



## **ABHI Response to HPRA Consultation**

04 August, 2015 - ABHI (see below) welcomes the opportunity to respond to HPRA's consultation on fees to cover the cost of device regulation. This is timely for us because, as you point out, the UK authorities are also considering levying fees on sales of devices to pay for the cost of regulation.

Our response is necessarily limited to general points of principle as we do not have a direct interest in the regulation of devices in the Republic of Ireland. Bearing this in mind we trust that the following observations will be of interest:

- As a matter of principle we believe that regulation should be funded from the public purse rather than by a levy or tax on the market. A copy of a paper detailing our arguments supporting this position is enclosed herewith.
- Notwithstanding this, we understand why Competent Authorities across the EU are looking for new sources of funding at this time and we expect to be involved in constructive debate as to how these funds can be raised in an equitable and effective manner
- Because Medical Device regulation is governed by EU law, we believe that any funding system should be pan European, much as you describe in paragraph 3 of section 2 of your consultation document.
- We agree that such a pan EU system would not be easy to put in place in the short term but this lends greater urgency to starting work on this without delay.
- Making a registration charge in connection with the planned EUDAMED III database would be a possible way forward, particularly as work to set this up is now starting in earnest.
- You also make the related point about harmonization of fee models (presumably before any Europe wide system is developed). We agree with this but are surprised to note that your proposed system is based on company size rather than on value of sales. This will mean that manufacturers based in Ireland would effectively pay twice when making sales in any member state where a levy is already in place.

We trust that you will find these observations helpful and we would be happy to answer to any questions you may have.

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**ENDS**

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### **About ABHI**

The Association of British Healthcare Industries (ABHI) is the industry association for the medical technology sector in the UK. ABHI's mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes. With over 250 members, ABHI leads the advocacy of the industry in order to advance access to medical technology. Our membership includes

some of the leading multinational businesses in the sector in the UK right the way through to small and medium sized enterprises. For further information, visit the ABHI website ([www.abhi.org.uk](http://www.abhi.org.uk)).

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