The Revised EU Medical Device Directive in Brief

Introduction

The European Commission must review the Medical Devices Directive (MDD) every five years. The new Directive 2007/47/EC was formally adopted on September 5, 2007, and published on September 21.1 The directive became effective on October 11, 2007.2 Member States must adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by December 21, 2008. It will go into effect on March 21, 2010.3

This GT Alert addresses only the changes that Directive 2007/47 made to the MDD. The changes made to Directives 90/385 on active implantable devices and 98/8 on biocidal products are not discussed here.

Relationship with the Advanced Therapies Regulation

Although the MDD does not apply to blood products, plasma or blood cells of human origin, or to human tissue engineered products as such, provision has been made to bring devices with an ancillary human tissue engineered product within the ambit of the legislation; this complements the new regulation on Advanced Medical Therapies4 and thereby avoids a regulatory gap. This, however, only concerns tissue engineered products containing viable cells.5 Products that do not contain any viable cells fall by the wayside, since neither of these instruments regulates them.

Extended Scope of Definition of Medical Device

The definition of a medical device according to Art. 1 of the revised MDD now includes software products as such,6 while software used to be covered only insofar as it was “needed for the proper application intended by the manufacturer.”

---

1 Official Journal L 247, 21/09/2007 p. 21
2 Article 5
3 Article 4 (1)
5 Article 2 (1) (b) of the Regulation
6 Article 1 (2) (a)
The revised Essential Requirements in Annex I to the MDD require that devices that incorporate software, or constitute medical software independently, be validated. This validation process must take into account the state of the art and consider the aspects of development lifecycles, risk management and verification.\(^7\) With respect to formal classification, "stand alone software is considered to be an active medical device" pursuant to section 1.4 of Annex IX to the revised MDD. As a result, the provisions on classification will apply to medical devices based on or incorporating software.

The demarcation vis-à-vis medicinal products now happens by means of the “principle mode of action.”\(^8\) Things have become more complicated with the adoption of the Advanced Therapy Products regulation, which provides for a regime among others somatic cell therapy medicinal products and tissue engineered products incorporating medical devices. As a result, a medical device can also constitute an integrative part of a (combined) advanced therapy product and need to be authorized through the procedure provided in that regulation.\(^9\)

The revised directive defines single use device as “a device intended to be used once only for a single patient.”\(^10\) This definition was included for the purpose of Annex 1, par 13.3 (f) concerning labeling, which in its amended version states that the labeling must indicate that the device is for single use, but also that the manufacturer’s declaration of single use must be consistent across the Community.

**Essential Requirements—General Requirements**

The level of technical knowledge, experience, education or training of the intended users is now explicitly a relevant factor in the evaluation of the safety of a medical device.\(^11\) Also, the information provided with the medical device must now be such as to use the medical device "safely and properly, taking account of the training and knowledge of the potential users."\(^12\) The revised MDD creates the possibility for the Commission to specify other means of providing instructions for use than via the instructions for use as described in Annex I.\(^13\) With regard to Class IIb and Class III devices, the manufacturer must now make available data giving a summary of the characteristics of the device. The procedures for this and in particular the data to be made available and the conditions under which it shall be available shall be adopted by the Commission’s Medical Devices Committee.\(^14\)

If certain medical devices are also hazardous to persons, article 3 MDD now specifies that where a relevant hazard exists, devices that are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery must also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to the Medical Devices Directive.

---

\(^7\) Annex 1, section 12.1a  
\(^8\) Art. 1 (5) (c)  
\(^9\) See article 2 (1) (d) of the regulation  
\(^10\) Article 1 (2) (n)  
\(^11\) MDD Annex I, section 1  
\(^12\) Annex 1, section 13.1  
\(^13\) Annex I, section 13.7  
\(^14\) Annex I, section 13.8
Borderline Products

Borderline products (medical devices incorporating medicinal products) were problematic under the old MDD because they needed to be evaluated by analogy with medicinal products. This section of Annex I has now been revised to provide for a procedure of scientific advice on the quality and safety of the substance. This advice is given by the European Medicines Agency (EMEA) in the case of medicinal products that already have been granted a marketing access under the regime of Directive 2001/83 or Regulation 726/2004, medicinal products specifically covered by Regulation (EC) No 726/200416 and human blood derivatives.

