Approval of Medical Devices

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Prepared by the Staff of the Global Legal Research Center

SUMMARY This report describes the approval process for medical devices in the European Union and fifteen countries, and also indicates whether or not an expedited approval procedure is available. Many of the countries reference EU law, including France, Germany, the Netherlands, and Switzerland. Israel more readily approves devices with a CE mark (indicating approval in the EU) or an indication that they are approved by the US Food and Drug Administration (FDA). In many nations, particularly those influenced by the EU, part of the review process is conducted not by the government but by private, independent organizations called "notified bodies." These organizations are designated by EU Member States.

In most of the countries in the survey, medical devices are categorized based on the risks associated with their use, and the approval process varies by category. For example, in the United Kingdom, manufacturers of low-risk devices may register with the government agency and simply declare that the devices meet the requirements to be approved. Devices classed as higher risk must undergo more detailed review, by a notified body.

On the question of an expedited approval process, Australia, Canada, China, Japan, Spain, and Switzerland permit some sort of rapid review in particular cases, often when a device is required for an individual patient and no substitute is available. Mexico has provided for more rapid approval of devices if they have already been approved in either Canada or the United States. No such procedure exists at present in Brazil, France, Israel, the Russian Federation, or the United Kingdom. The Russian Federation did have a rapid approval system in place prior to August 2014. Germany provides for temporary approval of devices in limited circumstances. South Africa is now considering draft legislation that would include expedited procedures in specified situations. The map included at the end of this report provides a visual overview of the status of expedited approval in the countries surveyed.

I. European Union

A. Current Medical Device Approval Process

The current European Union (EU) regulatory framework governing medical devices[1] includes Council Directive 90/385/EEC on Active Implantable Medical Devices[2] and Council Directive 93/42/EEC on Medical Devices.[3] *In vitro* diagnostic medical devices are governed by Directive

[1] *See* LAW LIBRARY REPORT FOR CONGRESS: EUROPEAN UNION REGULATION OF MEDICAL DEVICES (LL File No. 2011-005058) (Dec. 2010) (on file with author).

[2] Council Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, 1990 O.J. (L 189) 17, *as amended*, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01990L0385-20071011&rid=1.

[3] Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, 1993 O.J. (L 169) 1, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01993L0042-20071011&rid=1, *as amended by* Directive

98/79/EC.[4] Medical devices must be in conformity with the rules established by these directives prior to being marketed and/or put into service in the EU, the European Economic Area, or Switzerland. At the EU level, there is no centralized approach similar to that in the United States.[5] The European Medicines Agency of the EU, unlike the Federal Drug Administration in the United States, is not involved in the approval process of medical devices. Manufacturers, prior to placing their devices in the market, are required to determine the classification of a device, based on the risk factors associated with each device, and then to apply the appropriate conformity route. Medical devices are assessed for efficacy and safety by notified bodies, which are private organizations staffed by experts and certified by the EU Member States. In the final stage, medical devices, with some exceptions for such things as custom made devices and devices intended for clinical investigation, are given a CE marking, which ensures that medical devices are in conformity with EU rules and are ready to be marketed.[6]

EU Members are in charge of implementing the legislation and taking any measures required to ensure that medical devices meet the required criteria prior to being marketed in the EU and/or put into service.[7] Medical devices and *in vitro* medical devices produced in third countries (outside the EU) must conform with the EU legislation.

1. Classification Rules

The first step in the approval process is taken by the manufacturer, who is required to determine the class of its medical device in order to apply the appropriate conformity assessment rule. Medical devices are classified on a "risk-based" system.[8] The classification rules of medical devices, as established in Annex IX of Directive 93/42/EEC on Medical Devices, depend on the vulnerability of the human body, taking into account possible dangers inherent in the technical design and manufacture of the devices.[9]

Medical devices are grouped into four product classes: I, IIa, IIb, and III. Application of the classification rules is based on the intended purpose of the devices. Most devices fall within the classification rules, except for a small number of products that are difficult to classify, such as borderline products or those with an unusual nature. Classification rules are in conformity, to a

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2007/47/EC of the European Parliament and of the Council of 5 September 2007, art. 3, 2007 O.J. (L 247) 21, http://ec.europa.eu/health/medical-devices/files/revision_docs/2007-47-en_en.pdf.

[4] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *In Vitro* Diagnostic Medical Devices, 1998 O.J. (L 331) 1, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0079-20120111&rid=1.

[5] BOSTON CONSULTING GROUP, REGULATION AND ACCESS TO INNOVATIVE MEDICAL TECHNOLOGIES: A COMPARISON OF THE FDA AND EU APPROVAL PROCESSES AND THEIR IMPACT ON PATIENTS AND INDUSTRY (2012), http://www.eucomed.org/uploads/ModuleXtender/Newsroom/97/2012_bcg_report_regulation_and_access_to_innovative_medical_technologies.pdf.

[6] Directive 93/42/EEC, *supra* note 3, art. 4.

[7] *Id*. art. 2.

[8] *Id*. art. 9.

[9] *Id.*, Annex IX.

large extent, with the classification rules established by the Global Harmonization Task Force (GHTF).[10]

2. Approval Process

In general, all devices must meet the essential requirements irrespective of the class of the devise, be subject to the reporting requirements under the national supervisory system, and be CE marked, except custom-made devices and those intended for clinical investigation.[11] Clinical data are also required to ensure conformity with the requirements of the Medical Devices Directive[12] for class III devices and implantable medical devices.[13] The affixing of a CE marking on medical devices, which is the last stage in the approval process, indicates that those medical devices conform with the requirements provided for in the legislation. The legal value of the CE marking lies in its proof that the medical device concerned is in full compliance with applicable legislation. On the other hand, the CE marking does not represent quality, even though consumers often assume that products bearing the CE marking are of better quality than others.

For economic and practical reasons, medical devices are subject to a graduated system of control, whereby the level of control corresponds to the level of danger inherent in the type of device involved.[14] For class I devices, the conformity assessment procedure can be carried out by the manufacturer alone, due to the low level of risk associated with such products. For class IIa devices, the intervention of a notified body is mandatory at the production stage. For devices falling under classes IIb, such as implants and contraception products, and III, which pose a high risk, the notified body is tasked with being involved in the design and manufacture of the devices.[15]

Notified bodies play a vital role in the approval process since they are tasked to ascertain that medical devices marketed in the EU meet all requirements pursuant to the class assigned. Notified bodies are conformity assessment bodies, staffed by experts and designated as such by Member States. The Member States must report the names of the notified bodies to the Commission, which publishes a list of the bodies, along with the tasks assigned to them.[16] Their accreditation and monitoring is conducted by the EU Members.[17]

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[10] *Id*. art. 9 & Preamble.

[11] European Commission, DG Enterprise, Guidelines for the Classification of Medical Devices 4, MEDDEV 2.4/1 Rev. 8, July 2001, http://ec.europa.eu/health/medical-devices/files/meddev/2_2_4-1part1_07-2001_en.pdf.

[12] Directive 93/42/EEC, *supra* note 3, Annex I.

[13] *Id*., Annex X.

[14] European Commission, *supra* note 11, at 2.

[15] Directive 93/42/EEC, *supra* note 3, Preamble.

[16] *Id*. art. 16; Directive 90/385/EEC, *supra* note 2, art. 11.

[17] Commission Implementing Regulation (EU) No. 920/2013 of 24 September 2013 on the Designation and the Supervision of Notified Bodies Under Council Directive 90/385/EEC on Active Implantable Medical Devices and Council Directive 93/42/EEC on Medical Devices, 2013 O.J. (L 253) 8, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0008:0019:EN:PDF.

