Are We Wasting a Good Crisis? The Revision of the EU Medical Devices Directives and the Impact of Health Data Rules

Alex Denoon and Erik Vollebregt***

I. Introduction

The three Directives concerning medical devices[1] are currently under revision and a long process that started with a consultation in 2008 seems to be nearing its conclusion with two Regulation proposals in the pipeline and at the time of writing under discussion in the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI Committee). In this article we examine if the proposed Regulation for medical devices will deliver on the promises. We will focus on what we know to be the hot topics for industry. Since the article is forward-looking about draft legislation currently in the legislative process, it is by necessity speculative on points and the proposals may have changed by the time this article is printed.

1. Interlude: Joint Immediate Action plan

While the European Commission was preparing its proposals that were submitted on 26 September 2012[2], several scandals involving implantable medical devices rocked the market at the end of 2011 and caused public outrage. The European Parliament's ENVI Committee vowed that this could never happen again ("Learn the lessons of this fraud!"[3]), which has coloured the ENVI Committee's actions since. The Commission commenced the Joint Immediate Action Plan at the end of 2011[4] with a number of actions required from the Member States to significantly improve the quality of Member States' market surveillance and supervision of Notified Bodies, as well as improve the functioning of the vigilance system for medical devices and support the development of traceability tools and long-term monitoring in terms of safety and performance (e.g. Unique Device Identification systems and implant registers).

2. Some kind of agency control

The hanging question is whether the new system will require a form of pre-market approval ("**PMA**") such as exists for pharmaceuticals in the EU and both pharmaceuticals and medical devices in the US by the US Food and Drug Administration (FDA). The Commission initially considered a requirement for PMAs by a regulatory agency such as the European Medicines Agency (EMA), but concluded it would not improve the safety of medical devices.[5] In the end, the Commission proposed the compromise solution of an additional scrutiny procedure[6] con-

* Partner at Lawford Davies Denoon, London.

** Partner at Axon Lawyers, Amsterdam.

1 Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, OJ 1990 L 189/17; Council Directive 93/42/EEC Concerning Medical Devices, OJ 1993 L 169/1; Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, OJ 1998 L 331/1.

2 Commission Proposal for a Regulation of the European Parliament and of the Council on Medical Devices and Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM(2012) 542; Commission Proposal for a Regulation of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, COM(2012) 541.

3 European Parliament Committee on the Environment, Public Health and Food Safety Press Release, "PIP Breast Implants: Learn the Lessons of This Fraud", 25 April 2012, available on the Internet at: <www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bIM-PRESS%2b20120423IPR43732%2b0%2bDOC%2bPDF%2bV0%2f%2fEN> (last accessed on 17 September 2013).

4 European Commission Press Release IP/12/119, "Medical Devices: European Commission Calls for Immediate Actions – Tighten Controls, Increase Surveillance, Restore Confidence", 9 February 2012, available on the Internet at: <www.europa.eu/rapid/pressReleasesAction.do?reference=IP/12/119&format=HTML&aged=0&language=EN&guiLanguage=en> (last accessed on 17 September 2013).

5 Commission Staff Working Document: Impact Assessment of the Revision of the Regulatory Framework for Medical Devices, SWD(2012) 273.

6 The additional scrutiny measures are set out in Article 44 of the proposed Regulation on Medical Devices, *supra* note 4.

ducted by a new committee under the supervision of the Commission (the Medical Device Coordination Group, MDCG) that could request a second review of the review conducted by the Notified Body of any high-risk device. The ENVI's Committee rapporteur, after the ENVI Committee had taken the position in press releases that the market needed pharmaceuticals style PMAs, proposed a market authorisation process via EMA (for highest risk devices) and via the national authorities (for other high-risk devices). This proposal did not sit well with other ENVI members and caused significant pushback from the sector and caused a veritable deluge of amendments (approximately 900 for the entire medical devices proposal). At the time of writing of this article the ENVI Committee is in the process of preparing its compromise and other amendments for the vote scheduled on 25 September 2013.