When issuing its opinion, the EMEA must take into account the manufacturing process and the data related with the benefit of incorporation of the substance into the device. For advice in respect to other substances, the notified body must turn to the competent authorities designated by the Member States in accordance with the medicinal products Directive 2001/83/EC on the quality and safety of the substance. When issuing its opinion, the concerned competent authority shall take into account the manufacturing process and the data related to the benefit of incorporation of the substance into the device.

Clarification of Requirements for Design Examinations and Classification

The clarification of the requirements for design examinations is intended to support national notified bodies in their task of ensuring conformity with the Essential Requirements under Annex I. This measure helps end the practice of the European Commission to “promote” certain types of products (e.g., breast implants or joint implants) from a lower class into class III in an effort to impose sufficient by strict examination procedures. The European Commission employed this measure to counter the tendencies of certain notified bodies to laxly control and evaluate design documentation in lower classes. As the requirements for design examinations will be stated more clearly and will be more sophisticated, the need for such an approach will no longer exist.

Member States may now initiate a procedure whereby the European Commission is asked to review the validity of existing classifications under Annex IX of the revised MDD. This review of existing rules should take into account the technical progress as well as centrally reported incidents concerning the

---

15 Annex I, section 7.4
16 See the Annex of Regulation 726/2004: (1) medicinal products developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody methods, (2) medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals, (3) medicinal products for human use containing a new active substance which, on 20 May 2004 was not authorised in the Community, for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, and with effect from 20 May 2008 auto-immune diseases and other immune dysfunction and viral diseases (after 20 May 2008, the Commission may present any appropriate proposal modifying) and (4) medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.
17 Annex I, section 7.4
18 Article 9 (3) MDD
device. This used to be possible only by means of adaptation of the classification by the Medical Devices Committee.

Modifications in the annex related to the classification system will have consequences that many companies are not aware of. It will, for example, bring products for the disinfection of invasive devices into class IIb. The rule for the determination of the time of contact of invasive products has also been modified and it might have effect on the classification of some invasive devices. Software is considered an active medical device. As a consequence, companies may need to revisit the classification of their devices in some cases. This means that they may be required to certify and implement stricter procedures for the devices concerned within the deadlines set by the revised MDD.

Clinical Investigation

Explicit references to Annex X in the provisions of Annexes II to VII ensure that the new rules on clinical evaluation are enforced throughout the whole regulated area of medical devices. Clinical investigation of medical devices is now seen as a continuous process to identify, generate, document and evaluate clinical data.

The old MDD already provided that with respect to devices in Class III and implantable and long-term invasive devices in Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified the manufacturer within that period of a decision to the contrary based on considerations of public health or public policy. This has not been amended.

However, the revised MDD foresees that the competent authority shall communicate such decisions with regard to a refusal or halt of a clinical investigation to the other Member States.

With regard to side effects, the purpose of clinical investigations has been changed from a simple evaluation to discover undesirable side effects to side effects in general. Furthermore, determining the acceptability of the benefit/risk ratio of side effects against the intended performance of the device is included as one of the new purposes of clinical investigations. New obligations are:

- The outcome of clinical evaluations must be referenced in the technical documentation of the medical device;
- The obligation to update clinical evaluation and its documentation; and

---

19 Details of this procedure are laid out in Art. 7 para. 2 and Art. 5 and 7 of Decision 1999/468/EC.
20 Article 9(3) in the former version of the MDD
21 Annex IX, section 2.6
22 Article 15 (2)
23 Annex X, section 1.1
24 Annex X, section 1.1 read in conjunction with Annex I, section 6
25 Annex I, section 6a juncto Annex X, section 1.1b. In practice this means that companies cannot suffice with a technical risk/benefit analysis only, but must also perform a clinical risk/benefit analysis, in all risk classes (see Changes to clinical evaluation of devices and the role of NBs” in Clinica Special Supplement EU Notified Bodies, June 2007, p. 6)
• The obligation to keep Member States’ authorities informed by the competent authority of refusals of clinical investigations requests.27

Further requirements have been introduced in order to create transparency in the manufacturer’s decision-making process concerning clinical investigation. First, there is a new requirement to substantiate a decision not to demonstrate conformity with essential requirements by reference to clinical data.28 Secondly, the obligation has been amended to perform clinical investigations for class III devices unless relying on existing data is justified.29

Finally, the scope of clinical investigation requirements under the MDD extends to the phase of post-market surveillance (PMS).30 The clinical evaluation of a device has to be continued after the finalization of the clinical investigations and the marketing of a device by clinical evaluations in the post-market phase. Following Annex X, a post-market clinical follow-up (PMCF) is required.

