HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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)

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1 INTRODUCTION

1.1 General

The Minister for Health and the Department of Health (DoH) are responsible for determining national health policy as it relates to medical devices. The Health Products Regulatory Authority (HPRA) has been designated as competent authority for medical devices in Ireland. The role of the HPRA is to ensure the quality, safety and efficacy of medical devices available on the Irish market. The HPRA and DoH work in partnership to ensure the provision of an effective system of regulation for medical devices in Ireland, and providing an appropriate national contribution to the European regulatory network for medical devices. Both the HPRA and DoH recognise the importance of securing a mechanism for funding of regulatory activities for medical devices which is independent of exchequer sources in the interest of maintaining and further developing a secure regulatory system that affords patient safety and provides the medical device industry with a solid and secure environment to innovate and bring new medical technologies to the market. It is the decision of the Minister for Health that the regulation of the medical devices industry in Ireland should be self-funded and that the HPRA, as the competent authority for that industry, should establish and manage an appropriate fees regime to cover the costs of regulation.

Historically, the funding of medical device regulatory activities by national authorities has been provided from national exchequer sources. Since undertaking the role of competent authority in 2001, HPRA funding for medical devices has been predominantly provided by the DoH, with a small contribution from administrative fees applied in areas such as classification, assessment of clinical investigations, audit of manufacturers and the issuance of medical device export certificates. The DoH has requested the HPRA to explore national fee models to provide for full cost recovery for its medical device regulatory activities. Given the level of development in regulatory functions and activities for competent authorities for medical devices over the past two years in the context of the EU Commission's Joint Plan for Immediate Action, and the enhanced requirements of the revised legislation which is imminent, it is appropriate that a system of self-funding for regulatory activities should be implemented to support the necessary regulatory development for medical devices.

This consultation proposal details mechanisms through which securing a self-funded approach for medical device regulatory activities could be achieved. With the publication of this consultation document the HPRA is now inviting formal comments from all parties on these specific proposals. This is being conducted with a view to reaching a final submission for a model to be agreed with the DoH.

1.2 Requirement for funding

The HPRA provides a range of services which are conducted to protect patient and consumer health, and which also serve to support the large and vibrant medical devices industry in Ireland. These services include: oversight and designation of the Irish notified body

responsible for certification of medical devices; provision of post market vigilance and surveillance of medical devices; assessment checks on compliance of devices with safety and performance requirements; overseeing recalls of defective products when required; advice on classification of products; assessment of clinical investigations; registration of low risk products; and audits of medical device manufacturers.

The medical device system is a decentralised system reliant on third party certification by approximately sixty notified bodies, and as such the contribution of the HPRA as a competent authority in the European network is a predominant feature of its regulatory oversight role. In addition to this focus for the Irish market, the HPRA has a responsibility for the safety and quality of medical devices that have been manufactured in Ireland and made available throughout Europe. This is particularly pertinent in the case of devices which are manufactured here or for which an Irish based entity has the legal responsibility.

Recent years have seen considerable development in the European regulatory system for medical devices which has resulted in a significantly increased level of activity for the HPRA relating to medical devices. The legislation for medical devices has been in place at European level for over 20 years and it is now due to be substantially revised and developed with the planned introduction of the proposed new medical device Regulations. The proposals to revise the legislation also have taken into account developments identified during the 2012 crises relating to breast and hip implants. These crises also resulted in the EU Commission's Joint Plan for Immediate Action to strengthen and develop the existing regulatory system to better protect public health in advance of the broader legislative revision. These initiatives have led to a significant increase in the activities of all competent authorities throughout Europe including the HPRA. Specific areas where the HPRA has observed increased requirements are: the oversight of notified bodies for medical devices at national and European level; reinforcement of market surveillance throughout the lifecycle of a medical device; coordination and cooperation on medical device issues with the EU network and international regulatory partners; communication on medical device issues, in particular relating to reporting by users of medical device safety issues to the HPRA.

These changes have led to considerable improvements in the effectiveness of the regulatory system affording better protection for public health and also providing for greater consistency and predictability for the medical device industry. However, the maintenance of the regulatory system, and the further developments required to increase public confidence in the safety and quality of devices, require robust and secure funding. The introduction of a new fee model to support and sustain the discharge of the regulatory functions, on a cost recovery basis, is considered to be the optimal way to achieve this.

2 FEE BASED FUNDING FOR MEDICAL DEVICES IN EUROPE

There is broad recognition among national and European stakeholders that appropriate and adequate funding mechanisms must be available to the competent authorities of Member States in the short to medium term to secure and develop the regulatory system for medical devices. Currently it is not possible to introduce funding mechanisms at European level and so fee based models can only be achieved through measures taken at national level and these have to be sufficient to sustain the resourcing necessary to implement the on-going regulatory developments in the joint plan and other initiatives, in advance of the broader revision of the legislative framework coming into effect.