B. Pending Legislation

In 2012, the European Commission, due to diverging interpretations and applications of the legal regime on medical devices by the Members, new technological developments, and the public concerns raised by the scandal of a French manufacturer using industrial silicone for breast implants in France, moved to reform the legislation on medical devices.[18] In brief, the pending legislation establishes new rules on the traceability of medical devices back to the suppliers; stronger supervision of independent conformity assessment bodies (notified bodies) by national authorities; and additional powers for notified bodies vis-à-vis the manufacturers, including unannounced inspections in factories.[19]

A number of Member States urged the Parliament to establish a centralized EU premarketing approval process along the lines of the US system. It appears that the Parliament has not introduced such a procedure.[20] The proposal is expected to be adopted in 2014 and would gradually be implemented between 2015–2019.[21]

II. Individual Country Surveys

Australia

Pursuant to the Therapeutic Goods Act 1989 (Cth) and relevant regulations,[22] the Therapeutic Goods Administration (TGA) makes decisions regarding the market authorization of medical devices that are "imported, exported, manufactured, and supplied in Australia."[23] The legislative framework "adopts the philosophies of the Global Harmonization Task Force (GHTF), an international forum that was established to achieve greater uniformity between national medical

[18] Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, COM (2012) 542 final, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf; Proposal for a Regulation for *In Vitro* Diagnostic Medical Devices, COM (2012) 541 final, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf.

[19] Press Release, European Commission, Safer, More Effective and Innovative Medical Devices (Sept. 26, 2012), http://ec.europa.eu/health/medical-devices/files/revision_docs/pr_20120926_en.pdf.

[20] *EU Parliament Stops Short of U.S.-Style Approvals for Medical Devices*, REUTERS (Oct. 22, 2013), http://www.reuters.com/article/2013/10/22/us-eu-medtech-idUSBRE99L0TH20131022.

[21] European Commission, Memo, Questions and Answers: Commission Tables Proposals for a New EU Regulatory Framework for Medical Devices and *In Vitro* Diagnostic Medical Devices (Sept. 26, 2012), http://ec.europa.eu/health/medical-devices/files/revision_docs/qa_20120926_en.pdf.

[22] Therapeutic Goods Act 1989 (Cth), http://www.comlaw.gov.au/Details/C2014C00410; Therapeutic Goods Regulations 1990 (Cth), http://www.comlaw.gov.au/Details/F2014C00898; Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), http://www.comlaw.gov.au/Details/F2014C00912.

[23] *TGA Key Performance Indicators: January to June 2014: 2. Premarket Business Operations*, THERAPEUTIC GOODS ADMINISTRATION (TGA) (Aug. 2014), http://www.tga.gov.au/about/tga-kpi-1406-02-premarket.htm.

device regulatory systems."[24] The TGA also negotiates agreements with other international regulators, which include acceptance of decisions on specific products from some countries.[25]

The approval processes and regulatory requirements are explained in detail in the *Australian Regulatory Guidelines for Medical Devices*.[26] The requirements may vary "depending on what the device is and how it is to be used," and the level of assessment performed by the TGA "directly relates to the level of potential risk."[27] This is managed through the categorization of devices into different classes by manufacturers in accordance with the relevant rules.[28]

In order for a medical device to be supplied for sale in Australia, the sponsor must apply to have it listed in the Australian Register of Therapeutic Goods (ARTG).[29] Broadly, before doing so, the sponsor must be able to provide "conformity assessment evidence"[30] that demonstrates compliance with the "Essential Principles,"[31] which are the product requirements for the quality, safety, and performance of the device.[32] For devices other than "Class I non-sterile and non-measuring devices," the sponsor must submit relevant evidence to the TGA as part of the process.[33] If the device is manufactured overseas, the manufacturer obtains conformity assessment evidence from the TGA or an EU Notified Body and submits this to the TGA.[34] The TGA randomly selects some applications for a detailed application audit.[35] Applications related to specific high-risk devices must undergo a mandatory application audit.[36] For Class I nonsterile and nonmeasuring devices, the manufacturer prepares technical documentation and a Declaration of Conformity, but this information does not need to be submitted with an application to include the device in the ARTG.[37]

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[24] TGA, AUSTRALIAN REGULATORY GUIDELINES FOR MEDICAL DEVICES (ARGMD): PART 1 – INTRODUCTION 18 (version 1.1, May 2011), http://www.tga.gov.au/pdf/devices-argmd-p1-01.pdf. Pages 147 to 158 of this document provide information on differences between the European Union and Australian regulatory systems.

[25] *Id.* at 21, 159–62. As of March 2011, agreements were in place with Canada, Europe, Singapore, Switzerland, and the United States, and there were also cooperative arrangements with other regulators to share information on regulatory practices. *Id.* at 160.

[26] The full document is available on the TGA website, at http://www.tga.gov.au/industry/devices-argmd.htm (last updated Jan. 29, 2013).

[27] ARGMD: PART 1, *supra* note 24, at 20–21.

[28] *Id.* at 21, 74–104. The rules for classifying medical devices are contained in schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth).

[29] *Id.* at 27.

[30] *Id.* at 105–46.

[31] *Id.* at 27, 21, & 39–73.

[32] *Id.* at 21.

[33] *Id.* at 27 & 30.

[34] *Id.* at 140–43.

[35] *Id.* at 30–31, 37; *see also* TGA, ARGMD: PART 2 – PRE-MARKET 187–97 (version 1.1, May 2011), http://www.tga.gov.au/pdf/devices-argmd-p2.pdf.

[36] ARMGD: PART 1, *supra* note 24, at 22–23.

[37] *Id.* at 29; *see also* ARMGD: PART 2, *supra* note 35, at 174.

A Special Access Scheme "allows individual patients, with the support of their medical practitioner, access to unapproved devices in a range of circumstances."[38] This includes early access for terminally ill patients "to almost any device" without TGA approval.[39] Personal importation of devices not included in the ARTG is also possible under the law.[40]

The TGA has established target time frames for the processing of medical device market authorization applications. In its latest report, covering January to June 2014, the TGA stated that it had processed all the conformity assessments within the target time frame of 255 days. Thirty-eight percent of noncompulsory Application Audits were processed within the target time frame of thirty working days. In addition, 60% of Level 1 Application Audits were processed within thirty working days, and 60% of Level 2 Application Audits were processed within sixty working days.[41]

The TGA is currently implementing "a series of medical device regulatory reforms increasing the rigour of pre-market assessment of higher risk medical devices, to assure the quality, safety and performance of these devices."[42] Information about key reforms can be found on the TGA website.

Brazil

Article 12 of Law No. 6,360 of September 23, 1976, determines that no product of interest to health, whether domestic or imported, can be industrialized, marketed, or delivered to the consumer in the Brazilian market before being registered with the Ministry of Health.[43] The registration is valid for five years, may be renewed for equal and successive periods of time, and keeps the initial registration number.[44] The registration must be awarded within ninety days from the date of submission of the registration request, except in cases of breach of Law No. 6,360 or its regulations.

The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA), a federal agency subordinated to the Ministry of Health, is in charge of regulating, controlling, and supervising products and services that pose a risk to public health.[45]

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[38] ARMGD: PART 2, *supra* note 35, at 286.

[39] *Id.*

[40] *Id.* at 290.

[41] *TGA Key Performance Indicators: January to June 2014: 2. Premarket Business Operations*, *supra* note 23.

[42] *Medical Device Reforms*, TGA (July 4, 2014), http://www.tga.gov.au/industry/devices-reforms.htm.

[43] Lei No. 6360, de 23 de Setembro de 1976, art. 12, http://www.planalto.gov.br/ccivil_03/Leis/L6360.htm.

[44] *Id.* art. 1(§1).

[45] Lei No. 9.782, de 26 de Janeiro de 1999, art. 8, http://www.planalto.gov.br/ccivil_03/Leis/L9782compilado.htm. *See also* arts. 7(IX), 8(§1)(VI).

