

REACH: huge, complex demands shock industry as deadline approaches

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Will your company be compliant in time for the deadlines that are now looming for EU requirements for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)? Many may assume they will be, but those present at the REACH Day, organised by the Association of British Healthcare Industries on May 13 2008 were reeling by lunchtime. Is it really so complex? they were asking, while seeing the deadlines rushing towards them. Amanda Maxwell reports

All medical device and IVD companies will be impacted in some way by the EU requirements for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and some are in danger of losing the chemicals they need to manufacture their products.

Unless they act rapidly now, they will not meet the December 1 2008 deadline for the pre-registration (of chemicals already on the market). And then they may find their suppliers are unable or unwilling to continue providing these substances. That was the warning given by the two experts who co-hosted the REACH Day organised by the ABHI in its London offices last week, Peter Douben, of REACHwise, and senior environmental specialist, Professor George Howarth, chairman of the ABHI environment committee.

The requirements are onerous, costly and multi-layered. Delegates appeared completely taken aback by the complexities involved, which are likely to come as an even greater shock to the majority who were not present.

Indeed, it seems likely that a high percentage of EU SMEs are going to be forced out of business because of the costs and challenges of complying. To give some idea of the scale of the likely impact of the new requirements, some 25% of Hungarian SMEs possibly including medical device companies may go under because compliance is so difficult, Mr Douben suggested to *Clinica* during the break.

This is hardly surprising; the REACH Regulation is some 300 plus pages long and there are many accompanying guidance documents of even greater length, Professor Howarth told the meeting. But despite the complexities, there were three main immediate messages being delivered by the speakers.

1. identify chemical that are vital to your business and make sure these will be pre-registered by your supplier;
2. if you are an importer into the EU of chemical substances, preparations and/or articles, it is likely that you will need to pre-register between June and November 2008; and

3. it is important to identify any use of Substances of Very High Concern (SVHC) as these will be the focus of attention in early 2009.

Each of these issues are dealt with in more detail in this article.

Pre-registration list available first thing next year

By January 1 2009, the European Chemicals Agency, ECHA, will prepare a list of pre-registered substances on its website. It will then be possible for medtech manufacturers to find out if their current chemical suppliers intend to register the substances that they use. If a substance is not on the list, a user will be able to contact the ECHA with a request for help in identifying a supplier. The ECHA will then publish on its website the name of that substance, and on request from a potential user, the Agency will apply that user with the contact details of the manufacturer.

If the medtech importers do not comply, they may find the chemicals are no longer available to them. It is therefore imperative that medical device manufacturers pre-register via their suppliers as soon as possible in June to end of November in advance of the December deadline.

This is a double-edged sword, of course, since it means that the chemical manufacturers will then know just how essential their substances are to manufacturers and could use this information to increase their prices, not least to cover some of their costs associated with compliance with REACH. An average increase in chemical costs of 10% seems quite likely.

Manufacturers also need to be prepared since the impact of the additional costs of meeting the requirements for chemical manufacturers could mean that low volume chemicals may disappear from the market, that specialist chemicals are limited and that companies may need to supply to the chemical manufacturer their technical dossiers.

Pre-registration now will mean that the full registration will be delayed for many years ranging from the period between November 2010 and May 2018.

Industry needs to co-operate over list

The European medtech industry association, Eucomed, has drawn up guidance on "Registration or Notification of Substances in Medical Devices" which includes a number of examples.

Registration will be needed for 'loose' chemicals in containers (for example a spray can) and for any substances intended to be released from the medical device. If there are any Substances of Very High Concern (SVHC) present these will have to be Notified to ECHA.

"We need a debate now" on this list, Professor Howarth told the meeting, so that the medtech industry can be prepared. He invited companies to look at the examples, to consider if they can add to these, and to attempt to achieve a common understanding within industry. "If you have any doubts, then let the Eucomed working party know," he told the meeting.

Not everyone will be impacted, however, since dossiers only need to be provided for chemicals that are manufactured in the EU and/or imported into the EU in volumes over 1 tonne.

