An Update on the Proposed EU Revisions to the Regulation of Medical Devices

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The existing European legislation which established a regulatory regime for medical devices is over 20 years old. The current regulatory regime consists of three dovetailed directives relating to Medical Devices[1] (MDD), Active Implantable Medical Devices[2] (AIMDD) and In Vitro Diagnostic Medical Devices[3] (IVDMDD).

The proposed new regulatory regime will replace the three directives with two regulations. The subject matter of the MDD and the AIMDD will feed into a single regulation, while the current IVDMDD will be replaced by a wholly new regulation.

Background History and Update on Developments

In view of the continued advances in technology and to ensure the adequate protection of patients in the EU, an overhaul of the existing regulatory regime has long been overdue and the European Commission announced its intention to overhaul the current legal framework in September 2012. However, the text of the revised regulations must be agreed by the European Commission, the European Council and the European Parliament before the regulations are finally adopted and the laws come into force.

Following its declaration of intent, the European Commission proposed a new regulatory framework and in October 2013, the European Parliament voted broadly in favour of the proposals, but incorporated amendments of its own.

In April 2014, the European Parliament formalised its first reading position (the amendments to the European Commission proposals approved by the European Parliament in October 2013) and following the European Parliament elections in May 2014, the plan is for the new European Parliament to continue its work on the basis of the proposal voted for on 2 April 2014.

On 20 June 2014, the European Council had its last meeting under the Greek Presidency and discussed the proposed revisions to the medical devices regulations. The meeting did not progress the proposals significantly with the IVDMDD regulation left largely on the side lines of the debate. Revisions to the proposed regulations will continue until the European Council formally adopts a position at first reading.

The drafts to date provide for some significant reforms and revisions to the existing regulatory regime. The most significant areas of disagreement have been in relation to

notified bodies, vigilance and market surveillance, and governance. As the text of the revised regulations require agreement of all three European institutions, it is likely the drafts will continue to be revised and refined for some time and possibly even further additions to be made (especially with regard to post-marketing surveillance).

The Proposed New Regulatory Landscape

If the revised regulations remain in their current state, they may introduce a raft of new features to the regulation of medical devices including:

- **Devices for aesthetic purposes** - proposed to be brought into the scope of the regulatory regime;
- **Upgraded monitoring of Notified Bodies** - more rigorous auditing and monitoring of notified bodies;
- **Special Notified Bodies** - for higher risk devices such as Class III, implantable devices, and devices incorporating medicinal products;
- **Assessment Committee for Medical Devices ("ACMD")** - to be established to provide a case by case assessment of clinical data in relation to certain high risk medical devices;
- **Insurance** - manufacturers of medical devices will be obliged to take out liability insurance in excess of a minimum cover level to ensure that any patients injured by a faulty medical device are compensated;
- **Single Use Devices** - devices will be designated and labelled as either single-use or reusable;
- **Clinical Investigations** - the performance and safety requirements will have new definitions of 'performance' and 'safety'. There are proposals relating to the reporting of the safety, performance and outcome of clinical investigations for higher risk medical devices and the examination and approval of clinical investigations by an independent ethics committee;
- **Implant Cards** - manufacturers of implantable devices will need to provide a card containing all the information relating to a device, be responsible for recording the same information in the patient's medical records and need make an electronic version of the implant card available to hospitals and clinics; and
- **Penalties** - Member states will have the opportunity to set their own penalties for manufacturers which commit fraud or deceive the system in relation to medical devices.

While sharing many of the features of the new general and implanted medical devices regulatory regime, the regulatory regime for in vitro diagnostic medical devices will have the following new features:

- **Genetic testing** - these must only be conducted with free and informed written consent, with specialist counselling provided before and after testing;
- **Minors and incapacitated subjects** - the informed consent of the parents

(minors only) or legal representative will be required before testing; and

- **Prescription-only** - certain devices (in particular higher risk devices (Class D) and Class C devices in the following categories: (a) devices for genetic testing; (b) companion diagnostics) will only be able to be supplied on a medical prescription, with direct marketing of such prescription-only devices being unlawful.

The new regulatory regime in Europe for medical devices leading to the creation of two new regulations is still in development and a work in progress. As it traverses the legislative process through the European Commission, the European Council and the European Parliament, there will no doubt be more discussion and debate and this will inevitably lead to further revisions and refinements.

The original tentative date for final agreement on the content of the regulations to be reached was 2014, but this is highly unlikely to occur. It may be 2015, or even 2016 or 2017, when final agreement can be reached, but whenever it occurs, the resulting regulations will represent a paradigm shift in Europe in relation to the regulation of medical devices.

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[1] Directive 93/42/EEC

[2] Directive 90/385/EEC

[3] Directive 98/79/EC