Purcell: Director of Finance and Corporate Affairs**

**16 November 2011**