GSK Public policy positions

Hazardous Chemicals Management

The Issue

Chemicals, many of which are hazardous, are used at every stage in pharmaceutical, vaccine and consumer healthcare production. They are necessary to enable GSK to carry out research into the causes of disease, in the discovery of new medicines, in the manufacture of active pharmaceutical ingredients (API's) and in the formulation of our products. The types of chemicals used include reagents, catalysts, solvents, acids and bases, intermediates, surfactants, biocides, colours and flavourings and a wide variety of excipients.

Many requirements have been introduced into national and international legislation to protect people and the environment from the potential adverse effects of exposure to hazardous chemicals. New technology and testing methods have been deployed and there have been key developments in the regulation of chemicals, notably the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH).

This paper focuses on GSK's use of large quantities of chemicals during clinical development, in our manufacturing operations and in our marketed products. The research phase of our work is not covered in this paper, as any hazardous chemicals used in our research activities are handled in small quantities, by trained scientists, in conditions specifically designed and regulated to minimise any workplace exposure or environmental emissions.

The issue of pharmaceuticals entering the environment - through human excretion; unused medical products; or via discharges from manufacturing facilities - is the subject of a separate public policy available on gsk.com.

GSK's Position

- GSK recognises that hazardous chemicals must be used in a way that minimises any potential adverse effects on human health and the environment. Their use must be based on both an understanding of the risk they present and on the corresponding controls aimed at managing that risk.

- Our position is aligned to the 2002 Johannesburg World Summit target to "use and produce chemicals in ways which will lead to the minimisation of significant adverse effects on human health and the environment by 2020".

- Through implementation of our global Environment, Health and Safety (EHS) standards, we comply with all national and regional regulatory requirements. Where a GSK operation is subject to both GSK and regulatory requirements, the stricter requirement applies.

- We constantly monitor for chemicals designated as candidate Substances of Very High Concern (SVHCs) so that these can be identified and if necessary removed from our manufacturing processes and products. Where elimination or substitution is not possible, appropriate and responsible risk management approaches are adopted.

- GSK fully supports the aims of REACH, and we comply with all relevant aspects of this regulation. In recognition of the risk/benefit analysis that medicines bring to patients and public health we would support a more flexible approach from the European Commission in relation to the Authorisation process for certain substances used in their manufacture.

- We communicate EHS information internally and with relevant external stakeholders, including third parties, to enable them to adopt appropriate risk management approaches. We also publish EHS data on the hazardous properties of any chemicals used in our products and potential effects on human health and the environment in Safety Data Sheets on gsk.com.

- GSK has a role to play in encouraging responsible management of hazardous chemicals by our third parties, and we apply consistent standards to our contract manufacturing operations. GSK's Public Policy on Working with Third Parties outlines our expectations of compliance with our standards on quality, patient safety, health and safety and the environment. Appropriate action will be taken against those third parties found in breach of their undertakings, up to and including termination of their contract with GSK.

- We recognise the potential of 'green' or sustainable chemistry. We have an in-house team dedicated to embedding new methodologies to minimise the potential environmental impact of our chemistry. We also partner with academia and industry peers on exploring new aspects of green chemistry.

Background

Identifying hazards

A comprehensive understanding of intrinsic hazardous properties is critical for decision making and the sound management of chemicals. We therefore identify the key environmental and workplace health and safety (EHS) hazards and risks associated with GSK proprietary chemicals and products. For non-proprietary chemicals, we have robust processes in place to obtain EHS hazard information from our suppliers as well as published literature.

GSK is aligned to the **G**lobally **H**armonised **S**ystem (GHS) of classification and labelling of chemicals. GHS is a worldwide system for classifying, labelling and communicating the hazardous properties of industrial and consumer chemicals.

Governance and regulation

The manufacture, transport and supply of chemicals and their use in our operations are governed by a substantial body of national and regional legislation enacted to protect health and safety and the environment.

Our global EHS Standards set out our expectations and requirements for managing EHS risks. Through their implementation, we comply with all national and regional regulation.

The EU's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is widely regarded as the benchmark worldwide for regulating chemicals. It aims to enhance the protection of human health and the environment through the better assessment of chemical substances and better communication and management of risks arising from their use. It mandates manufacturers and importers to register and demonstrate safe use of any existing and new chemicals they produce or use. It also requires careful management of certain chemicals, or 'Substances of Very High Concern' (SVHCs). The entire system, or elements of it, is being replicated by other countries.

GSK is subject to REACH because we manufacture and use chemicals to produce our pharmaceuticals, vaccines and certain consumer health products. We also have REACH obligations due to chemicals in the packaging materials we use.

As an EU regulation, REACH primarily affects GSK operations in Europe - where failure to register a substance means it cannot be manufactured in or imported into the EU. Sites outside the EU are also affected, however, if they source raw materials from the EU or export chemicals back into it.

Risk management options under REACH

Medicinal products and active pharmaceutical ingredients (APIs) are exempt from REACH. This reflects the fact that they are already subject to extensive regulatory requirements.

Other substances evaluated and designated as a SVHC by the European Chemicals Agency (ECHA), such as some processing solvents and intermediates used in API manufacturing, are not exempt. Authorities can manage the use of SVHCs in different ways. They can restrict their use, or make their use the subject of an Authorisation.

An Authorisation provides for continued use of a SVHC for a finite period, whilst potential substitutions are researched.

In the pharmaceutical sector substitution is not always technically feasible within the established timelines for an Authorization, if at all. This is due to strict product regulatory and quality requirements to ensure that any changes in manufacturing do not adversely affect the safety or efficacy of the medicine.

Authorisation as a risk management option within the established timelines can therefore impact on the supply, safety and availability of medicines should substitution not be technically feasible. We therefore seek extended Authorisation periods from the European Commission for specific substances we use in manufacturing. This is based on their risk profile (taking into account how our industry uses these substances), and the value they can bring to patients and public health in the manufacturing of medicines.

Embracing "Green Chemistry"

We recognise the potential of green chemistry (also known as sustainable chemistry) and its focus on designing products and processes that minimise the use and generation of hazardous substances.

We have a group of GSK chemists dedicated to embedding new methodologies designed to minimise the potential environmental impact of our chemistry. We also invest in academic collaborations exploring different aspects of green chemistry around the world. One example is our partnership with the Singapore Economic Development Board, to which we have committed £24 million to support research in sustainable manufacturing. We are also co-funding (with FAPESP, a São Paulo state agency) the Centre of Excellence for Research in Sustainable Chemistry in Brazil.

We also collaborate with industry peers. We are a member of the American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable (ACS GCI PR). In the UK our flagship programme is our involvement in the carbon neutral laboratory at the University of Nottingham, which opened in 2016.

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