On October 22, 2001, ANVISA issued Resolution RDC No. 185, which regulates the registration of medical devices and classifies them into four classes of risk associated with their use.[46] The process of registering a medical device incudes filing a registration request with ANVISA, along with a series of documents and information described in Resolution RDC No. 185 and other relevant laws. No provision to expedite the procedure is available.[47]

Canada

Medical devices are defined in the Food and Drugs Act,[48] which "covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition."[49] The approval process for medical devices is regulated by the Medical Devices Regulations.[50] Approvals are made by the Medical Devices Bureau of the Therapeutic Products Directorate (TPD), "the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada."[51] The TPD operates under Health Canada. In Canada,

> certain devices must have a Medical Device Licence before they can be sold. To determine which devices need a Licence, all medical devices have been categorized based on the risk associated with their use. This approach means that all medical devices are grouped into four classes with Class I devices presenting the lowest potential risk (e.g. a thermometer) and Class IV devices presenting the greatest potential risk (e.g. pacemakers).[52]

Health Canada outlines three steps in the approval process:

1. When a company decides that it would like to market a medical device in Canada, it submits a Medical Device Licence Application. The amount of information that must be submitted varies depending on the class of the device.
2. The TPD reviews the application.

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[46] MINISTÉRIO DA SAÚDE, ANVISA, Resolução RDC No. 185, de 22 de Outubro de 2001, Anexo [ANNEX], Regulamento Técnico [Technical Rules], Part 2, § 1, http://portal2.saude.gov.br/saudelegis/leg_norma_espelho_consulta.cfm?id=3727179&highlight=&tipoBusca=post&slcOrigem=0&slcFonte=0&sqlcTipoNorma=186&hdTipoNorma=186&buscaForm=post&bkp=pesqnorma&fonte=0&origem=0&sit=0&assunto=&qtd=10&tipo_norma=186&numero=185&data=%20&dataFim=&ano=&pag=1 (access full text of Resolution by clicking on "Texto completo").

[47] *Id.* Part 3, § 4.

[48] Food and Drugs Act, R.S.C., 1985, c. F-27, http://laws-lois.justice.gc.ca/eng/acts/f-27/. For a definition of "device," *see id*. § 2.

[49] *Medical Devices*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php (last updated July 7, 2014).

[50] Medical Devices Regulations, SOR/98-282, http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html. " '[*M*]*edical device*' means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals." *Id.* § 1.

[51] *Safe Medical Devices in Canada*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/fs-fi/medevfs_matmedfd-eng.php (last updated July 7, 2014).

[52] *Id.*

3. If the information provided meets the requirements of the *Medical Devices Regulations*, a Licence is issued.[53]

According to Health Canada, the "length of the review varies depending on the class of the device, Class III & IV Licence applications have a target review time of 75 days and 90 days respectively and Class II Licence applications have a 15 calendar day target."[54] In Canada, a priority review can be granted to Class III or Class IV medical device license applications if they meet a certain criteria, including if the "product is intended for the treatment, prevention or diagnosis of very serious illnesses or conditions."[55] These priority review applications have a target review time of forty-five days, including screening and review time.[56] Canada also has a Special Access Programme (SAP), which "allows doctors to gain access to medical devices that have not been licenced in Canada. The SAP is used in emergency situations or when conventional therapies have failed, are unavailable, or are unsuitable to treat a patient."[57]

China

In China, medical devices are classified into three categories according to their risk levels and are regulated by the China Food and Drug Administration (CFDA). The categories are Class I: low-risk devices; Class II: moderate-risk devices; and Class III: high-risk devices.[58] A listing process is applied to Class I medical devices, which requires only the submission of specified materials for records. Class II and Class III medical devices are subject to a mandatory registration process prior to marketing.[59] In order to receive approval from the food and drug authorities to register Class II or Class III devices, registration, inspections, and clinical tests must be conducted.[60] Some Class II and Class III devices may be exempted from the

[53] *Id.* Requirements for application for a medical device license are stipulated under § 32 of the Medical Devices Regulations, *supra* note 50. For documents that explain "why Health Canada authorized certain medical devices for sale in Canada," see *Summary Basis of Decision (SBD) Documents: Medical Devices*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/prod pharma/sbd-smd/md-im/index-eng.php (last updated Aug. 1, 2014).

[54] *Safe Medical Devices in Canada*, *supra* note 51.

[55] MCMILLAN LLP, HEALTH LAW IN CANADA 3 (2010), http://www.mcmillan.ca/files/Health_Law_in_Canada.pdf.

[56] *Management of Applications for Medical Device Licences and Investigational Testing Authorizations*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/mdlapp_demhim_pol-eng.php (last modified Feb. 4, 2014). There is also an *Interim Policy on Priority Review of Medical Device Licence Applications* but it appears to be unavailable online, and may be under review.

[57] *Safe Medical Devices in Canada*, *supra* note 51; *see also Medical Devices – Special Access Programme*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/index-eng.php (last updated Mar. 13, 2013).

[58] Yiliao Qixie Jiandu Guanli Tiaoli [Regulations on the Supervision and Administration of Medical Devices] (promulgated by the State Council, Mar. 7, 2014, effective June 1, 2014), art. 4, Central People's Government official website, http://www.sda.gov.cn/WS01/CL0784/97814.html English translation provided by Westlaw China (by subscription).

[59] Yiliao Qixie Zhuce Zhuce Guanli Banfa [Administrative Measures for the Registration of Medical Devices] (promulgated by the CFDA, July 30, 2014, effective Oct. 1, 2014), arts. 3 & 5, CFDA official website, http://www.sda.gov.cn/WS01/CL0053/103756.html, English translation provided by Westlaw China.

[60] *Id.* arts. 16 & 22.

requirement of clinical tests; the CFDA maintains and publishes a list of devices that may be exempted.[61]

Under the registration process, within three workdays of receiving the application, the food and drug authorities must pass on the application materials to a technical review institute. The technical review institute has sixty workdays to review a Class II medical device and ninety workdays to review a Class III device.[62] The authorities must make the decision on whether to approve the device within twenty workdays after the completion of the technical review and issue the medical device registration certificate to the applicant within ten workdays from the day the approval decision was made, if the application complies with the registration requirements.[63]

An emergency approval process is available that applies to medical devices urgently needed to respond to public health emergency incidents.[64] Under this process, the CFDA has three days to decide if an emergency approval process may be launched.[65] For Class I devices, the technical review and administrative review by the food and drug authorities must be completed within five days. The technical review of Class II devices must be completed within five days, and the limit is ten days for Class III devices. Upon completion of the technical review, the food and drug authorities have another three days to approve a Class II or Class III device.[66]

France

Approval of medical devices in France is closely based on European Union regulations.[67] Medical devices must have the CE label, indicating conformity with European standards.[68]

Medical devices are divided into four product classes (I, IIa, IIb, and III) according to their level of risk.[69] Medical devices in Class I (with the lowest level of risk) that do not need to be sterile can be auto-certified by the manufacturer.[70] All other medical devices must be assessed by a special body (called a "notified body") approved by the European Commission and the Agence

[61] *Id.* art. 22.

[62] *Id.* art. 33.

[63] *Id.* art. 36.

[64] Yiliao Qixie Yingji Shenpi Chengxu [Emergency Procedures for Examination and Approval of Medical Devices] (promulgated by the CFDA, Aug. 28, 2009), http://www.sda.gov.cn/WS01/CL0055/41117.html, English translation provided by Westlaw China.

[65] *Id.* art. 6.

[66] *Id.* arts. 11–13.