Initial tasks for downstream users

Medical device and IVD manufacturers will mostly act as "downstream users" in terms of the Regulation. As such, it is their duty to inform their suppliers of the use to which they put the chemicals they purchase, and they will need the support of the chemical supplier in registering unique applications of substances.

The chemical manufacturers have to then specify what the "downstream use" of their chemicals is to the ECHA and the associated risks and safety measures.

Where no support is available and the medical device manufacturer is using the substance outside those uses specified by the supplier, the manufacturer is then on its own and, as long as the amounts involved are over one tonne use of the substance a year, must apply directly to the ECHA for authorisation, bearing in mind the restrictions listed in annex XVII of the Regulation concerning Substances of Very High Concern (SVHC), see below.

In such cases, the medical device or IVD manufacturer may need to prepare its own dossier, or chemical safety report, including details on the so-called exposure scenario for uses outside the conditions detailed by the supplier, Mr Douben explained.

Where the medtech industry is impacted

Substances used in the medtech area that are likely to be impacted by the registration and authorisation requirements of REACH include:

- metal alloys;
- additives in plasticisers;
- surface treatment chemicals; and
- harmful chemicals.

In particular, chemicals in medical devices that are considered of concern are those where there is the intended release of chemicals, and those where SVHC are present in amounts of 0.1% weight per weight.

Safety data sheets and exposure scenarios

In summary, then, downstream users must not place on the market or use any substances which are not registered in accordance with REACH either through their suppliers, or directly themselves. Through their suppliers, or directly, if they have needed to act directly with the ECHA (as an importer), manufacturers will receive information on dangerous substances and preparations, including risks

from their use and measures to control these risks in the form of safety data sheets (SDS) as of 2009. These SDS will trigger obligations for medtech manufacturers. Some of these SDS will have an annex called an "exposure scenario" which will detail the limits of exposure in different situations as well as measures to reduce any risk. Medtech companies will need to follow the instructions in the SDS and the exposure scenarios, Mr Douben told the meeting, and where their use is not covered will need to communicate with the supplier with the aim of having their use covered by the exposure scenario, or may need to develop their own chemical safety report.

It is essential that manufacturers comply with the risk management measures, and with any restrictions on the use of the substance. If manufacturers have new information on the hazard of the substance or preparation, and do not believe that the risk management measures are appropriate or that their circumstances lead to a higher exposure than described, then they must contact their suppliers and even the ECHA. Guidance on exposure scenarios is due out next month, but will not make easy reading. It is expected to be enough to fill two lever arch files.

There is clearly a role in estimating exposure scenarios for different types of chemicals in medtech products for the trade associations, Mr Douben said.

Substances of Very High Concern

But among those dossiers that are submitted, where there are substances of very high concern (SVHC) that are being manufactured in the EU or imported in an amount greater than a tonne, a specific authorisation procedure will be necessary, in addition to registration.

The European Commission is in the process of establishing a 'candidate' list of those substances affected, and the expectation is that the list will start to be published and populated by 2009, Professor Howarth told the meeting.

Once this list is established, authorisation will only be granted where it is established that the risks are controlled and that the benefits outweigh the risks where no alternatives are available. If there is no authorisation, then all other products in this so-called annex XIV will be prohibited.

The impact of this on medical device manufacturers could be future restrictions on the type of use of some chemicals. Moreover, medical device manufacturers will need to remain alert to the updates to the candidate list which could impact them in the future.

Manufacturers will not only have a legal obligation to notify ECHA of the SVHCs in their products via their suppliers - or directly if they are an importer, or not covered by their suppliers, but also to notify customers about the SVHCs contained in their products. They must provide customers with sufficient information to enable safe use of these articles and at least the name of the SVHC.

The requirements to notify SVHCs start on June 1 2011. After that, they apply six months after each new substance appears on the list, Mr Douben told delegates.

Impact of retaining SVHCs

While it may well be possible to obtain authorisation to use SVHCs in medical devices, companies would do well to ask themselves about the impact of doing this given the need for these to be mentioned on the labelling and the increasingly sensitive reaction among the public and decision-makers to the use of chemicals that are regarded as risky. The likelihood is that the UK hospital trusts and chemist stores will want to ban products with such labels to avoid adverse publicity, Mr Douben said. If they keep them, then ordinary consumers may ask for more information and the retailer needs to provide this by law. On the other hand, there will be occasions when use of

the substance is critical and the manufacturer will have to defend it.

