

REACH AND ITS IMPACT ON MEDICAL DEVICES

September 2008

In June 2007, the European Union's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (the so-called "REACH Regulation")¹ entered into force. The REACH Regulation imposes sweeping requirements on both manufacturers and importers of chemicals and products containing them. In particular, REACH imposes new requirements on producers of medical devices, which are in addition to those of EU specific medical device legislation.

REACH requires producers of medical devices, or their chemical suppliers, to examine and disclose the characteristics of the substances they use, permanently defend the continued use of substances that are particularly dangerous, and in some cases even face an outright ban on them. Over time, producers of medical devices could also face more limited choice as chemical suppliers seek to specialize their portfolios by narrowing the number of substances on offer and thus reducing cost of compliance with REACH.

The REACH Regulation imposes different requirements on medical devices depending on whether they are preparations or articles, and on whether they are manufactured in, or imported into, the EU/EEA. Preparations are defined as mixtures or solutions of two or more substances, such as dental filling materials, lubricants, bone cement, contact lens solutions, and anti-clotting agents. Articles, on the other hand, are objects that during production are given a special shape, surface or design that determines their function to a greater degree than does their chemical composition. Examples of articles include cardiac pace makers, catheters, corrective glasses, surgical gloves, and defibrillators.

On that basis, the Regulation is likely to impose, among other burdens, the following requirements on EU/EEA manufacturers and importers of medical devices:

DISCLOSURE OF INFORMATION

- By **JUNE 2007**, EU/EEA manufacturers of medical devices in the form of preparations or articles and importers of medical devices in the form of preparations (other than those invasive or used in direct contact with the human body) will be required to report to their suppliers any new information they have available on the hazardous properties of the substances they use, and any information affecting the risk management measures indicated in the safety data sheets that suppliers provide to them and affecting identified uses. The same information must also be provided to national authorities or the European Chemicals Agency upon their request.
- By **OCTOBER 2008**, the European Chemicals Agency is likely to have identified the first list of "substances of very high concern" ("SVHC"), which may later be subject to the prior authorization requirement. SVHCs may include Cat. 1 and 2 carcinogens, mutagens and toxic to reproduction substances ("CMRs"), persistent, bioaccumulative and toxic substances ("PBTs"), very persistent and very bioaccumulative toxic substances ("vPvBs"), and other substances giving rise to "an

¹ A copy of the Regulation is available at:
(http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf).

equivalent level of concern.” EU/EEA manufacturers, importers or distributors of medical devices in the form of articles containing more than 0.1% of a substance that the Agency has listed as SVHCs must provide their professional customers (e.g., health institutions) with the name of the substance and information allowing the safe use of the article. They must also supply the same information to consumers within 45 days of their request.

- By **JANUARY 3, 2011**, EU/EEA manufacturers and importers of medical devices may be required to report to the European Chemicals Agency the chemical classification of substances that are used in medical devices that are subject to registration (e.g., imported in quantities of one ton or more per importer per year) or that are classified as dangerous unless such classification has already been reported as part of the registration of the substance.

REGISTRATION OF SUBSTANCES

- REACH requires the registration of substances that are manufactured or imported on their own or in preparations in quantities of one ton or more per chemical manufacturer or importer per year. Both new and old substances, including those that were listed in the EU’s EINECS list, will be subject to the registration requirement. So-called “phase-in” substances (mostly EINECS listed substances) may benefit from a phase-in period only if they are pre-registered between June 1 and December 1, 2008.

Registration will require submitting (i) a technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will entail substantial testing and data gathering; and (ii) a chemical safety report assessing the hazards, exposure, and risks of use during the entire life cycle for substances manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year. Registration will be substance specific and chemical manufacturer or importer specific: only those chemical manufacturers and importers that have registered within the deadlines will be allowed to market their substances.

Substances in articles are also subject to registration or notification requirements unless the use of the substance in the article has already been included in the registration of any third party. In particular, manufacturers and importers of articles must register substances (i) present in their articles in quantities exceeding one ton per manufacturer per importer per year; and (ii) intended to be released during normal and reasonably foreseeable conditions of the article’s use.