[67] HAUTE AUTORITÉ DE SANTÉ [HEALTH HIGH AUTHORITY], PARCOURS DU DISPOSITIF MEDICAL, GUIDE PRATIQUE [THE MEDICAL DEVICE'S PATH: PRACTICAL GUIDE] 9 (2013), http://has-sante.fr/portail/upload/docs/application/pdf/2009-12/guide_pratique_dm.pdf.

[68] CODE DE LA SANTE PUBLIQUE [CODE OF PUBLIC HEALTH] art. R5211-12, http://www.legifrance.gouv.fr/affichCode.do;jsessionid=C412D9EC284C4DC0E965EA268D88AF72.tpdjo14v_1?cidTexte=LEGITEXT000006072665&dateTexte=20140908; PARCOURS DU DISPOSITIF MEDICAL, *supra* note 67, at 9.

[69] CODE DE LA SANTE PUBLIQUE art. R5211-7; PARCOURS DU DISPOSITIF MEDICAL, *supra* note 67, at 10.

[70] PARCOURS DU DISPOSITIF MEDICAL, *supra* note 67, at 10.

nationale de sécurité du médicament (National Agency for Medication Safety).[71] The assessment involves an audit of the manufacturer's quality control system and an inspection of the design dossier, which should include clinical data.[72] The approval of most Class III devices (with the highest level of risk) requires clinical trials.[73] There does not appear to be any special procedure for expedited approval. The CE certificate is valid for a maximum of five years, but is renewable.[74] Follow-up audits are undertaken even after the certificate is issued, and another in-depth audit is done before it can be renewed.[75]

Germany

With the exception of custom-made devices and medical devices manufactured in-house, medical devices pursuant to section 11(1) of the Act on Medical Devices (Medizinproduktgesetz, MPG)[76] and medical devices intended for clinical investigation, or *in vitro* diagnostic medical devices intended for performance evaluation, may only be placed on the market or put into service in Germany if the essential requirements and the conformity assessment procedure prescribed for the medical device have been conducted.[77] These requirements are directed by EU law.[78] Devices are classified according to the risk they pose to the patient.[79] Unlike medicinal products, medical devices do not undergo an official authorization procedure. Certain low-risk medical devices can, for example, be assessed by the manufacturing company itself.[80] Devices with higher risks are to be certified by so-called "Notified Bodies," private entities that are certified by the EU Member States.[81] The time for issuing a certification by the Notified Bodies is variable.[82] In 2012, 56% of all newly admitted medical devices on the German market

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[71] *Id.*; CODE DE LA SANTE PUBLIQUE art. L5211-3*; Mise sur le marché des dispositifs médicaux et dispositifs médicaux de diagnostic in vitro* [*Market Introduction of Medical Devices and In Vitro Diagnostic Medical Devices*], AGENCE NATIONALE DE SECURITE DU MEDICAMENT ET DES PRODUITS DE SANTE [NATIONAL AGENCY FOR MEDICATION AND HEALTH PRODUCTS SAFETY], http://ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/%28offset%29/0 (last visited Sept. 8, 2014).

[72] PARCOURS DU DISPOSITIF MEDICAL, *supra* note 67, at 11.

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] MEDIZINPRODUKTEGESETZ [ACT ON MEDICAL DEVICES], Aug. 7, 2002, BUNDESGESETZBLATT [BGBL.] I at 3146, *as amended through* Act of July 21, BGBL. I at 1133, http://www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf.

[77] *Id.* § 6(1).

[78] Council Directive 93/42/EEC, *supra* note 3; Council Directive 90/385/EEC, *supra* note 2; Directive 98/79/EC, *supra* note 4.

[79] *See*, *e.g.*, Council Directive 93/42/EEC, *supra* note 3, Annex IX.

[80] *Id.*, Annex VII.

[81] *Id.* art. 16.

[82] AOK-BUNDESVERBAND, MEDIZINPRODUKTE – MYTHEN UND WAHRHEIT: GEMEINSAMES ARGUMENTATIONSPAPIER VON DEN SPITZENVERBÄNDEN DER GESETZLICHEN KRANKENKASSEN IN DEUTSCHLAND [MEDICAL DEVICES – MYTHS AND TRUTH: COLLECTIVE ARGUMENTATION PAPER OF THE CENTRAL FEDERAL

could undergo assessment by the manufacturer.[83] Research shows that the European concept of certification offers quick access to the market, which especially benefits small- and mid-sized businesses.[84]

However, Germany's Federal Institute for Drugs and Medical Devices may issue a temporary permission for certain medical devices in the interest of health protection. This temporary permission is valid for Germany only and may only be granted if the regular assessment procedure cannot be completed. The temporary permission is also not available when substitute medical devices exist.[85] Research indicates, however, that temporary permissions are not often demanded, since the permission is valid for Germany only and the process is considered slower than the regular assessment.[86]

Israel

Israel's Medical Devices Law, 5772-2012, generally requires the registration of all medical products as a precondition for production and distribution.[87] Special exemptions may apply under limited circumstances and for purposes such as the provision of essential medical treatment, research, development and manufacturing of the medical device, and personal use, among other.[88]

Registration of medical devices requires the submission of an application to the Ministry of Health Medical Institutions and Devices Licensing Department (known as AMAR).[89] The application requires presentation of a list of documents,[90] including, in the case of Israeli

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ASSOCIATION OF HEALTH INSURANCE FUNDS IN GERMANY] 7 (July 19, 2013), http://www.aok-bv.de/imperia/md/aokbv/politik/versicherte/thesenpapier_gross_0713_dt.pdf.

[83] Bundesverband Medizintechnologie [German Federal Association of Medical Technology], *Der lange Weg eines Medizinproduktes von der Idee bis zur Anwendung* [*The Long Way of a Medical Device from the Idea to the Application*] (Feb. 2014), http://www.bvmed.de/download/poster-a2-der-lange-weg-eines-medizinproduktes-von-der-idee-bis-zur-anwendung (diagram).

[84] FEDERAL MINISTRY OF HEALTH, MARKTZUGANGSVORAUSSETZUNGEN FÜR MEDIZINPRODUKTE – ZUSTÄNDIGKEITEN IN DEUTSCHLAND [MARKET ACCESS CONDITIONS FOR MEDICAL DEVICES – COMPETENCES IN GERMANY] 2 (June 2010), http://www.bmg. bund.de/fileadmin/dateien/Downloads/M/Medizinprodukte/Medizin_Produkte_Marktzugangsvoraussetzungen_fuer_Medizinprodukte.pdf.

[85] ACT ON MEDICAL DEVICES § 11(1), Aug. 7, 2002, BGBL. I at 3146, *as amended through* Act of July 21, BGBL. I at 1133, http://www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf.

[86] Andrea B. Gall, Vergleich von Medizinproduktegesetz und Arzneimittelgesetz unter besonderer Berücksichtigung des Inverkehrbringens und der klinischen Prüfung 104 (Dissertation, University of Bonn, 2009), http://hss.ulb. uni-bonn.de/2010/2135/2135.pdf.

[87] Medical Devices Law, 5772-2012, SEFER HAHUKIM (Book of Laws, Official Gazette), p. 394.

[88] *Id.* § 4.

[89] *See Medical Institutions and Devices Licensing Department*, AMAR, http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/AMAR/Pages/default.aspx (last visited Sept. 5, 2014).

[90] *See* Medical Devices (Registration of a Medical Device in the Register and its Renewal) Regulations, 5773-2013, § 3, KOVETZ HATAKANOT [KT] No. 7258, p. 1311.

manufactured devices that are not registered or authorized in any "recognized country,"[91] a risk analysis, a clinical evaluation, a summary of the clinical trials, and expert opinions regarding the device's safety and usefulness. Additional requirements may apply during the registration period, including follow-up reviews, to improve the quality and safety of the devices.[92]

According to regulations issued by Israel's Minister of Health in June 2013, a decision on a request to register a medical device must be delivered within 120 days from the date of the request.[93] This period may be further extended if additional information or documentation is requested. The current rules for the registration of medical devices do not provide for an expedited approval process.

