Outcome of the Process - Public Consultation on the introduction of a fee based funding model to support the conduct of Medical Device Regulatory Activities by the Health Products Regulatory Authority (HPRA)

1 NUMBER OF RESPONSES

The HPRA received sixteen responses from representatives of the medical devices sector including responses from the industry representative groups the Irish Medical Devices Association (IMDA) and the Irish Medical and Surgical Trade Association (IMSTA).

The HPRA welcomes all the suggestions and contributions made and this document outlines the summary of responses received, the HPRA review of these responses and the proposed next steps.

2 SUMMARY OF RESPONSES RECEIVED

The responses received acknowledged the rationale for introduction of a fee based funding model for the regulatory activities for medical devices in Ireland while some stressed that on principle, regulation should be funded from the public purse. Overall, industry representatives highlighted the need for a pan-European funding system in order to ensure a fair and equitable model across the European network. Many of the submissions questioned the basis of the funding model with some suggesting alternate models based on either: the value of sales; a transaction based model linked to specific regulatory activity; a registration charge linked to the new EUDAMED system (MDR- Eudamed).

Additional comments included clarification of terms and definitions used and to align definitions with those used in the legislative texts; more transparency on the activities of the HPRA in regulating medical devices in Ireland; the need to consider the device risk and suggestions to consider levying the fees according to the risk of the devices being manufactured/ placed on the market in order to reflect the regulatory oversight were also made.

One area raised from the medical device supply sector specifically was around the introduction of a registration system for distributors. This will be discussed further with the Department of Health as to whether it is appropriate.

3 HPRA RESPONSE

HPRA agrees that a European fee model would be the preferred system for recovering the costs of regulatory activities in Europe. However given the complex nature of the EU regulatory system for medical devices establishing such a fee model has many challenges and it is unlikely to be achievable in the short-term. In the meantime, implementing a fair and equitable fee structure to the Irish market is a priority for HPRA and for the Department of Health.

The HPRA has noted the points raised by the industry representatives regarding increased transparency on our regulatory activities. In response to this, in 2017 we will prepare a guidance document on the activities carried out by the HPRA in regulating medical devices on the Irish market. This guidance will be available on our website, www.hpra.ie.

In relation to clarification of terms, definitions, and specific clarifications on aspects of the fee model, the proposal has been annotated to address these issues.

Various methods were considered as to ensure the fee model based was stratified according to the size and nature of the economic operator's activities. In the absence of submissions of alternate proposals, the model as presented was submitted to the Department of Health.

4 CONCLUSION

The modified proposal has been submitted to the Department of Health for review and consideration. The Department of Health has advised that fees for medical devices will be implemented based on the model proposed, with the clarifications on definitions and terminology included, with a timeframe of Q1 2017. A table outlining the fee structure to be adopted is included in Appendix I and the definitions and clarifications are further outlined in Appendix II.

We would like to thank all those that contributed to the consultation process. The HPRA reviews all of its fees on an annual basis following a consultation procedure. We encourage further specific engagement on this aspect and we anticipate that based on further information we will require adjustment to our model and levels over the first number of years on implementation.

September 2016.
HPAR Medical Devices

Appendix I – Proposed Fee Model

Fee Model	Amount
Manufacturers and authorised representatives	
Manufacturers>150 employees	€30,000
Manufacturers 50-150 employees	€25,000
Manufacturers 15 to 49 employees	€15,000
Manufacturers 5 to 15 employees	€5,000
Manufacturers less than 5 employees or annual turnover < €500k	€250
Manufacturers – legal manufacturer/AR status (subject to a cap-see point 1 below)	€1,000
Authorised representative (subject to a cap -see point 2 below)	€5,000
Distributors	
Large Distributor turnover > €15 million	€5,500
Medium Distributor turnover €3 to €15 million	€3,500
Small Distributor turnover under €3 million	€1,250
Distributor turnover < €500k	€250
Miscellaneous	
Cert of free sale issuance (per certificate)	€250

Accompanying Notes

1. Manufacturers based in Ireland that hold legal manufacturer or authorised representative status for some or multiple entities pay an additional fee per entity up to a maximum of €10,000 per year. Additional fees associated with legal manufacturers and authorised representatives are to account for the increased activity and responsibility of HPRA in relation to these specific products on behalf of the European Union.

2. Entities who act as authorised representatives, without being a medical device manufacturer per year are charged an additional fee up to a maximum of €30,000.

3. In relation to both points above the fee is calculated based on designation as a legal manufacturer or authorised representative for a particular manufacturer, which may cover a range of medical devices.

4. The fee applies to manufacturers of all types of medical devices including general medical devices, *in-vitro* diagnostic devices and active implantable medical devices.

5. Where one organisation has multiple manufacturing sites based in Ireland, the organisation will be charged per manufacturing site to a maximum fee for sites of €60,000.