Manufacturers and importers of articles must also notify the substances contained in their articles if the following four conditions are met: (i) the substances are listed as SVHCs (*i.e.*, Cat. 1 and 2 CMRs, PBTs, vPvBs, and substances raising “an equivalent level of concern”), (ii) the substances are present in the articles in quantities above 1 ton per manufacturer or importer per year, (iii) the substances are present in the articles in concentrations of more than 0.1%, and (iv) exposure to humans or the environment cannot be excluded. In certain cases, the Agency may also require the registration of any substance contained in articles.

The respective registration or notification obligations lie with different persons, depending on the circumstances. EU/EEA manufacturers and importers of medical devices in the form of articles (e.g., catheters, corrective glasses) will, where relevant, be liable for registration, pre-registration and/or notification of the substances contained in the devices unless any third party has already registered the use of the substance in the medical device. Importers of medical devices in the form of preparations (e.g., dental filling materials, lubricants) will be liable for pre-registration and registration unless they ensure that their foreign suppliers do so by means of an Only Representative in the EU/EEA. Similarly, EU/EEA manufacturers of medical devices importing substances or preparations to manufacture their products will also be liable for pre-registration

and registration unless their foreign suppliers do so.

In contrast, EU/EEA manufacturers of medical devices purchasing substances from EU/EEA chemical suppliers are considered “downstream users” in terms of the REACH Regulation (except for substances contained in the articles they manufacture and that are subject to registration and/or notification) and may rely on their suppliers’ pre-registrations and registrations.

- As of **JUNE 1, 2008**, producers of medical devices in the form of preparations or articles will have to ensure that their non phase-in substances (mostly non-EINECS listed substances) contained in, or used in the EU/EEA manufacture of, medical devices are registered.
- Between **JUNE 1** and **DECEMBER 1, 2008**, producers of medical devices must ensure that all “phase-in” substances contained in, or used in the EU/EEA manufacture of, their medical devices, and that are subject to registration, are pre-registered. Where a phase-in substance is not pre-registered within the deadline, producers of medical devices will be liable for its registration as of June 1, 2008.
- Between **NOVEMBER 30, 2010** and **MAY 30, 2018**, producers of medical devices must ensure that pre-registered “phase-in” substances contained in, or used in the manufacture of, their medical devices are registered. The first deadline (*i.e.*, November 30, 2010) applies to Category 1 and 2 CMRs, R50/53 substances (*i.e.*, classified as very toxic to aquatic organisms that may cause long term adverse effects in the aquatic environment) if manufactured or imported in quantities of 100 tons or more per manufacturer/importer per year, and other substances manufactured or imported in quantities of 1000 tons or more per manufacturer/importer per year.
- By **JUNE 2011**, EU/EEA manufacturers and importers of medical devices in the form of articles (*e.g.*, cardiac pace makers) must notify the Agency of the presence of substances identified as SVHCs in their articles unless the use of the substance in the article has already been included in the registration of any third party.

DOWNSTREAM USER OBLIGATIONS

- Where suppliers register their substances, EU/EEA manufacturers of medical devices in the form of preparations or articles, and importers of medical devices in the form of preparations (a limited exemption applies to those invasive or used in direct contact with the human body), will be required to check whether their specific use of the substance is covered in the exposure scenarios communicated in the supplier’s safety data sheet, which should reflect those of the supplier’s chemical safety report. If their specific use of the substance is not covered, producers of medical devices may be required to submit a limited notification to the Agency and prepare a chemical safety report of their particular uses if the substances or the preparations containing them are “dangerous,” PBTs, vPvBs or substances raising an “equivalent level of concern;” and they use the substance in quantities of one ton or more per year and in concentrations above specified thresholds (*e.g.*, 0.1%).

The chemical safety report of importers of medical devices in the form of preparations must assess the health and environmental risks resulting from the use of the substance when contained in the medical device. In contrast, EU/EEA manufacturers of medical devices must assess the environmental and health risks of the use of the substance during the manufacture of the devices and those resulting from the use of the substance contained in the medical device.