According to information posted on the website of a regulatory consulting firm, however,

> medical devices without a CE-Mark or FDA-approval are rarely issued a license, [but] [d]evices with both CE-Mark and FDA-approval will often meet the requirements of AMAR without delay.
>
> The official timeframe for registration in Israel is 120 days, however, registration is usually completed within 6–9 months because the authorities will often require further documentation in the course of their evaluation. If [in] the documentation, for example a clinical trial, is not provided within 45 calendar days, the application will be voided. AMAR is currently undergoing efforts to reduce registration times that have been lengthened by current practices.[94]

Japan

The Japanese Pharmaceutical Affairs Law defines medical devices as "devices, etc. intended for use in diagnosis, treatment or prevention of disease in humans or animals, or intended to affect [the] structure or functions of [the bodies] of humans or animals, and which are designated by Cabinet Order."[95] In order to engage in marketing medical devices, companies are required to obtain marketing business (Marketing Authorization Holder, MAH) licenses.[96]

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[91] A "recognized country" is defined in section 1 of the Medical Devices Law as one of the countries listed in the First Annex, including the US. Medical Devices Law, 5772-2012, § 1.

[92] *Id.* § 7.

[93] Medical Devices (Registration of a Medical Device in the Register and its Renewal) Regulations § 5(a) (in Hebrew), KOVETZ HATAKANOT [KT] No. 7258, p. 1311.

[94] *Country at a Glance: Israel*, ARAZY GROUP (MAY 30, 2013), http://arazygroup.com/blog/register-medical-device-in-israel/.

[95] Pharmaceutical Affairs Law, Act No. 145 of 1960, last amended by Act No. 69 of 2014, art. 2, para. 4, *translated in* YAKUJIHŌ, YAKUJIHŌ SHIKŌREI, YAKUJIHŌ SHIKŌ KISOKU, IYAKUHIN IRYŌKI SŌGŌ KIKŌHŌ [PHARMACEUTICAL AFFAIRS LAW, ENFORCEMENT ORDINANCE, ENFORCEMENT REGULATIONS & LAW FOR THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY] 2009/2010 (Jiho Inc., 2009) (translated version of Act last amended by Act No. 84 of 2006).

[96] *Id*. art. 12.

Medical devices are classified as Class I, II, III or IV, according to their risk level. To market medical devices in Japan, the MAH must register the device through the following procedures:[97]

> Pre-market Submission (*Todokede*) – Class I Medical Devices
> To register and market General Medical Devices (Class I devices),[98] the MAH only need to file Pre-Market Submission to the Pharmaceuticals and Medical Devices Agency (PMDA) with no assessment by the PMDA.[99]
>
> Pre-market Certification (*Ninsho*) – Class II Medical Devices
> Class II devices which are described as Specified Controlled Devices[100] are subject to Pre-Market Certification. To register and market a Specified Controlled Medical Device, the MAH needs to file a Pre-Market Certification application with a registered certification body (third party) and obtain their certification.[101]
>
> Pre-market Approval (*Shonin*) – Classes II, III & IV Medical Devices
> To register and market a Highly Controlled Medical Device,[102] the MAH needs to file a Pre-Market Approval Application with the PMDA[103] and obtain an approval from the Minister of Health, Labour and Welfare.[104] Class II devices that are not Specified Controlled Devices are also subject to Pre-Market Approval.

Japan's Minister of Health, Labour, and Welfare may grant emergency approval upon consultation with the Pharmaceutical Affairs and Food Sanitation Council if a medical device satisfies both of the following conditions:

- The medical devices are required for use in emergencies to prevent the spread of diseases or other damage to health that might have major effects on the life and health of the public and for which no appropriate methods other than such drugs or medical devices exist; and
- the devices are authorized for sale, gift, storage, or exhibit for sale or gift by an authority of a foreign country (limited to countries which have a system of approval of medical devices for marketing that assures that the medical device has quality, efficacy and safety equivalent to those obtained in Japan, or an equivalent system, as specified by Cabinet Order).[105]

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[97] *Japan PMDA Medical Device Approval and Certification*, EMERGO, http://www.emergogroup.com/services/japan/medical-device-approval-japan (last visited Sept. 8, 2014). *See also*, Atsushi Tamura, Understanding Japanese Medical Device Requirements, Presentation at 2011 AHC Workshop on Medical Devices (Seoul, Korea, July 4–5, 2011), slide 9, http://www.pmda.go.jp/regulatory/file/english_presentation/device/D-E3tamura.pdf.

[98] Pharmaceutical Affairs Law art. 2, para. 7.

[99] *Id*. art. 14-9.

[100] *Id*. art. 2, para. 6.

[101] *Id*. art. 23-2.

[102] *Id*. art. 2, para. 5.

[103] *Id*. art. 14-2.

[104] *Id*. art. 14.

[105] *Id*. art. 14-3.

Mexico

Mexico's Regulation of Health Supplies provides that medical devices require a sanitary registration in order to be produced, sold, and distributed.[106] For purposes of registration, medical devices are classified into three categories depending on the level risk that their use entails, as follows:

- Class I: Devices known in medical practice and whose safety and efficacy are proven and, generally, are not introduced into the human body.
- Class II: Devices known in medical practice whose components may have variations and, generally, are introduced into the human body for less than thirty days.
- Class III: New devices or devices that have been recently accepted in medical practice, or devices that are introduced into the human body and stay there for more than thirty days.[107]

The registration procedure is administered by Mexico's Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), which is part of Mexico's Federal Department of Health.[108]

In order to obtain the sanitary registration of medical devices, an application with supporting documentation must be submitted. The documentation must include

- scientific and technical information to demonstrate that the device is safe and effective;
- a proposal of the label in the Spanish language, pursuant to applicable regulations;
- if applicable, instructions or a manual for the use of the device in the Spanish language;
- a description of the manufacturing process of the device;
- a description of the structure, materials, parts, and functions of the medical device;
- information on laboratory tests conducted to verify the specifications of the device; and
- bibliographic references.[109]

Applications for "Class I" devices are processed in thirty days.[110] If the processing of the application does not conclude in that period of time, the application is deemed approved.[111]

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[106] Reglamento de Insumos para la Salud [Regulation of Health Supplies], *as amended* through Mar. 2014, art. 82, DIARIO OFICIAL DE LA FEDERACIÓN [D.O.], Feb. 4, 1998, *available on* the website of Mexico's Supreme Court, *at* http://legislacion.scjn.gob.mx/reglamentos/Reformas.aspx?IdLey=11369.

[107] *Id.* art. 83.

[108] *Registros Sanitarios de Dispositivos Médicos* [*Sanitary Registration of Medical Devices*], COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS, http://www.cofepris.gob.mx/AS/Paginas/Registros%20Sanitarios/RegistroSanitarioDispositivosMedicos.aspx (last updated Sept. 3, 2014).

[109] Reglamento de Insumos para la Salud, *supra* note 106, art. 179.

