COELHO RIBEIRO E ASSOCIADOS
SOCIEDADE CIVIL DE ADVOGADOS

# New Regulations on Medical Devices and *in vitro* Diagnostic Medical Devices adopted by the EU Council and the Parliament

**CRA – Coelho Ribeiro e Associados, SCARL**

**Jaime Medeiros**

**Portugal**

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The European Council and the European Parliament adopted last 5 April the new Regulations on Medical Devices and *in vitro* Diagnostic Medical Devices. These Regulations, once published, shall repeal Council Directives 90/385/EEC and 93/42/EEC (the union regulatory framework for medical devices) and Directive 98/79/EC of the European Parliament and of the Council (the union regulatory framework for in vitro diagnostic medical devices)[1]. This was the peak of a long legislative process started in 2012, with the first regulation proposals presented by the Commission.

The Regulations on Medical Devices (MD) and *in vitro* Diagnostic Medical Devices shall apply, respectively, three and five years after their publication in the Official Journal.

This brief note is primarily focused on the Medical Devices Regulation (MDR), which will have a substantial impact on all MD manufactures.

Firstly, it was the Regulation intention to clarify that software specifically intended by the manufacturer to be used for a medical purpose qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, in line with EC's revised MEDDEV of 15 of July of 2016, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the

[1] The final versions of the Draft regulations can be found at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:PE_14_2017_INIT&from=EN and at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:PE_15_2017_INIT&from=EN.

software's location or the type of interconnection between the software and a device. This clarification will have an impact on the mHealth sector.

Secondly, new groups of products without an intended medical purpose will fall under the Medical Devices framework, taking into account the existing harmonised standards for analogous devices with a medical purpose, based on similar technology (such as contact lenses, dermal fillers, etc., as listed in Annex XVI). Such products will be subject to risk management procedures and whenever necessary, to clinical evaluation.

Thirdly, as far as traceability and labelling of MDs are concerned, the Unique Device Identification system (UDI system) is introduced and shall apply to all devices placed on the market except custom-made and investigational devices. The obligation to place the UDI carrier on the label of the device will vary from one to five years, after the day the Regulation enters in force, depending upon the class of the device concerned.

Fourthly, manufactures should implement a risk management system for each MD. Risk management is understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

(a) establish and document a risk management plan for each device;
(b) identify and analyse the known and foreseeable hazards associated with each device;
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
(d) eliminate or control the risks referred to in point (c);
(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and
(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures.

Fifthly, relating to stricter rules on MDs clinical evaluation and investigation as well as the availability of data reports. Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or within three months of the early termination or

temporary halt, the sponsor shall submit by means of the electronic system on clinical investigations a report accompanied by a summary presented in terms that are easily understandable to the intended user.

The last but not the least note relates to the Authorized Representatives' liability, which increases under the MDR. For manufacturers who are not established in the Union, the Authorised Representative shall be legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the Authorised Representative is without prejudice to provisions of Directive 85/374/EEC, and accordingly the Authorised Representative should be jointly and severally liable with the importer and the manufacturer.