REACH
AND ITS IMPACT ON PHARMACEUTICALS

The European Union has just adopted Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (the “REACH Regulation”), which will enter into force on June 1, 2007. The Regulation contains broad exemptions for pharmaceuticals but there remain important regulatory obligations. In addition, there is some room for interpretation of the exemptions and a narrow reading could significantly increase the burdens for industry.

1. General Impact for Pharmaceutical Companies

The REACH Regulation exempts substances “used in” medicinal products that fall within the scope of Regulation 726/2004 (governing the centralized procedure), the Human Use Directive 2001/83 and the Veterinary Use Directive 2001/82 from the main provisions on registration, evaluation, authorization, and downstream use of chemicals. The other provisions of the Regulation remain applicable, and are likely to include the following:

✓ Disclosure of Information: By June 2007, EU manufacturers of medicinal products will be required to report to their suppliers any new information they have available on the hazardous properties (from a human and environmental perspective) 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 that affect their identified uses. EU manufacturers must also supply such information to national authorities or the European Chemicals Agency upon their request.

✓ Restrictions: The REACH Regulation also establishes a fast track procedure through which the Commission may, as from the end of 2009 onwards, ban the marketing and use of substances that pose an “unacceptable” health or environmental risk. The procedure will probably only rarely be used for substances that are mainly used by the pharmaceutical industry, but it may more easily be applied to substances with multiple uses.

In particular, a Commission Statement to the new Paediatrics Regulation provides that the Commission will request from the Committee for Medicinal Products for Human Use an opinion on the use of excipients that are carcinogens, mutagens and toxic to reproduction substances in medicinal products for human use, and that it will inform the Parliament and the Council of the action necessary on the basis of such opinion.

¹ A copy of the Regulation is available at:
In addition, suppliers of ingredients that are also used in other products may be subject to all the REACH requirements for those other uses and may decide not to further support the ingredients so as to avoid the regulatory obligations.

2. Processing Aids and Other Substances Not Used as Ingredients

The main exemption for pharmaceuticals only covers substances that are “used in” medicinal products and thus does not cover processing aids, growth media, etc. These substances are likely to be subject to the full scope of REACH, including the need for registration and, for substances of very high concern, authorization. Substances of very high concern may include Cat. 1 and 2 CMRs, persistent, bioaccumulative and toxic substances (“PBTs”), very persistent and very bioaccumulative toxic substances (“vPvBs”) and other substances giving rise to “an equivalent level of concern.”

3. Possible Narrow Interpretation of the Exemption

The main exemption for medical products could be interpreted narrowly, especially in two respects:

- The REACH Regulation does not clearly state that the exemption also applies to ingredients before they are incorporated in pharmaceuticals (be it in bulk or in final packaging). A narrow reading of the exemption would in principle make all ingredients (active substances and excipients) and intermediates subject to the full REACH regime, and there are recent developments that suggest that the Commission is inclined to adopt a restrictive approach.

- The exemption covers use in medicinal products “within the scope of” the medicines rules. If this is interpreted strictly, magistral preparations, hospital preparations, named patient sales and compassionate use (except when reviewed under Article 83 of Regulation 726/2004) would be fully subject to REACH. The same applies to investigational products used in clinical trials, but REACH does provide specific exemptions for research and development.

In addition, the exemption most likely does not cover immediate and outer packaging, which will thus normally be subject to REACH.

**MAIN RECOMMENDATIONS**

Pharmaceutical companies should consider the impact of REACH on their business. In particular, they should consider the following steps:

- Identify all substances used in production within the EU but not contained in the finished product, and, for each substance, determine its regulatory status (e.g., EINECS listed, current and likely chemical classification), gather information on its properties, and assess volumes, specific uses, and concentrations. Even if the substances are not subject to most of the REACH requirements when intended for medicinal products, pharmaceutical companies may be affected by the restrictions applying to their suppliers.
✓ Review with suppliers the ongoing availability of ingredients, especially with regard to ingredients that are also used in other types of products.

✓ Carefully monitor and try to participate in the process of interpretation and implementation of the REACH Regulation in more detailed legislation and guidelines.

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The REACH Regulation is technical in nature and this note can only provide a brief overview. There will also be important developments in the interpretation and implementation of the Regulation.

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.

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