[110] *Id.*

[111] *Id.*

Applications for approval of devices falling under Classes II and III should be processed in thirty-five and sixty days, respectively.[112]

The Mexican government has issued a Directive that allows for streamlined approval of medical devices in Mexico, provided that they have previously been approved by the US Food and Drug Administration (FDA) or by Health Canada (HC).[113] The Directive indicates that the procedures followed by the FDA and HC in the approval of medical devices in the United States and Canada are equivalent to those provided by Mexican law.[114] Therefore, applicants for approval of such devices may present evidence that they have been previously duly approved in the United States or Canada in order to streamline the process in Mexico.[115] That process may take up to thirty business days, if such evidence is provided.[116]

Netherlands

The United States is the largest producer of medical devices world-wide, but in Europe, according to 2012 figures, the Netherlands ranked second only to Germany in the volume of import and export trade in such devices.[117] Regulation of medical devices in the Netherlands is governed by three European Union directives[118] along with the Netherlands' Medical Devices Act,[119] Medical Devices Decree,[120] Active Implants Decree,[121] and In-Vitro Diagnostics

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[112] *Id.*

[113] Directive that recognizes that the requirements set forth under articles 179 and 180 of the Regulations for Health Supplies, and that the technical assessment procedures carried out by Mexico's Federal Commission for the Protection against Sanitary Risk are equivalent to grant the registration for health supplies under Chapter IX, Title 2 of the Regulations for Health Supplies, to the requirements set forth under sections 510 (k) and 514 of the Federal Food, Drug and Cosmetic Act and by Title 21, Chapter 1, Subchapter H of the Code of Federal Regulations of the United States of America, as well as those set forth by the Food and Drug Act and the Medical Devices Regulations of Canada to allow to market medical devices in their territory, and to the tests and inspections carried out by the Food and Drug Administration of the United States of America and by Health Canada of Canada in order to allow to market medical devices in their territory, D.O. (Oct. 26, 2010), *available on* the website of COFEPRIS, *at* http://www.cofepris.gob.mx/AS/Paginas/Registro%20de%20Dispositivos%20Medicos%20por%20Equivalencia/Marco-Legal.aspx. *See also Registro de Dispositivos Médicos por Equivalencia*, COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS, http://www.cofepris.gob.mx/AS/Paginas/Registro%20de%20Dispositivos%20Medicos%20por%20Equivalencia/Registros-de-Dispositivos.aspx (last visited Sept. 8, 2014).

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] Chart, *Exports and Imports of Medical Technology by Country, 2012*, *in* MEDTECH EUROPE, THE EUROPEAN MEDICAL TECHNOLOGY INDUSTRY IN FIGURES 7 (2013), http://www.eucomed.org/uploads/Modules/Publications/the_emti_in_fig_broch_12_pages_v09_pbp.pdf.

[118] Council Directive 93/42/EEC, *supra* note 3; Council Directive 90/385/EEC, *supra* note 2; Directive 98/79/EC, *supra* note 4.

[119] Wet van 15 januari 1970, houdende regelen met betrekking tot medische hulpmiddelen (Wet op de medische hulpmiddelen) (Jan. 15, 1970, *as last amended*, *effective* Feb. 15, 2014), http://wetten.overheid.nl/BWBR0002697/geldigheidsdatum_04-09-2014.

Decree.[122] In the Netherlands, the EU's CE mark is obtained through review by its notified body, the Inspectorate for Health (Inspectie voor de Gezondheidsorg, IGZ), supported by the Medicines Evaluation Board.[123]

Medical devices are classified and, for high-risk classifications, subject to notified body inspections in accordance with the EU Medical Devices Directive.[124] Dutch manufacturers of medical devices who wish to market Class I (non-invasive devices) or in-vitro diagnostic (IVD) medical devices must first register themselves and the product with the Ministry of Public Health, Welfare, and Sport (Ministerie van Volksgezondheid, Welzijn en Sport) through the NOTIS system. This procedure also applies to the authorized representatives of non-EU manufacturers that have been established in the Netherlands.[125] Medical devices registered with NOTIS are automatically registered with Eudamed, the European Union databank for medical devices.[126] Medical devices not registered with NOTIS are to be registered by the notified bodies with the IGZ and then with Eudamed.[127]

Farmatec, under the CIBG, an agency within the Ministry of Public Health, deals with applications for authorizations of manufacturing and wholesale distribution and handles Class I and low-risk IVD device registrations. Farmatec has ninety days from the date of receipt of an application to make a decision on it; if it cannot meet this deadline, it is obligated to so inform the applicant.[128]

No information was found on a fast-track procedure for medical devices in the Netherlands.

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[120] Besluit van 30 maart 1995, houdende regels met betrekking tot het in de handel brengen en het toepassen van medische hulpmiddelen, alsmede tot wijziging van enige algemene maatregelen van bestuur (Besluit medische hulpmiddelen) (Mar. 30, 1995, *as last amended, effective* Mar. 21, 2010), http://wetten.overheid.nl/BWBR0007307/geldigheidsdatum_04-09-2014.

[121] Besluit van 5 juli 1993, houdende regels met betrekking tot het in de handel brengen van actieve implantaten (Besluit actieve implantaten) (July 5, 1993, *as last amended, effective* Mar. 21, 2010), http://wetten.overheid.nl/BWBR0006060/geldigheidsdatum_04-09-2014.

[122] Besluit van 22 juni 2001, houdende regels met betrekking tot het in de handel brengen en het toepassen van medische hulpmiddelen voor in-vitro diagnostiek (Besluit in-vitro diagnostica) (June 22, 2001, *as last amended, effective* July 1, 2012), http://wetten.overheid.nl/BWBR0012610/geldigheidsdatum_04-09-2014.

[123] TTOPSTART B.V., CERTIFICATION AND REGISTRATION: MEDICAL DEVICES ON THE EUROPEAN MARKET 12 (Oct. 2013), http://www.ttopstart.com/uploads/ttopstart_-_spottlight_-_Certification_and_registration_of_medical_devices.pdf.

[124] Besluit medische hulpmiddelen art. 8 (1). However, breast implants and hip, knee, and shoulder replacements are classifed in Class III. *Id*. art. 8(2).

[125] *NOTIS*, CIBG, https://hulpmiddelen.farmatec.nl/en/ (last visited Sept. 9, 2014).

[126] TTOPSTART B.V., *supra* note 123, at 16.

[127] *Id*.

[128] *Medicinal Product Regulation and Product Liability in The Netherlands: Overview*, PRACTICAL LAW (Mar. 1, 2014), http://uk.practicallaw.com/3-500-7575?service=crossborder.

Russian Federation

According to article 38 of the Federal Law on Fundamentals of Healthcare in the Russian Federation,[129] only medical devices registered pursuant to a procedure established by the government can be used. The Law defines "medical devices" as any machines, equipment, instruments, or materials, including software, used for purposes of prevention, diagnosis, treatment, or rehabilitation of illnesses; monitoring human health; conducting medical research; a change or substitution of the human body's anatomic structure or physiological functions; the prevention or termination of a pregnancy, all of which have no pharmacological, immunological, genetic, or metabolic impact on the human body.[130]

Government Regulation No. 1416 of December 27, 2012, implemented this provision of the Law and approved Rules for State Registration of Medical Devices.[131] According to the Rules, devices created in response to specific requests of those patients who have special individual needs as defined by medical personnel and that will be used by the patient personally are exempt from government approval. All other devices are subject to the government registration process.

Registration is conducted by the Federal Service on Healthcare Supervision, a part of the Federal Ministry of Health Protection, and requires submission of an application and technical documentation for the device. Expert evaluation of the quality, effectiveness, and safety of each device submitted for registration is required. This evaluation includes clinical testing. The Federal Service on Healthcare Supervision certifies individuals and institutions eligible to conduct the evaluations. A document entitled Administrative Procedures for State Registration of Medical Devices was issued by the Federal Service on Healthcare Supervision on October 14, 2013, and entered into force on August 12, 2014.[132] The Procedures established that state registration of medical devices cannot take longer than fifty business days; however, this period does not include the duration of the clinical testing and expert evaluation. Also, the fifty-day period stops running if errors are found in the documents submitted for registration, and the papers are returned to the applicant for correction.[133]

The current rules for the registration of medical devices do not provide for an expedited approval process. An opportunity for expedited approval was foreseen by the registration procedure that existed before August 12, 2014.[134] Under the previous registration procedure, all medical devices were divided into four categories depending on the degree of potential risk associated with their usage. Devices of low- and medium-risk levels equivalent to their analogs were

[129] Federal Law No. 323 of Nov. 21, 2011, SOBRANIE ZAKONODATELSTVA ROSSIIKOI FEDERATSII [SZ RF] [COLLECTION OF RUSSIAN FEDERATION LEGISLATION] (official gazette, in Russian) 2011, No. 48, Item 6724.