The respective positions adopted by the European Parliament and industry seem entrenched as regards the possible beneficial effects of a PMA approval system, such as that currently conducted by the FDA. Will this be an improvement for Europe? Let's look at the facts.

First, research commissioned by industry shows that there are not more recalls of medical devices in the EU than in the US, while the EU's approval process via Notified Bodies is faster and requires less clinical data upfront. Conversely, the FDA leaked an internal report[7] of a number of medical devices that were admitted in the EU, but not in the US, suggesting that the EU system regularly admits unsafe medical devices. We take the view that the FDA's internal report does not support this conclusion.

Secondly, the EMA itself is considering abandoning the current front-loaded market approval mechanism for pharmaceuticals as part of its Roadmap 2015[8] because it is not conducive to innovation and demands too much clinical data that would not necessarily need to be provided upfront, depriving patients from new medicines that could enter the market quicker.[9] The adaptive licensing model advocated by the EMA[10] looks surprisingly like the medical devices approval system currently in place in the EU, with stronger post market clinical follow up as currently already in place in the Post Market Clinical Follow Up MEDDEV.[11] [12]

Thirdly, Member States and Notified Bodies oppose the system because they are not convinced that the EU can generate the political momentum to set up specific EU level and national approval agencies for medical devices because neither the resources nor the experts are available. The Member States are reluctant to transfer the competence to a centralised European body.

At the moment of writing it is clear that the member states are not happy with the model advocated by the European Parliament. This was quite clearly expressed at the Health Council meeting in Brussels on 10 December 2013. What does seem clear from the rumours we pick up from the market is that the end result will be a compromise as we can only make them in Europe. EU legislative compromise is about giving everybody just enough of a little something so each of them can claim success. The French have something like an agency sign off[13], ENVI rapporteur Roth-Behrendt has the EMA in the mix[14], the Notified Bodies stay involved[15], the Member States have committees that play an important role[16] and the Commission is the spider in the web[17], so you

7 US Food and Drug Administration (FDA), "Unsafe and Ineffective Devices Approved in the EU That Were Not Approved in the US", May 2012, available on the Internet at: http://www.elsevier-bi.com/~/media/Supporting%20Documents/The%20Gray%20Sheet/38/20/FDA_EU_Devices_Report.pdf (last accessed on 17 September 2013).

8 European Medicines Agency, "Road map to 2015, The European Medicines Agency's Contribution to Science, Medicines and Health", 16 December 2010, available on the Internet at: <www.ema.europa.eu/docs/en_GB/document_library/Report/2011/01/WC500101373.pdf> (last accessed on 17 September 2013).

9 Eichler HG, Oye K, Baird LG, Abadie E, Brown J, Drum CL, Ferguson J, Garner S, Honig P, Hukkelhoven M, Lim JC, Lim R, Lumpkin MM, Neil G, O'Rourke B, Pezalla E, Shoda D, Seyfert-Margolis V, Sigal EV, Sobotka J, Tan D, Unger TF, Hirsch G, "Adaptive licensing: taking the next step in the evolution of drug approval", 91(3) Clin Pharmacol Ther. (2012), pp. 426 *et sqq*.

10 See by way of example, Hans-Georg Eichler, "Adaptive Licensing: A Useful Approach for Drug Licensing in the EU?" presentation held at the European Medicines Agency (EMA), London, March 2012.

11 Erik R. Vollebregt, "Is the European Commission Meeting the Needs of Patients, Healthcare Professional and Manufacturers with the new medical devices regulation proposal?", *Journal of Medical Devices Regulation* (2013), pp. 6 *et sqq*.

12 Commission Guidelines on Medical Devices Post Market Clinical Follow-up Studies: A Guide for Manufacturers and Notified Bodies, MEDDEV 2.12/2 rev2, January 2012.