The development of an appropriate fee funded model to cover the cost of the provision of the medical device regulatory system has also been the subject of considerable discussion at European level much of which has been facilitated and promoted by the HPRA. Over the last number of years an increasing number of European countries have introduced fee models to cover most or all of the cost of their regulatory activities relating to medical devices. At this point regulatory authorities for medical devices in at least ten countries have introduced or retained systems to recoup all, or the majority, of their costs associated with the regulation of medical devices. These countries include Austria, Belgium, Croatia, Denmark, France, Germany, Italy, Latvia, Lithuania, Portugal and Spain. The mechanisms through which fees have been introduced vary and include approaches such as levies placed on manufacturers or economic operators placing a medical device on the market, fees related to number of employees of economic operators, and sales taxes. It is anticipated that the number of Member States with a fee model will increase further over the next 3 years. Given the close operation of the markets it is also of particular relevance that the UK Authorities are planning introduction of fees in the UK in 2016 (a consultation process in the UK is anticipated in the near future).

The European revision of the medical device legislation will include specific provision for full cost recovery through fees levied by national authorities. It is anticipated that more national device fee models will emerge in advance of, and in preparation for, the new legislation coming into place. As such an array of different fee models for medical device authorities at each national level is likely to emerge. The most effective fee structure would be a European level model with a single fee for each device, with an ongoing single annual maintenance payment, to cover all of Europe with funding distributed to competent authorities in accordance with their activities and responsibilities. This is unlikely to be achievable in the short to medium term without substantial change to the administration of the regulatory framework at European level.

Developing common principles or harmonisation of fee models by European device authorities is desirable in the absence of a single European solution. The HPRA will continue to work to achieve this goal and ensure that national fees for devices are harmonised in so far

as possible and are fair, transparent and low burden in terms of implementation. We would hope to reflect these principles in the approach established at national level.

3 REQUIREMENT FOR A NATIONAL APPROACH TO FEES

The developments set out under the EU Commission's joint plan and the on-going revision of the legislation provide for a more robust system of regulation which will significantly improve and secure the system but will be more costly to maintain.

Currently the HPRA charge some transaction based fees associated directly with a specific service, for example applications for clinical investigations, requests for classification, designation as notified bodies, registration of self-declared medical devices and issuance of certificates of free sale. However, the primary activities conducted by the HPRA arise from market surveillance activities which are part of our broad service provision and may not be readily linked to a specific transaction. To be effective, market surveillance involves the monitoring of the safety and performance of a medical device on the market place throughout its lifecycle. Robust market surveillance is fundamental to the medical devices regulatory system and is essential to ensure that public health is protected across Europe. In addition, surveillance enables an environment for safe and timely innovation and market access for new technologies and a secure marketplace in which companies can flourish without exposure to unfair competition from disreputable or poorly regulated companies and notified bodies.

It is proposed that an annual fee is charged to cover the cost of the HPRA's market surveillance activities. The amount charged should reflect the level of activity of a manufacturer (or other economic operator) taking into account its potential impact on the European/global market place and the level of regulatory responsibility that the manufacturer and/or operator represents for the HPRA. While there are many approaches through which this could be achieved, using a factor such as company size, which reflects the capacity of the manufacturer or economic operator to impact the market place, would seem appropriate. Specific fees should also be applied where the HPRA has additional responsibility for authorised or legal representatives.

In this regard, there are many strong comparisons with other sectors regulated by the HPRA which operate on a full cost recovery basis. The fee based regime applied to pharmaceuticals is most relevant in this regard. The pharmaceutical regulatory activities conducted by the HPRA are fully self-funded and supported by a mature system of fees which include annual maintenance fees for marketing authorisation holders to cover some of the costs associated with pharmacovigilance and market surveillance activities. The system is open and transparent. Fees are reviewed annually and this involves consultation with industry stakeholders. The HPRA intend to apply a similar approach to the development of a fee system for medical devices.

On conclusion of this consultation, a final proposal will be submitted to the DoH for agreement on implementation. Thereafter fees will be set on a statutory basis. The HPRA acknowledges that many manufacturers are required to pay fees for the pre-market conformity assessment and certification of their products. The proposal here applies to the aspects of the regulatory framework for medical devices which are carried out by the HPRA in the pre- and post-market phases, broadly categorised as market surveillance of medical devices. As outlined, to be effective the medical devices regulatory system in Europe depends on robust market surveillance conducted by regulatory authorities to monitor the safety and performance of a medical device in wider usage. This compares well with the pharmaceutical sector, where market surveillance activities by regulatory authorities are also directly funded through industry fees.

The HPRA has already had extensive dialogue with the medical device industry in Ireland, which raised many of the concepts of this fees proposal, and the options for management of our costs from 2016 onwards. Feedback from this process has been taken on board as part of the development of this proposal. In particular we believe that the fee model set out below which has annual charges for manufacturers and distributors clearly links to the key service provided by HPRA as part of its medical device regulatory activities, namely market surveillance.

The HPRA also explored the concept of a fee per medical device on the Irish market with related fees. However, such a model was found to be unfeasible under the current regulatory framework but may be appropriate in the future with the revision of the medical device Regulations at European level. As part of its annual fee review the HPRA will re-consider this model as the regulatory framework changes.

3.1 The introduction of fees for 2016

It is intended that the new fees regime will be introduced in 2016. The new fees will have to replace the existing exchequer contribution and the projected increases in cost.