[130] *Id*.

[131] SZ RF 2013, No. 1, Item 14.

[132] Order No. 737 of the RF Ministry of Health Protection, http://www.roszdravnadzor.ru/administrative_regulations/approved?year=&page=1 (click on document No. 2, in Russian).

[133] *Id*. §§ 12–14, 64.

[134] Order No. 735 of the RF Ministry of Healthcare and Social Protection of October 30, 2006, http://www.roszdravnadzor.ru/administrative_regulations/approved?year=&page=2 (click on document 2, in Russian).

subject to a mandatory expedited approval process. Expedited approval required ultimate registration of medical devices within a two-month period, while the regular registration procedures continued for four months, with the possibility of a three-month extension.[135]

South Africa

South Africa does not have a comprehensive regulatory framework governing medical devices. At present, only listed electronic products (also known as electromagnetic medical devices or radiation emitting devices) must be registered before they can be sold, leased, used, operated, or applied in South Africa.[136] A person interested in engaging in any of these activities involving electronic product must first apply to and obtain an approval from the Director General of the National Health and Population Development (the Director General).[137] The Director General's refusal to grant a license can be appealed to the Minister of National Health (the Minister).[138] However, the applicable laws do not appear to impose a particular time frame for the completion of the registration process or provide an option for fast-tracking the process. This is likely to change soon, however.

In April 2014, South Africa published for public comment draft rules designed to regulate all medical devices.[139] The draft regulations include a provision for a four-tiered, risk-based

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[135] *Id*. § 3.3.1.

[136] Hazardous Substances Act 15 of 1973, §§ 1, 3 & 4, available on the University of Pretoria website, *at* http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/hazardous-substances-act-15-of-1973/act/15-of-1973-hazardous-substances-act-24-feb-2000-to-date-pdf/download; Hazardous Substances Act 15 of 1973: Regulations Relating to Group III Hazardous Substances § 2, Government Notice [GN] R690, 286 GOVERNMENT GAZETTE [GG], No. 11823 (Apr. 14, 1989), http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/hazardous-substances-act-15-of-1973/regulations-and-notices/15-of-1973-hazardous-substances-act-regs-gnr-690-14-apr-1989-to-date-pdf/download; Hazardous Substances Act 15 of 1973: Group III Hazardous Substances Schedule GN R1302, GG 13299 (June 14, 1991), http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/hazardous-substances-act-15-of-1973/regulations-and-notices/15-of-1973-hazardous-substances-act-regs-gnr-1302-14-jun-1991-to-date-pdf/download.

[137] Hazardous Substances Act §§ 1, 3 & 4; Regulations Relating to Group III Hazardous Substances § 3.

[138] Hazardous Substances Act § 6; Regulations Relating to Group III Hazardous Substances § 4.

[139] This includes

. . . any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent−

(a) used for purporting to be for the use or manufactured or sold for use in−

(i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function; or

(iii) the diagnosis or prevention of pregnancy,

and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or

(b) declared by the Minister by notice in the Gazette to be a medical device,

and includes any part or an accessory of a medical device; . . . .

classification system of medical devises and in vitro diagnostic medical devices (IVDs); classification of medical devices and IVDs would be determined by the Medicines Control Council (MCC).[140] The regulations would require the registration of all medical devices (except custom-made devices) and IVDs with the MCC before they can be sold or used in South Africa.[141] While the draft regulations do not appear to impose a specific time frame for the completion of a regular registration process, they would permit expedited registration of medical devices or IVDs if

- the medical devices or IVDs in question are in short supply or are unavailable;
- the Minister determines that expedited registration is in South Africa's national interest; or
- the South African government makes an international tender for a medical device or IVD and such medical device or IVD is not already registered at the time of the tender.[142]

In these instances, the MCC is required to inform the applicant of its decision within nine months of the receipt of the application.[143]

Spain

The Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spanish Agency on Drugs and Health Products) is responsible for ensuring the quality, safety, efficiency, and accuracy of information on drugs and medical devices in order to protect and promote health in both human beings and animals.[144]

The AEMPS is in charge of the evaluation and authorization of medicine and medical devices for human and animal use, to include the authorization of clinical trials and the monitoring of medical products safety once on the market and the inspection of laboratories.[145]

Medicines and Related Substances Act 101 of 1965, § 1, http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/medicines-and-related-substances-act-101-of-1965/act/101-of-1965-medicines-and-related-substances-act-2-may-2003-to-date-pdf/download.

[140] Medicines and Related Substances Act, 1965 (Act No. 101 of 1965): General Regulations Relation to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs), § 14, 586 GG No. 37579 (Apr. 22, 2014), available on the South African government website, *at* http://www.gov.za/documents/download.php?f=213278. The Medicines Control Council is a "statutory body that regulates the performance of clinical trials and registration of medicines and medical devices for use in specific diseases." *The Medicines Control Council*, DEPARTMENT OF HEALTH, http://www.sanctr.gov.za/YourRights/TheMedicinesControlCouncil/tabid/176/Default.aspx (last visited Sept. 8, 2014).

[141] *Id*. § 8.

[142] *Id*. §§ 2 & 3.

[143] *Id*.

[144] *Misión Y Visión de la Agencia Española de Medicamentos y Productos Sanitarios*, AGENCIA ESPANOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS) (Mar. 2009), http://www.aemps.gob.es/laAEMPS/mision/home.htm.

[145] *Quienes Somos?*, AEMPS (Mar. 2013), http://www.aemps.gob.es/laAEMPS/presentacion/ home.htm.

Real Decreto 1591/2009[146] por el que se Regulan los Productos Sanitarios (Royal Decree that Regulates Health Products) provides for the definition of "medical device" and the requirements that such a device must meet for its release to the public. According to this regulation, a medical device is a product used in health care services that is not medicine, for example, instruments to correct deficiencies such as glasses or hearing aids, diagnostic equipment, active and inactive implants, dental products, ophthalmic and optical products, electromedical and mechanical products, reusable instruments such as surgical instruments, and hospital equipment.[147]

The AEMPS is the authority within the Ministry of Health and Social Policy in charge of approving medical devices for general public use.[148] The manufacturer of a medical device who intends to put one of these products into the Spanish market must file a petition before the AEMPS with documentation of its design, the manufacturing process, sterilization, operational tests, clinical trials, and any other relevant technical information.[149] After the requirements are fulfilled, and if the result of the tests is favorable, the AEMPS issues a certificate of conformity that allows the product to be released for its use.[150] In exceptional circumstances a physician may request the use of a medical device or product not previously authorized in Spain, either because there is no similar product already available in the market or because he or she considers the product in question to be a better alternative for a patient, considering other available options.[151] In such a case, there is an expedited procedure for the release of medical devices to be used before final approval is completed.[152] A special form to be filed with the AEMPS needs to be presented to petition for an expedited approval of a medical device under the strict supervision of the physician involved. The filing may be done online.[153]

Switzerland

Unlike medicinal products, medical devices do not undergo an official authorization procedure in Switzerland. Rather, Switzerland has adopted the European Union (EU) system of compliance assessment and certification, based on bilateral agreements.[154] Compliance with internationally

[146] Real Decreto 1591/2009 por el que se Regulan los Productos Sanitarios [Royal Decree that Regulates Health Products], BOLETÍN OFICIAL DEL ESTADO, Oct. 16, 2009, *available at* AEMPS, http://www.aemps.gob.es/legislacion/espana/ productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf.

