

# **Public Consultation on Proposed fees for Enforcement and Controlled Drugs for 2010**

## **Outcome of the Process**

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The Irish Medicines Board (IMB) receives funding from the Department of Health and Children (DoHC) for its Human Products Enforcement and Controlled Drugs activities. In 2009 the DoHC informed the IMB that its non-fee funded services, which include the above activities should migrate from Vote Subvention to a fee-based model as soon as possible. Fees levied should seek to recover the fully absorbed costs of services. DoHC proposes to move Enforcement (an IMB activity since 2000) and Controlled Drugs (resident at the IMB since 2005) to fee-funding from 1st January 2010. DoHC has requested the IMB to prepare a proposal for these fees and provide an opportunity for comment by way of public consultation. Interested parties were invited to make submissions on the proposals to the IMB and also to the DoHC.

The consultation document was available for public comment on the IMB's website from the 4<sup>th</sup> – 27<sup>th</sup> November 2009.

## **Number of Responses**

The IMB received 8 responses; 4 from industry representative groups and 4 from individuals, 3 of whom were in the University sector and 1 distributor. We also met with 1 industry group and have agreed to meet with a second group.

The IMB welcomes all the contributions made and has summarised the main thrust of the points made below. We acknowledge that the proposal for any additional fees/charges is not welcome and we will send this document to the Department of Health and Children.

## **Summary of Responses Received**

Of the 8 responses received, those received from the representative bodies of the main pharma industry, both originator and generic, were primarily concerned with the proposed fees to cover the Enforcement function. The representatives of the wholesalers were equally concerned with the Enforcement and Controlled Drugs fees. The responses from the university sector related to Controlled Drugs only. In general the submission opposed the introduction of fees (for Enforcement) and the increased fees (for Controlled Drugs) and a number of views were common across all the submissions including the following:

- It is inappropriate to introduce new fees in a period of economic crisis and a period of deflation where most regulators are decreasing or freezing fees.
- Many of the respondents referred to the direct financial pressure on their businesses and the inability to absorb the extra cost.
- The notice period for the implementation of such change is too short as most businesses have already agreed their budgets for 2010.

## **Enforcement**

In relation to the proposal for Enforcement fees, in addition to the views above, the following points were made:

- All the companies, both originators and generics, were satisfied to state that their products were not contributing to the work of Enforcement and therefore they should not have to fund this activity.
- Wholesalers are suffering in the current economic environment and are seeking to reduce costs by reducing salaries, numbers employed and overheads, therefore they require reduced fees from the regulator and not substantially increased fees.
- The companies understood the public health remit but believe strongly that this should not be funded by them but by central Government.
- The companies believe that Enforcement deals with a whole range of illegal substances and activities which have nothing to do with the licensed industry and should not be funded by them, they all suggested that other sectors such as the herbal sector and the pharmacy sector should also carry part of the burden.
- Both originators and generics representative bodies believed that charging both MA holders and manufacturers a separate fee represented a double charge.
- The originators suggested that a fee per MA would be fairer than the fee based on the size of the entity defined by number of MAs.
- The generic industry believes that the originator industry should pay a higher burden (90%) of the fees as counterfeiting is primarily focused on originator products.

## **Controlled Drugs**

- It was a universal response that the scale of the increases was a shock and that parts of the industry do not have the capacity to deal with these increases in one step in 2010.
- Wholesalers are suffering in the current economic environment and are seeking to reduce costs by reducing salaries, numbers employed and overheads. Therefore, they require reduced fees from the regulator, not substantially increased fees.
- One company wrote confirming that it is withdrawing from its' business activities involving Controlled Drugs as a result of the difficult trading environment combined with the proposed increased regulatory fee.
- The university sector which put in a number of individual responses and a response representing the 7 universities, argued strongly that the level of fees proposed would be a significant barrier to research and development as many of the substances in category 1 of the controlled precursor-chemical list are commonly used in research laboratories as chiral auxiliaries and as resolving agents.

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## **IMB Response**

The IMB fully acknowledges the effects of the current economic environment and the pressure that this places on industry. However, these proposals are as a direct result of that economic environment and a Government decision that these activities should no longer be funded by the Exchequer. As the IMB does not have the option of ceasing these activities, and indeed the submissions recognised the necessity of the services, we have in our proposals sought to structure the fees in a fair and transparent way.