13 France is the Member State that has been publicly pro-EMA market approval from the start.

14 She helped draft the legislation that provided the legal basis for the EMA.

15 This is what the Member States want: not too much transfer of sovereignty to the EU.

16 E.g., the Medical Devices Coordination Group (MDCG) and other committees.

17 The Commission will move to chair all committees and coordinate all activity in relation to the proposed Regulation.

can just draw the picture by connecting the dots of interests involved. That kind of process never leads to the best legislative solution, but inevitably to the most overcomplicated and unclear one. Neither will help, as we need legislation that is clear, precise and serves its own purpose. Not somebody else's political purpose. Currently it is not even sure that the regulation proposals will be finalised before the EU elections in May 2014, because notably the UK and the Netherlands are very much against the PMA system as proposed by the Parliament. This will likely lead to the project being delayed by the Council until it cannot be finsihed in time.

3. Surprise inspections by Notified Bodies

As part of the Joint Immediate Action Plan and to prepare for the Regulation the Commission is working on measures to make the Notified Bodies do what the Member States should have been doing to prevent the PIP scandal: supervise production of medical devices. The measures planned are a recommendation on unannounced audits by Notified Bodies and an accompanying Commission regulation for implementation of unannounced audits by the Member States.[18] The recommendation will trigger applicability of the clauses on unannounced audits in the Notified Bodies Code of Conduct.[19] As we understand the contents of the draft recommendation and Regulation the focus will be on at least one 'surprise' inspection during the CE marking stage and afterwards according to timetable defined by the Notified Body not disclosed to the manufacturers. The inspections will be conducted both at the manufacturer himself and at his critical subcontractors, and each of them has to be able to accommodate an audit whenever production is in progress.

Will these inspections help? We are not convinced that they will solve the problem. First, it was not necessary – legally speaking – to impose this on Notified Bodies. Under current legislation, each Member State can currently: (a) inspect manufacturers or their subcontractors; (b) require Notified Bodies to conduct such inspections as condition for accreditation. To us, these new measures seem window-dressing for the real problem of a historical lack of supervision of Notified Bodies by Member States and lack of Member States' commitment of resources to active market surveillance. This problem is compounded by unwillingness to cooperate for effective cross-border enforcement. It is our contention that inspections should be reserved to inspectors with investigative powers, not to auditors. The companies that remain committed to cheat their auditors like PIP, the company that deliberately misled its Notified Body, will find ways to continue to do so. The companies that are already doing their best to assure production quality will only be faced with additional burdens and costs.

II. Data protection and health data

In parallel with the replacement of the current Medical Devices Directives with a new Medical Devices Regulation, the European Parliament intends to replace the current Data Protection Directive with a new Data Protection Regulation. It should be stressed that the proposed amendments to the data protection regime are not motivated by concerns regarding the life sciences sector (let alone medical devices) *per se*. The clear focus of the proposed stricter requirements relate to identity theft, the use of personal information on the internet and recent revelations regarding the extent to which the US National Security Agency has been accessing personal data of European citizens.[20]

1. Specific Amendments – Penalties and Rights

Parliament intends to strengthen individuals rights, by creating new rights and remedies and the introduction of eye-watering penalties for breaches of data protection law. It is proposed that the increased penalties for breach will be up to 2 % of global turnover.

18 See for details, Erik Vollebregt's medical devices legal and regulatory blog, available on the Internet at <http://medicaldeviceslegal.com/2013/07/25/in-the-mean-time-joint-immediate-action-plan-and-other-things-over-the-summer/> (last accessed on 17 September 2013).

19 Code of Conduct for Notified Bodies under Directives 90/385/EEC, 93/42/EEC and 98/79/EC, "Improving Implementation of the European CE Certification of Medical Devices Through Harmonization of Quality and Competence of Notified Bodies", version 3.0., 10 October 2012, available on the Internet at: <www.team-nb.org/documents/2013/Code_of_Conduct_Medical_Notified-Bodies_v3-0.pdf> (last accessed on 17 September 2013).

20 See e.g. Viviane Reding, Vice-President of the European Commission, EU Commissioner for Justice, "Data protection reform: restoring trust and building the digital single market", speech 13/720 held at the 4th Annual European Data Protection Conference, Brussels, 17 September 2013.

