GSK Public policy positions

The EU REACH Regulation

The Issue

The European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was formally entered into force on 1 June 2007. It aims to enhance the protection of human health and the environment through the better and earlier identification of the hazardous properties of chemical substances and better management of risks throughout their use. It is a major landmark in chemicals policy, putting duties on manufacturers and importers to register and demonstrate safe use of any existing and new chemicals they produce.

GSK is affected by the REACH Regulation in the following ways:

– As a manufacturer and importer of chemicals
– As a downstream user of chemicals and chemical products
– As a supplier of products/preparations

GSK's Position

– GSK fully supports REACH's objective of enhancing the protection of human health and the environment against the hazardous properties of chemical substances. REACH is consistent with GSK's public policy position on Hazardous Chemicals Management.

– GSK welcomes the efforts made by all parties in the development of REACH to ensure that the Regulation is workable and does not impose unnecessary costs on industry.

– GSK welcomes the exemption from the principal requirements of REACH agreed for substances used in human medicinal products. The exemption was necessary to ensure that the Regulation did not adversely impact industry's ability to deliver essential therapeutic products to patients. We are confident that human health and the environmental risks of pharmaceuticals are adequately addressed by other existing EU legislation on medicines.

– Notwithstanding the exemption for APIs, excipients and some intermediates from the requirements for REACH, GSK's use of certain chemicals (e.g. starting materials, reagents, solvents, catalysts and certain intermediates) in synthesising drug actives means we are still affected by REACH.

– GSK recognises and fully supports the efforts made in REACH to minimise testing on vertebrate animals and to promote use of alternative test methods where this does not compromise the assessment of human and environmental hazards. We will only use animals where there is no alternative and our scientists are guided by the principles and standards known as the '3Rs' (reduction, refinement, replacement).

– We remain concerned about the economic burden placed on European suppliers of chemical intermediates in demonstrating strict control. The December 2010 revision of the European Chemicals Agency (ECHA) Guidance on intermediates prescribes a precautionary approach to handling intermediates that is likely to drive an increase in unnecessary animal testing or adoption of over engineered containment strategies which in many cases will not enhance worker or environmental protection. We urge ECHA to consider adopting a more pragmatic approach to regulating chemical intermediates.

– As a downstream user of chemicals we are concerned that a lack of common understanding around what constitutes "strict control" has resulted in a large number of substances being registered in 2010 as intermediates by EU suppliers and importers. We would encourage the ECHA and chemical industry resolve this issue to mitigate any unnecessary supply risks to downstream user industries.

– GSK is encouraged by improvements that REACH has driven in the quality of hazard information available in safety data sheets for substances we purchase. However, we remain concerned that the concept of an extended safety data sheet is overly complicated and will only serve to confuse downstream users. We therefore question whether extended safety data sheets will deliver expected improvements in worker and environmental protection.

– We welcome the Commission's commitment to examine the workability of REACH and possible overlaps with other EU legislation. We believe there is scope for better alignment of EU legislation on worker safety (Chemical Agents Directive) with REACH, especially in relation to occupational exposure reference levels; Indicative Occupational Exposure Limit Values (IOELV's) and Derived No Effect Limits (DNELs). It is not logical that health based limits derived using different regulatory processes should be so different as to drive different risk management measures. This only serves to confuse users and will not lead to improvements in workplace health and safety.

– It is important that the Commission regularly monitors the cost and economic benefits of REACH to inform future decision making when REACH is reviewed.

Background

REACH replaces 40 existing pieces of EU legislation, including the Notification of New Substances (NONS), with a unified, comprehensive strategy.

Registration requires that manufacturers or importers of new or existing ("phase-in") chemicals submit a basic data package to the European Chemicals Agency (ECHA) in Helsinki. This technical dossier is required to contain information on the substance and information on how to manage effectively the risk entailed by using it.

Evaluation of the dossier allows the regulatory authorities to assess whether the information provided complies with requirements and to decide on proposals for animal testing. For selected substances, where a risk to health or the environment is suspected, substance evaluation provides a mechanism to require the submitter to obtain more information. Evaluation may also lead to the conclusion that action should be taken under the authorisations or restrictions procedures.

Authorisation may be required for substances of very high concern (carcinogens, mutagens, substances toxic to the reproductive system, and substances which are persistent, bioaccumulative and toxic or very persistent and very bio-accumulative or of equivalent concern) It is estimated that 1,500-2,000 chemicals may fall into this category.

Restrictions are the safety net of the system. Any substance on its own, in a preparation or in an article, may be subject to Community-wide restrictions if its use poses unacceptable risks to health or the environment. Restrictions can be decided for the use of a substance in certain products, for use by consumers or even for all uses (ie. a complete ban of a substance).

Exemptions

Chemicals used in finished pharmaceutical products (drug active, excipients) as well as certain intermediates are exempt from the REACH Registration, Evaluation and Authorisation processes. GSK advocated for this exemption because similar requirements are already included in the EU medicines legislation. Finished pharmaceutical products could still be subject to Restriction under REACH, although this is unlikely in practice.

REACH and Animal Testing

Acquiring the necessary knowledge on the properties of substances will in some cases entail animal testing. However, REACH has been designed to reduce animal testing to the absolute minimum by including provision for using in vitro, read-across and/or structure activity predictions in the information gathering process. Unnecessary tests are avoided due to the obligation to share all data generated through testing on vertebrate animals, and by

the provision that testing proposals must be approved by the Agency before a new test on animals can be performed. This will ensure that the proposed testing programme does not duplicate studies already in existence.

REACH also mandates a public consultation period of 45 days before certain tests can be carried out, to verify whether the data is already available and consequently the tests are unnecessary.

GSK and REACH

Many chemicals purchased or manufactured by GSK are affected by REACH. These include chemicals used in the synthesis of drug actives (e.g. starting materials, reagents, solvents, catalysts, certain intermediates), ingredients in oral healthcare products and chemicals used in packaging materials. The size and complexity of GSK's supply chain makes it challenging to ensure that all these materials have been registered and will continue to be available under REACH.

REACH primarily affects GSK operations in Europe but also affects some GSK operations beyond. Failure to register a substance means that it cannot be manufactured, imported or used in the EU. Sites outside the region are therefore affected if they source raw materials from Europe or export chemicals back into it.

All our GSK manufacturing sites have evaluated substances used in the manufacturing of our products and our Procurement Department has undertaken a project to ensure that our EU suppliers are aware of REACH and are meeting their compliance responsibilities. We constantly monitor for substances designated as Substance of Very High Concern (SVHCs) so that these can be identified and if necessary removed from our manufacturing processes and products in line with commitments made in our public policy position on Hazardous Chemicals Management.

Further Information

European Commission website on REACH:
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

GSK Public Policy Position Paper on Hazardous Chemicals Management
http://www.gsk.com/policies/GSK-on-hazardous-chemical-management.pdf

GSK Public Policy Position Paper on the Care, Welfare and Treatment of Animals
http://www.gsk.com/policies/GSK-on-the-Care-Welfare-Treatment-of-Animals.pdf

European Chemical Agency website on REACH
http://ec.europa.eu/index_en.htm

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