## **Enforcement**

All the industry representatives have requested that the IMB set out how the activities of the IMB Enforcement function matches to the products that they manufacture, sell and distribute and that any fee charged should use this as a basis for the fee structure. This of course is not possible as the IMB Enforcement function deals with many activities that are not product specific including monitoring the internet, monitoring imports, illegal diversion, illegal substances claiming to be medicines, counterfeits, so-called life style drugs and international surveillance and co-operation, among other activities. What the activities of the IMB Enforcement function are designed to do is to keep the Irish market and the legitimate supply chain free from illegal activity and thus protect public health but also, as a direct consequence, protect the interests of those operating legitimately in that market.

As regards the suggestion from the main industry group that the fee should be a cost per MA, this suggestion was in fact included in the proposal published for consultation and the cost would be €100 per MA. The IMB has no difficulty with this if it is the industry preference but advises that, as demonstrated in the consultation document, charging in this way will have little overall impact on the level of fees paid by individual companies.

Both industry groups raised the issue of MA holders and Manufacturers having to pay separate fees. The IMB has to recoup the cost of this service from the industry and we have sought in the proposal to share the burden between manufacturers and MA holders. If we were to amend the proposed fee structure where both MA holders and manufacturers paid one fee, or some reduced combination of fee, the net result would be substantially increased fees for those that are only MA holders or only manufacturers. There are also practical issues with this suggestion as many companies hold manufacturing licenses in separate legal entities and manufacturers can produce product for a number of different MA holders. We are happy to further model these scenarios but would do so with the proviso that we are still required to cover our total costs.

It was also suggested that the IMB should charge other sectors for some of the costs associated with the Enforcement function. Clearly the main focus of Enforcement activity is the illegal trade and clearly also there is no way to charge them fees. As regards other sectors that are not regulated by the IMB, it is a matter for Government to legislate if it wants the IMB to charge those sectors. Currently it is outside our legal remit.

It was also suggested that originator companies should pay a greater amount of fees than the generic companies to reflect the fact that there is limited counterfeiting of generics. While there may be some level of truth in this, the work of the IMB is as stated earlier focused on public health protection and protecting the overall market place from

illegal and counterfeit products, and all licensed companies benefit from this activity. It is a matter of policy for Government as to how the charge is passed on to the components of industry and we will revert to Government for its views on this.

The wholesale industry has made particular representation on the financial difficulties that their business is suffering in the economic downturn. Having regard to the substantial role of the wholesale sector in the distribution of product and the level of Enforcement activities concentrated in this area overall, the IMB included this sector in the overall proposed fee model. The IMB specifically excluded cash & carry and similar small wholesalers from the proposed fees based on size and due to the fact that medicines are not their primary business. Any decision to exclude all wholesalers from the Enforcement fee proposals would be a matter of Government policy and we will revert to the Government on this.

### **Controlled Drugs**

The university sector made strong representation that research in universities will be damaged if the proposed fees are implemented. The IMB would like to emphasise that it is not its intention to damage research and on this basis proposes to leave the fees charged to the university sector at the existing 2009 rates with a further review in 2010.

The IMB accepts the view that the proposed level of fee increases are difficult to manage in the current economic climate. We note, however, that these fees were set in 1972 and last increased in 1988, that cost of living increases over this period account for 300 % of the increases proposed and that the original fees were very modest and completely inadequate to cover the cost of the service delivered to those who are involved in Controlled Drugs.

It is also important to highlight that since undertaking the Controlled Drugs function the IMB has focussed on improving the efficiency and delivery of the service provided to industry through introducing on-line licence processing. The fee increase also takes into account costs incurred in improving the efficiency of service in this area.

### **Conclusion**

Significant concerns in relation to the proposed fees were expressed which we have summarised above. Ultimately, as this proposal arose from a decision from Government, any change to the proposal must also come from Government.

The IMB will look at the Enforcement fee modelling and will reduce the proposed Controlled Drugs fees for the university sector.

The IMB will now submit the proposed fee structure as outlined in the original consultation document and the result of this consultation to the Minister for Health and Children for consideration and decision.

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

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