Petri Pommelin

The Survival Guide to EU Medical Device Regulations

The Survival Guide to EU Medical Device Regulations

Petri Pommelin

The Survival Guide to EU Medical Device Regulations

Publisher: BoD™ – Books on Demand, Helsinki, Finland

Printed and bound: BoD – Books on Demand GmbH, Norderstedt, Germany

ISBN: 978-951-568-120-1

CONTENTS

Introduction

It was August 1992 when I joined the Finnish competent authority for medical devices. During the first week I started reading the Active Implantable Medical Devices Directive (AIMDD) and the draft proposal for the Medical Devices Directive (MDD). Finland had applied for the membership of the European Union (EU), which also meant transposition of huge amount of existing EU legislation into the national law and regulations. I was deeply engaged with the transposition of the MDD and the AIMDD.

During 1997 and 1998 I participated in the negotiations on the directive of in vitro diagnostic medical devices (IVDD) at the EU Council working party. I was in charge of the daily operations of the Finnish competent authority until October 2006 when I changed into another job. However, I continued to follow actively the development of the EU regulatory system for medical devices.

I was invited to give lectures in a course on regulatory requirements for medical devices at Tampere University of Technology, and a couple of years later also at Tampere University of Applied Sciences. In 2011 the two courses were combined. In spring 2017 I had given 12 courses and altogether 425 students had attended.

As the Regulations for the medical devices were progressing I thought that the simplified story of the new requirements I was giving to the students could also be useful to manufactures and other economic operators. So, I decided to compile this book to support the reading of the challenging content of the new Regulations. I hope that you find this guidance helpful.

Tampere, June 2017

Petri Pommelin

1. Where are we coming from?

The time of harmonised EU legislation for medical devices began January 1, 1995. It was the end of the transitional period of the AIMDD and the start of the transitional period of the MDD. The manufacturers of medical devices experienced the first challenge of adapting their operational systems to the new provisions and procedures. The deadline was June 14, 1998.

Simultaneously, the drafting of the IVDD was launched. The IVDD was adopted December 7, 1998, and enforced June 7, 2000 with transitional period ending December 12, 2005. The Commission issued two Directives on reclassification of breast implants (2003) and hip, knee and shoulder joint replacements (2005). The BSE issue resulted in the Commission Directive (2003) on medical devices manufactured utilising tissues of animal origin. Some of the major shortcomings of the MDD and the AIMDD were repaired by the Directive 2007/47/EC.

The IVDD was supplemented by three Commission Decisions on Common Technical Specifications (2002, 2009 and 2011) and the Commission Directive on Variant Creutzfeld-Jakob Disease assays (2011). The Commission Regulation on medical devices manufactured utilising tissues of animal origin was issued in 2012. The infrastructure of the EU regulatory framework was improved by the Commission Decision on the European Databank on Medical Devices aka Eudamed (2010) and the Commission Implementing Regulation on the designation and the supervision of notified bodies (2013). In addition, the Commission has published during the years several legally non-binding guidance documents (MEDDEVs), consensus statements and informative documents that pursue the objective of ensuring uniform application of the relevant provisions of the directives within the EU.

Problems with diverging interpretation of the Medical Device Directives as well as some incidents with breast implants and metal hip implants highlighted the weaknesses of the current legal system and damaged the confidence of patients, consumers and healthcare professionals in the safety of medical devices. In September 2012, the European Commission finally published the proposals for the Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR).

> Thus a fundamental revision of these Directives was needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation (MDR Recital 1, IVDR Recital 1).

On 5 April 2017, two new Regulations on medical devices (MDR[1] and IVDR[2]) were adopted replacing the existing three Directives (AIMDD, MDD and IVDD).

> This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. (MDR Recital 2, IVDR Recital 2)

> This Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected. (MDR Recital 2)

> This Regulation sets high standards of quality and safety for in vitro diagnostic medical devices by ensuring, among other things, that data generated in performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected. (IVDR Recital 2)

2. Where are we going from here?

A directive is a form of legislative act addressed to the EU Member States. The directive binds the Member State to reach certain objectives in their national legislation. In practice Member States are required to make changes to their laws (commonly referred to as transposition) in order for the directive to be implemented correctly.

A regulation is a legal act of the EU that becomes immediately enforceable as law in all Member States simultaneously. When a regulation comes into force, it overrides all national laws dealing with the same subject matter and subsequent national legislation must be consistent with and made in the light of the regulation.

The MDR and the IVDR introduce a life-cycle approach and takes into account the guidance developed for medical devices at international level. This approach

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

also incorporates some existing European guidance (MEDDEVs[3]), *i.e.* the Guidance on Authorised Representation, Vigilance System, Post-Market Clinical Follow-Up and Clinical Evaluation, into the regulations.

> Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety. (MDR Recital 4, IVDR Recital 4)

> To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations. (MDR Recital 5, IVDR Recital 5)

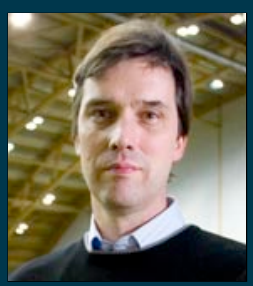
> There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned. (IVDR Recital 5)

As the MDR and the IVDR were published in the EU Official Journal on 5 May 2017 it meant that the transitional periods under the regulations started 26 May 2017. The chapter 18 of this guidance gives more information on the transitional provisions.

STEP 1	Find the regulations in suitable language from the web site of the EU Official Journal[4] and start the exploration.

[3] http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
[4] http://eur-lex.europa.eu/oj/direct-access.html

The Regulations for medical devices and in vitro diagnostic medical devices were published in the Official Journal of the European Union on 5 May 2017, and they entered into force 26 May 2017. A regulation is a legal act of the European Union that becomes immediately enforceable as law in all Member States simultaneously. This book gives guidance on the definitions, the key concepts and the main elements. The intention is to provide an introduction that supports the further reading of the challenging content of the Regulations.



The writer worked for the Finnish competent authority for medical devices from 1992 till 2006. Despite the change into another job he kept following actively the development of the EU regulatory system. Since 2005 he has regularly given lectures in a course on regulatory requirements for medical devices at Tampere University of Technology and Tampere University of Applied Sciences.

9 789515 681201

BoD™ BOOKS on DEMAND

www.bod.fi