The annual value of the medical device manufacturing industry in Ireland is in excess of €8 billion. The cost to the HPRA in overseeing the regulation of medical devices in absolute terms is a very small proportion of this value (estimated to be 0.065%).
As for the actual introduction of fees for medical devices, any formal decision on the introduction of a fee regime remains a policy matter for determination by the Minister.

3.2 Proposed fee model

The medical device sector in Ireland has a notable composition with a higher proportion of export based manufacturing compared to medical devices being placed on the market in Ireland. The implementation of a fee model on a national basis is not without challenge. In development of a fee model to support our regulatory activities our focus has to include the safety and performance of devices that are directly available to Irish patients and those which

are supplied to other jurisdictions from the large manufacturing base here and in respect of which the HPRA a regulatory responsibility.

In respect of any fee model that is introduced, it is intended that we will review and as appropriate revise the model on a periodic basis and more regularly during the first number of years of implementation; this will include the impacts of the introduction of the revised regulatory framework in Europe. The initial model is based on estimates of the size of the manufacturing and distribution sectors and any over or underestimates will be addressed after the first year of operation.

The proposed model involves an annual fee being charged to all manufacturers and other economic operators supplying or manufacturing medical devices in Ireland. This annual fee would vary according to the company's size and activity. Specific considerations will be incorporated to recognise the importance of micro and small enterprises which are fundamental to innovation and the medical device industry. We believe that this model is simplest and least burdensome to administer and is linked to service provision by the HPRA. Manufacturers would be registered as entities in order to administer this fee but given an annual fee is applied to the manufacturer no fee would be associated with the registration process itself.

3.3 Proposed model: Annual fee for all economic operators

This model would involve an annual fee charged to each economic operator in the supply chain based on the size and nature of the activity of the entity (as set out in the Appendix). This would include:

1. An annual fee charged to manufacturers of medical devices in Ireland proportionally allocated on the size of the operation.

2. An additional fee component for manufacturing sites which hold the European legal responsibility or authorised representative status for medical devices[1] (with a maximum limit where one manufacturing site holds multiple legal responsibilities or authorised representative status). This is to recognise additional responsibility conferred on the HPRA in such circumstance.

[1] The EU legal responsibility status is to describe when a specific manufacturing site is identified as the lead in terms of the legal responsibility for the device in Europe on the registration or certification under the Medical Device Directive.

3. An annual fee charged to entities, which are not manufacturers, designated as authorised representatives for medical devices in Ireland (with a maximum limit where one entity holds multiple legal responsibilities).

4. An annual fee charged to distributors of medical devices proportionate to the size of the distributor.[2]

5. For Certificates of Free Sale, while maintaining the 5 year validity of such Certificates, charges could be increased to €250. In line with the increased fee, the HPRA proposes to introduce an expedited service for issuing all such certificates. This can be accommodated in the current fees legislation.

6. Provision should be made that fees charged to SMEs will be fixed at a reduced rate

A worked example of this model is provided in Appendix I.

4 CONCLUSIONS

The HPRA considers that the introduction of a national fee system for medical devices to cover costs incurred in the discharge of medical device regulatory functions is critical to ensuring future capability, security and confidence in the regulatory system for medical devices. The HPRA believes the fee model set out in the current proposal takes into account the nature of the medical device and IVD industries in Ireland in terms of structure and various scales of operation. This is considered a suitable approach in terms of equity and minimising burden, in advance of a wider solution being achieved at European level. The aim is to introduce fees at national level early in 2016.

5 CONTRIBUTION TO THE CONSULTATION

The HPRA welcomes comments on this proposal and invites respondents to comment and provide input into the model as set out. Stakeholder feedback will play an important role in informing future policy decisions in relation to this matter**.**

[2] This fee will also apply to manufacturers who distribute medical devices they do not directly manufacture themselves i.e. they are distributing on behalf of another entity or affiliate. This distributor fee will not apply to manufacturers who provide direct distribution services for devices they manufacture on site.

Contributions to the consultation on this proposal may be provided to the HPRA by the 6th of August 2015. Contributions should be sent by e-mail to MDConsultation@hpra.ie.

HPRA
06 July 2015

APPENDIX I PROPOSED FEE MODEL

Annual fee based on manufacturer size and other factors

Fee Model	Amount
Manufacturer with more than 150 employees	€30,000
Manufacturer with 50 - 150 employees	€25,000
Manufacturer with 15 - 49 employees	€15,000
Manufacturer with 5 - 15 employees	€5,000
Manufacturer with less than 5 employees or a turnover of less than €500,000	€250
Manufacturer – 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
Large distributor with a turnover of more than €15 million	€5,500
Medium distributor with a turnover of €3 to €15 million	€3,500
Small distributor with a turnover of less than €3 million	€1,250
Distributor with a turnover of less than €500,000	€250
Certificate of Free Sale issuance	€250

Accompanying notes

Additional fees associated with legal manufacturers and authorised representatives are to account for the increased activity and responsibility of the HPRA in relation to these specific products on behalf of the European Union.

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.
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. Companies considered as SMEs should comply with all the registration and data provision requirements and pay an annual fee of €250.