PRIOR AUTHORIZATION REQUIREMENTS

- Producers of medical devices may be required to apply for the prior authorization of the use of SVHCs, if they are also listed as subject to authorization, that they use in the manufacture of, or are contained in, their medical devices.
- By **THE END OF 2010**, the European Commission could adopt its first list of substances SVHCs that are also subject to authorization. Priority substances to be listed include PBTs and vPvBs and substances with wide dispersive use or in high volumes.

The list will specify the date by which manufacturers and importers of medical devices must ensure that they or their suppliers have applied for an authorization to use the substance in medical devices, or in their manufacture, and the date (so-called “sunset date”) after which non-authorization applicants or holders must no longer market or use the substance.

In particular, EU/EEA manufacturers of medical devices must ensure that they or their suppliers apply for the authorization of the specific use of listed substances that they use in specified concentrations (e.g., 0.1%) in the manufacture of their medical devices (in the form of preparations or articles), or that are contained in specified concentrations in their medical devices in the form of preparations. In contrast, importers of medical devices in the form of preparations (but not articles) must ensure that they or their suppliers apply for the authorization of the use of the substance in the preparations. The use of SVHCs in imported medical devices in the form of articles (e.g., equipment) will not be subject to the authorization requirement.

EU/EEA manufacturers and importers of medical devices will not be allowed to use the listed substances after the sunset date unless they or their suppliers have applied for authorization.

Authorization applicants will be required to show that the risks resulting from the use of their substances are adequately controlled, or that the socio-economic benefits of the use outweigh the risks and there are no suitable alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available.

The REACH Regulation makes clear that when granting authorization the Commission must not assess the health risks (in contrast to the environmental risks) resulting from the use of the substance in the medical device (but not during their manufacture). Thus, the authorization procedure should not apply to the use of Cat. 1 and 2 CMRs in medical devices.

Applicants who do not obtain an authorization will be banned from using listed substances, unless their supplier or downstream user has obtained such authorization. All medical devices in the form of preparations marketed in the EU/EEA and containing substances that have been authorized will have to be labeled with the number of the authorization that EU/EEA manufacturers or importers of medical devices, or their suppliers, have obtained.

Where suppliers obtain an authorization covering the use of producers of medical devices, the latter must notify the Agency of their use of the substance.

RESTRICTIONS PROCEDURE

- The REACH Regulation also establishes a fast track procedure through which the Commission may ban the marketing and use of substances that pose a “unacceptable” health or environmental risk. This procedure may also apply to substances in medical devices, and, in particular, the Regulation foresees that it should be applied to substances that have been identified as SVHCs (*i.e.*, Category 1 and 2 CMRs, PBTs, vPvBs and substances raising “an equivalent level of concern”) and that are contained in articles, such as medical devices.
- From the end of 2009 onwards, the Commission could issue its first bans under REACH of the use of substances in order to address the human health and environmental risks arising from the use of the substance during the EU/EEA manufacture of, or their presence in, medical devices.

ELECTRONIC MEDICAL DEVICES

- Electronic medical devices (*e.g.*, defibrillators, scanners) will be subject to requirements that are exponentially higher than those that the RoHS Directive may impose as such devices will be subject to the REACH requirements applying to substances used in the EU/EEA manufacture of, or contained in, articles.

In particular, EU/EEA manufacturers of electronic medical devices will be subject, with respect to the substances that they use during their manufacturing processes, to the requirements described in this memorandum on disclosure of information to suppliers and authorities, downstream user obligations, authorization, and marketing and use restrictions. EU/EEA manufacturers and importers will also be subject, with respect to the substances contained in their electronic devices, to the requirements on reporting classification, disclosure of information to professional customers and consumers, pre-registration, registration and/or notification of the substances contained in the devices, and marketing restrictions.

The REACH Regulation is technical in nature and several important provisions are open to different interpretations. It will be important to monitor how the rules are being implemented in more detailed provisions and guidelines.

The information in this memorandum is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

For further information, please contact:

Peter Bogaert

Richard Kingham

Cándido García Molyneux

32.2.549.5243

202.662.5268

32.2.549.5261

pbogaert@cov.com

rkingham@cov.com

cgarciamolyneux@cov.com