The new system of clinical evaluation as defined in Art. 15 and Annex X is now the standard approach to show conformity with safety standards.

Authorised Representative

Art. 14 of the new MDD provides that companies that are not established in the EU must have a single “authorised representative” in the European Union. This person or entity represents the manufacturer of medical devices in case the manufacturer does not have a place of business within a Member State. The authorised representative stands in lieu of the manufacturer with regard to information obligations towards the authorities and its name and address appear on the CE-marking, the outer packaging or the information for use.

The Medical Devices Committee

The authority of the Commission to define procedures for implementation of the MDD through its Medical Devices Committee pursuant to Art. 7 has been considerably extended under the revised MDD. In the past, the Medical Devices Committee has not been very active in exercising its authority under the MDD. The amendments to the MDD show that the Commission intends to change this: in addition to its current authority under the former MDD, the Committee is now entitled to define procedures for classification, registration of authorised representatives, registration of clinical investigation data and confidentiality of information.31

---

26 Annex X, section 1.1c  
27 Article 15 (6)  
28 Annex X, section 1.1d  
29 Annex X, section 1.1a  
30 Annex X, section 1.1c  
31 See articles 9 (3), 13 (1), 14a, 14a (3) and 20
The additional authority for the Committee will likely lead to a significant increase of the procedural documents to be produced by the Commission in the future. However, no drafts for these documents have been published thus far.

**Cooperation Between National Authorities**

The increased need to coordinate activities of national authorities regarding issues relating to the MDD that concern a number of Member States and/or third countries has prompted the EU to create a legal basis for coordination of such activities.

The new Art. 20a foresees that Member States shall take appropriate measures in order to encourage that the competent national authorities cooperate with each other and provide each other and the Commission with information in order to ensure the consistent application of the MDD. Furthermore, Art. 20a provides that the cooperation can also take place within initiatives at an international level, as long as this takes place without prejudice to the provisions of the MDD.

**Reprocessing of Medical Devices**

One of the most sensitive issues in the revision of the MDD was whether and how the reprocessing of medical devices should be regulated on an EC level. Instead of addressing the current difference in national rules on reprocessing the Commission has postponed deciding on the issue by means of the new article 12a. This provides that the Commission shall submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community by 5 September 2010. The Commission shall subsequently submit to the European Parliament and to the Council any additional proposal it may deem appropriate. This way the Commission keeps all of its options open in this politically difficult dossier. The devil is in the details, however: the essential requirements now provide for an information obligation relating to medical devices that have been marked as for single use in respect of the risks related to reprocessing in Annex I, point 13.6.32 This way, the manufacturer is defacto forced to justify intending a medical device for single use only. This leads to an extra administrative burden for manufacturers. In addition, there is the question of what happens if a device is reprocessed and an incident occurs that has not been indicated by the manufacturer as a possible risk related to reprocessing. In that case the manufacturer may be forced to prove that he had no knowledge of that risk and therefore did not describe it.

**Conclusion**

The majority of the amendments aim to clarify the process of bringing medical devices to market and monitoring said devices. At the same time, they seek to close certain loopholes and update the framework for dealing with new developments, like the increasing importance of software in medical devices. In addition, increased safety is achieved through the emphasis on clinical evaluation

---

32 “If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request”.
documentation as part of the file, which notified bodies must now evaluate. The question is whether all notified bodies are up to this important responsibility. On the other hand, the Commission should have made up its mind with regard to reprocessing of medical devices for single use. By not having done so it has prolonged the current controversy with regard to this issue, including the inclearity for manufacturer and the health risks for patients. The reclassification of certain devices may catch companies unawares. Companies are well advised to ascertain themselves timely of whether their devices need to comply with stricter standards and start to implement procedures in time.

The Medical Devices Committee will play a much more important role in refining and providing procedural rules under the revised MDD.

This GT Alert was written by Erik Vollebregt, of counsel, Greenberg Traurig Amsterdam (vollebregte@eu.gtlaw.com; Tel: +31 20 301 7436). Erik’s practice focuses on (medical) technology, healthcare and life sciences. He has broad experience in both litigation and transactional work in these areas, as well as in the application of antitrust law to medical technology and pharmaceutical products.