Device manufacturers act directly as importers

There are circumstances where a medtech manufacturer may find it necessary to register directly with the ECHA. In brief, it is not only the EU chemical manufacturers that have to register, but also any importer into the EU of the substances covered by REACH.

So, if medical device companies import into EU chemicals, preparations or medical devices designed to release chemicals then they should pre-register these individual chemicals. When it comes to import registration requirements, there are different requirements according to which of the three below the importer fall into:

- substances;
- preparations; and
- substances in articles (medical devices) i) with intended release; or ii) SVHC (notification required).

Separating out which is which, and therefore which requirements apply in the case of import, is no easy task. But essentially, manufacturers of medical devices are dealing with "articles" and the following definitions are the foundation on which decisions need to be made, Mr Douben explained:

- **substance:** a chemical element and its compounds, including all substances obtained by the chemical manufacturing process and its additives and impurities;
- **preparation:** a mixture of two or more substances (for example, paints, varnishes, inks and many dyes); and
- **article:** an object which, during production, is given a special shape, surface or design which determines its function to a greater degree than its chemical composition.

In other words, an article is when the physical form is the most important thing. A chemical in an article is when the chemical is "slopping about" so needs a container or carrier, for example, photocopy toner; wet wipes; or when the chemical is intended to be released.

So, medical device manufacturers are most likely to be impacted by the requirements impacting substances in articles when it comes to importing. REACH regulates substances or preparations in containers, or articles with substances or preparations that are intended to be released, although the exact definitions of these are complex and merit close study. If the manufacturer concluded that the "article" does in fact contain a "substance" or in a "preparation, in combination with an article", then that manufacturer will be subject to pre-registration, registration or authorisation requirements. Where the product meets the REACH definition of an "article", then there are four possible obligations.

1. possible registration of substance;
2. possible notification of substance;
3. communicate information to users on certain substances; and
4. comply with the restrictions.

Examples of medical device substances in containers or carriers are the following:

- recombinant enzyme solution;
- AP-conjugated antibody solution;
- Culture media containing casein hydrolysate;
- foam dressing;
- bandage spray;

- bone cement; and
- bone cement containing antibiotic (antibiotic exempt).

** Active pharmaceutical ingredients are not within the scope of REACH, and so drug/device combinations are not impacted.*

Examples of products with intended release are more difficult to find, but Professor Howarth mentioned plaster with antisepticum (a biocide), although antisepticum may already be registered as a biocide and all biocides are automatically placed on the REACH registration list.

Among those articles with SVHCs but no intended release are PVC gloves containing the DEHP plasticisers, but otherwise few examples have been put forward by Eucomed members as yet. All substances in these articles must be registered with the chemical supplier, or directly with the ECHA, if imported in volumes above one tonne. In the case of SVHCs, these must be notified to the ECHA.

On the other hand, there are a great number of products that are not acting as carriers, and where there is no intended release or SVHC is not present, and where the medical and diagnostic industries have no obligations under REACH. Those cited at the meeting included the following:

- silver-coated adhesive bandage;
- coated stent;
- adhesive tape;
- incontinence catheter;
- silicone tube with plasma coating;
- drug dressing;
- PVC glove with non SVHC plasticiser;
- silver coated suture;
- resorbable suture;
- titanium implant;
- purified antibody solution;
- radiolabelled antibody; and
- control serum.

Don't panic

For many companies there is going to be a huge volume of work associated with REACH compliance, but Mr Douben was at pains to emphasise the need for companies to keep calm and to plan their schedules realistically.

Eucomed has prepared a substances inventory guide which includes spread sheets for substances, preparation and articles to help companies manage the number of substances they are dealing with, the type of regulatory control that they will be subject to and the timelines.

In summary, the only substances that will be available to downstream users in the future will either:

- have been registered; or
- have been pre-registered and therefore have a later registration deadline; or
- be exempt from registration; or
- be produced/imported by the supplier in amounts below 1 tonne per year.

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