[147] *Id.* art. 2.1.a. & 3.

[148] *Id.* arts. 4–6.

[149] *Id.*, Anexo VII.

[150] *Id.* art. 13.

[151] Aplicación de Envíos Telemáticos:Autorización Expresa de Utilización de Productos Sanitarios [Online Application for Expedited Authorization of Medical Products] (Oct. 28, 2013), https://sede.aemps.gob.es/PSCH/PS/autorizacionexpresa_ps.htm#documentacion.

[152] Real Decreto 1591/2009, art. 15.

[153] Instrucciones para la Solicitud de Autorizaciones Expresas de Importación y Utilización de Productos Sanitarios en Interés de la Salud Bajo Responsabilidad Médica [Instructions for the Application for Expedited Authorizations of Import and Use of Medical Products in the Interest of Public Health Under Physician Responsibility], AEMPS (Feb. 2011), http://www.aemps.gob.es/productosSanitarios/docs/instrucciones-solicitud-autorizacion.pdf.

[154] ABKOMMEN ZWISCHEN DER SCHWEIZERISCHEN EIDGENOSSENSCHAFT UND DER EUROPÄISCHEN GEMEINSCHAFT ÜBER DIE GEGENSEITIGE ANERKENNUNG VON KONFORMITÄTSBEWERTUNGEN [AGREEMENT ON MUTUAL

valid norms is evaluated by private entities. Medical devices are attributed to various categories that require varying assessment procedures.[155] Devices are classified according to the risk they pose to the patient.[156] Certain low-risk medical devices can be assessed by the manufacturing company itself.[157] Devices with higher risks are to be certified by so-called "notified bodies," private entities that are certified by the EU Member States.[158] The time for issuing a certification by the Notified Bodies is variable.[159] The Swiss Agency for Therapeutic Products (Swissmedic) can grant special permission for certain medical devices not fulfilling the qualifications. However, this special permission can only be issued to products for use by a single person.[160]

United Kingdom

Three European Directives govern how the UK regulates the approval process for medical devices.[161] The Directives aim to harmonize the regulation of medical devices across the EU. The United Kingdom has given effect to these regulations through the Medical Devices Regulations 2002.[162]

The term "medical devices" in the UK covers a range of items, from wound dressings to artificial hips.[163] Generally, a medical device requires a CE marking, which allows it to be marketed and

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RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION] OF JUNE 21, 1999, as amended through Dec. 17, 2012, SYSTEMATISCHE RECHTSSAMMLUNG [SR] [CLASSIFIED COMPILATION] 0.946.526.81, Annex 1, ch. 4.

[155] *Medical Devices*, SWISSMEDIC, https://www.swissmedic.ch/medizinprodukte/01175/index.html?lang=en (last visited Sept. 5, 2014).

[156] *See*, *e.g.*, Directive 93/42/EEC, *supra* note 3, Annex IX.

[157] *Id.*, Annex VII.

[158] *See*, *e.g.*, *id.* art. 16.

[159] AOK-BUNDESVERBAND, *supra* note 82, at 7.

[160] Medical Devices Ordinance [MepV] of Oct. 17, 2001, *as amended through* Apr. 1, 2010, SR 812.213, art. 9(4), https://www.swissmedic.ch/ueber/00134/00493/00500/index.html?lang=de&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCDdIB2gWym162epYbg2c_JjKbNoKSn6A--.

[161] Directive 93/42/EEC, *supra* note 3; Directive 90/385/EEC, *supra* note 2; *and* Directive 98/79/EC, *supra* note 4.

[162] These regulations are issued under the Consumer Protection Act 1987, c. 43, http://www.legislation.gov.uk/ukpga/1987/43.

[163] A "medical device" is defined in the regulations as

. . . an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a

sold across the EU.[164] This mark shows that the device meets regulatory requirements, works as intended when used, and has an acceptable safety level that complies with the Essential Requirements of the EU Directives.[165]

The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates medical devices across the UK. Before medical devices can be marketed and used in the UK, they must be approved by private-sector organizations known as "notified bodies."[166] These bodies conduct a conformity assessment procedure in order to approve products, and devices will only receive the CE mark if the evidence shows that the potential benefits of the device outweigh the likely risks.[167]

Devices are classified into four groups, and each group has different criteria that must be met in order to receive a CE mark.[168] Low-risk device (class I) manufacturers may register with the MHRA and make a declaration that the product meets the statutory requirements to receive the CE mark.[169] Medium-risk (classes IIa and IIb) and high-risk (class III) devices (which include, for example, *in vitro* devices, active implantable devices, and sterile devices used for measuring) must meet more stringent criteria.[170] Obtaining a CE mark for medium-risk devices involves a declaration by the manufacturer that the product conforms with the provisions of the Medical Devices Regulations and the relevant essential requirements. This must then be verified by an assessment by the notified body, which can be one of the following selected by the manufacturer: an examination and testing of each product or a batch of products; an audit of the product quality assurance system; an audit of final inspection and testing; or an audit of the complete quality

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medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device . . . .

Medical Devices Regulations 2002, SI 2002/618 ¶ 2, http://www.legislation.gov.uk/uksi/2002/618/regulation/2/made.

[164] MHRA, MEDICINES & MEDICAL DEVICES REGULATION: WHAT YOU NEED TO KNOW ¶ 7 (2012), http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf.

[165] *What Kinds of Decisions Are Made About Medicines and Medical Devices?*, MHRA, http://www.mhra.gov.uk/Howweregulate/Whatkindsofdecisionsaremadeaboutmedicinesandmedicaldevices/index.htm (last visited Sept. 9, 2014).

[166] Notified bodies are independent certified bodies responsible for verifying that devices work effectively and as intended in an acceptable safe manner. The MHRA appoints and audits these bodies to ensure they perform to high standards. MHRA, MEDICINES & MEDICAL DEVICES REGULATION, *supra* note 152.

[167] *What Kinds of Decisions Are Made About Medicines And Medical Devices?*, *supra* note 153.

[168] The classes are class I (low risk), class IIa and IIb (medium risk), and class III (high risk). Classification of the device involves assessing a number of factors, including whether the device is intended to be used continuously, is invasive, or is implantable or active. The purpose of the device, as stated by the manufacturer, determines the class in which the device is placed. *Medical Devices Classification*, MHRA, http://www.mhra.gov.uk/Howweregulate/Devices/Classification/index.htm (last visited Sept. 9, 2014).

[169] *Who Makes the Decisions*, MHRA, http://www.mhra.gov.uk/Howweregulate/Whomakesthedecisions/index.htm (last visited Sept. 9, 2014).

[170] *Id*.

assurance system.[171] High-risk devices generally require clinical trials to demonstrate their safety.[172] In order to conduct a trial in the UK, the MHRA agree to such trials. The MHRA generally approves four out of five of these types of applications, and the refusals are on the ground of patient safety or health policy restrictions.[173] There does not appear to be a process to expedite the conformity assessment procedure.

[171] *Conformity Assessment and the CE Mark*, MHRA, http://www.mhra.gov.uk/Howweregulate/Devices/Complyingwithlegislation/ActiveImplantableMedicalDevicesDirective/ConformityassessmentandtheCEmark/index.htm (last visited Sept. 9, 2014).

[172] *Id.* A flow chart of the procedure for the different classifications of devices is available at *Class I Medical Devices – Routes to CE Marking*, MHRA, http://www.mhra.gov.uk/home/groups/dts-bs/documents/websiteresources/con286776.pdf (last visited Sept. 9, 2014).

[173] MHRA, MEDICINES & MEDICAL DEVICES REGULATION, *supra* note 152, ¶ 9.

Expedited Process for Approval of Medical Devices