The introduction (or codification) of various "data rights" consistent with the Lisbon Treaty is also a new development. In essence, data subjects will have a right of access and a right to "data portability". This entails a right, to obtain free of charge data concerning the data subject in commonly used, interoperable, and where possible open source electronic format. As a result, medical device companies will have to manage the data that they hold in respect of individuals (patients, clinicians and trial subjects) in a format that is commonly used, interoperable, and probably open source. In addition, data subjects will have a "right to be forgotten".

2. Reconciling Conflicting Requirements

These new rights pose significant practical challenges for the medical devices sector. The proposed new Medical Devices Regulation will impose stricter requirements as regards:

(a) clinical data prior to being placed on the market with a CE Mark;
(b) clinical data after launch through enhanced vigilance, more detailed PMS plans including a presumption in favour of post marketing follow-up studies and the use of registries; and
(c) traceability.

These requirements, while commendable in principle, can be difficult to reconcile with the proposed amendments to data protection law under the new Regulation. By way of example, if a patient has had a medical device implanted and therefore the traceability obligations will apply. However, these requirements will conflict with the nebulous concept of the right to be forgotten. No statutory mechanism has been proposed to reconcile these conflicting requirements.

These requirements become even more extreme in respect of relatively small patient populations, as the clinical data supporting the CE Mark may disproportionately depend on the data provided by each clinical trial subject.

3. Consent

At the very commencement of any clinical study (which are intended to dramatically increase under the new Medical Devices Regulation), compliance with the new data protection regime will be problematic. Obviously, manufacturers will want to obtain the consent of the patient/study-subject to the use of the data arising from the study. Under the proposed regime, consent will only be valid if it is freely given, genuine, explicit, specific and informed. Further, the consent should cover all processing activities that might be carried out in respect of the data. For clarity, it will not be possible to have "consent by silence" whereby patients are required to opt-out if they do not want their data used in a particular study.

In addition, consent to the use of the patient's data should be given independently from other matters. This could require the healthcare practitioner to obtain consent to the use of the patient's data in a separate consultation from the consultation regarding the patient's treatment. In such circumstances, the doctor (or manufacturer as the case may be) bears onus of proving that the patient gave valid consent to the use of his or her data. Finally, consent will *prima facie* be invalid if it is given in circumstances where there is a clear imbalance between the data subject and the controller, which would virtually always apply in the relationship between a doctor and a patient.

There is no recognition of the special nature of (and critical role performed by) clinical studies in the Data Protection Regulation despite the fact that there is good evidence to suggest that overly formalised consent regimes lead to skewed patient groups.

As a result, it will be very difficult (if not impossible) to be confident that the patient's consent satisfies these requirements for the purposes of the Data Protection Regulation. By way of example, it is difficult to be confident that consent to the processing of a patient's data be valid:

– If consent was a condition of entry into a clinical investigation? Will this constitute freely given and genuine consent?
– When given in a clinical investigation of product X which serendipitously leads to a new product Y? Will this satisfy the requirements that the consent must be explicit and specific and must address proposed processing?
– What if X was a HPV diagnostic and Y a new "morning after" pill?
– When given in the same consultation as the consent to treatment or recorded in a single document with the consent to treatment? Will this breach

the requirement that the consent must be provided "independently from other matters"?
– When given by a patient to a doctor? Will this constitute an imbalance of power?

Thus, despite the enthusiasm for additional clinical data, the consent requirement alone will make this problematic.

The Data Protection Regulation does contain a derogation from the requirement to obtain consent to the use of personal data where such use is for *research purposes*. However, the latest draft of the Data Protection Regulation proposed by the Rapporteur Albrecht imposes the following conditions on the derogation where it relates to the use of personal data concerning health:

(1) The research must serve *an exceptionally high public interest;*
(2) That research *cannot possibly be carried out otherwise*;
(3) The data must be anonymised or pseudonmyised under the *highest technical standards; and*
(4) Any such processing must be *approved* by the relevant competent authority.