6. Provision for small scale economic operators

Companies considered as small scale economic operators (based on less than 5 employees or turnover of <€500,000 (independent of the number of employees) shall comply with all the HPRA registration and data provision requirements and pay an annual fee of just €250.

7. Organisations who manufacture/represent/distribute multiple health product types

Where one organisation (e.g. distributor) is dealing across a range of different health products (e.g. medicinal products, medical devices and cosmetics), the applicable fee will be based on the total turnover relating to medical device business only (based on self-declaration). The HPRA will when possible try to ensure that regulatory inspections in each of these product sectors are aligned for such entities to minimise on inspection fees.
Where one organisation is dealing across a range of different products the total staff numbers are calculated based on the number of employees, directly or indirectly involved in the design, manufacture, testing, supply, regulatory, governance and application of the quality management system for the devices manufactured. This will be based on self-declaration.

8. Manufacturers that also distribute medical devices in Ireland

Where entities recognised in the manufacturer section above also act as distributors of medical devices to the Irish market for the purposes of intercompany distribution (from other EU and non EU sites) and distribution of 3rd party devices the fee shall apply. The turnover metric applied to these activities shall be based on self-declaration.

9. Transaction based fees

In addition to the annual registration fees outlined above the HPRA will continue to charge specific transaction based fees. One such transaction is listed above as 'Certificates of Free Sale', the cost of which will be set at €250. Fees for audit of manufacturing sites and distributors of medical devices will be charged separately arising from specific activities and in line with our current fee guidance. All HPRA fees are reviewed on an annual basis.

Appendix II – Definitions and Clarifications

1. APPLICATION OF FEE PER MANUFACTURER OR MANUFACTURING SITE

In accordance with the current data available to us, the fee model is based on fees levied per manufacturing site and is subject to a cap per organisation. Where organisations have multiple manufacturing sites under the one legal entity, fees will be applied to each manufacturing site up to a cap for site fees of €60,000. The HPRA has requested data and would encourage engagement from the industry on their different corporate structures in order that this definition can be refined and resultant fees proportionate.

2. APPLICATION OF FEES TO ORGANISATIONS WHICH HAVE OTHER HEALTH PRODUCT ACTIVITIES

The HPRA recognises that many organisations may manufacture, distribute or be responsible for products other than medical devices. In these cases fees are calculated based on the quantum of the medical device portion of the business only. This would be based on self-declaration by the organisation and confirmed by market surveillance checks by HPRA.

3. APPLICATION TO DIFFERENT ENTITIES

- Contract manufacturers.

Contract manufacturers that are subject to regulatory oversight activities (e.g. audits, quality management system review, and certificate of free sale service) will fall within the scope of the current fee proposal. If such contract manufacturers are also placing product on the market under their own name they will be subject to a fee as a medical device manufacturer the quantum of which would be calculated based on the cumulative manufacturing activity.

A contract manufacturer for the purposes of the fee proposal is defined as an entity that manufactures a finished device to another establishment's specifications.

- Own brand label manufacturers

This term is commonly used to describe manufacturers of medical devices who place devices on market under their own name which are manufactured on their behalf by a contract manufacturer. Such contract manufacturers may supply multiple 'own brand label' manufacturers and may place the device on the market under their own name.

For the purposes of this proposal the 'own brand label' manufacturer shall be considered as a specific manufacturer of a medical device and the relevant fees applied. If the 'own brand label' manufacturer also manufactures other medical devices and placed them on the market under their name they shall be subject to a fee based on the cumulative activity.

- Critical suppliers or service providers

In general, critical suppliers would not be subject to fees as a manufacturer of medical devices. However if the supplier is manufacturing critical components of the finished device these will be considered on a case-by-case basis depending on the impact that the component supplied has and whether it is consider essential in terms of safety and performance of the finished device.

It is not proposed that fees are applied to service providers like sterilisation services unless such entities are operating as manufacturers, distributors or authorised representatives in their own right.

4. ESTIMATION OF THE QUANTUM OF FEES ENVISAGED TO PROPOSED FEE MODEL CATEGORIES

The HPRA has set the quantum of fee associated with each fee model category with a view to cover the costs of its regulatory activities and account for the level of responsibility or likely activity in medical device market surveillance for that entity. The HPRA has formulated its model based on its estimates of the number and size of entities and types of activities undertaken. More detailed information on the size, structure and nature of the medical device industry in Ireland has been requested to ensure that we are proportionate, fair and equitable. The HPRA aims only to recover costs directly associated with medical device regulation.

The HPRA reviews all of its fees on an annual basis following a consultation procedure. We encourage further specific engagement on this aspect and we anticipate that based on further information we will require adjustment to our model and levels over the first number of years on implementation.