In our view, a huge proportion of medical device investigations (both before and after market launch) will struggle to satisfy these startlingly high standards. It seems extremely unlikely that any health technology assessment would be able to satisfy these criteria. Thus the sector will need to reconcile the increasing demand for clinical data under the new Medical Device Regulation (and the increasing demands for health economic data under reimbursement systems) with the extraordinary demands required for valid consent and the startlingly high requirements to satisfy the research exemption.

The authors are also aware of a number of research projects that will not be conducted in Europe as a result of the uncertainty created by these proposals.

4. Practical Steps

While a number of these amendments are highly controversial[21], all of the authors' clients (from manufacturers to researchers) are preparing for a new enhanced data protection regime.

As an absolute minimum, one should seriously consider:
– reviewing and updating consent forms, including adding very specific descriptions of the projects and possible uses of the data;
– preparing detailed (and possibly externally reviewed by independent ethics committees) justifications for holding data;
– minimising the amount of identifiable data held, whether by deleting data or anonymising existing data;
– improving systems to anonymise and secure data;
– improving systems to anonymise and secure data; and
– unfortunately, whether to conduct studies in Europe at all.

III. Genetics

We do not have enough time or space in this article to comment on the startling (and in our view unworkable) proposals regarding genetic tests in the proposed In Vitro Diagnostic (IVD) Regulation in detail.[22] Essentially, it is proposed to make genetic testing conditional upon application of a mandatory informed consent procedure for use of the device on the patient's sample based on
– "appropriate information on the nature, the significance and the implications of the genetic test"
– provision by the physician to "the test subject concerned with appropriate and comprehensible genetic counselling without prejudging the outcome. The genetic counselling shall include medical, ethical, social, psychological and legal aspects"
– while the "consent shall be given explicitly in writing. The consent may be revoked at any time in writing or orally."

21 See by way of example, the strongly worded statement by many of Europe's leading biomedical research bodies and patient groups "Impact of the draft European Data Protection Regulation and proposed amendments from the rapporteur of the LIBE committee on scientific research", March 2013, available on the Internet at: www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm054713.pdf (last accessed on 17 September 2013).

22 See for an overview Erik Vollebregt, "ENVI's IVD regulation amendments", available on the Internet at: <http://medicaldeviceslegal.com/2013/05/28/envis-ivd-regulation-amendments/> and "Rapporteur Liese's IVD regulation amendments are out: not so horizontal as expected", available on the Internet at: http://medicaldeviceslegal.com/2013/04/17/rapporteur-lieses-ivd-regulation-amendments-are-out-not-so-horizontal-as-expected/ (last accessed on 17 September 2013).

The proposals as regards the treatment of genetic data and genetic tests under the Data Protection Regulation and the IVD Regulation, which at their most charitable reflect a certain paranoia about genetic data and genetic tests, will have unintended consequences for those who look at genetic markers in the course of developing novel medical devices. By way of example, an assay which gathers data to see if the therapeutic outcomes of a particular intervention vary for patients with different genetic markers (such as receptors which have a genetic origin) may constitute unauthorised (and therefore criminal) genetic tests or genetic IVDs. These proposals are already inhibiting the development of this crucial aspect of personalised or stratified medicine. Like the measures discussed above around consent with respect to health data these measures will in practice create more problems than they solve. For example, what happens when the consent to conduct the genetic test is revoked after the test has been performed? Does that invalidate the test results and can't they be used anymore? What if medical treatment has been initiated based on these results?

IV. Conclusion

Our conclusion is that the EU is wasting a good crisis by not remedying the true problems of the EU medical devices system: insufficient and inefficient *ex post* supervision by Member States' authorities, by bolting on invasive compromise measures to a legislative proposal that should have been a midlife update of a system that already works well.

These problems are compounded by a proposal for a system that on the one hand will require medical devices manufacturers to provide vastly more clinical data. However, the proposal for the general Data Protection Regulation will complicate the collection and processing of clinical data to an extent that possibilities for clinical research in the EU will be severely compromised.

None of the stakeholders (researchers, developers, manufacturers, clinicians and patients) involved stands to benefit from the window-dressing measures currently proposed. Worse, these proposals jeopardise the advantage currently enjoyed by European patients, namely, expedited access to novel medical devices.