Our position on
Hazardous Chemicals Management

What is the issue?

Chemicals, many of which are hazardous, are used during medicine and vaccine production. They are needed to carry out research into the causes of disease; to support discovery of new medicines; in the manufacture of active pharmaceutical ingredients (APIs) and vaccines; and in the formulation of our products. The types of chemicals used could include reagents, catalysts, solvents, acids and bases, intermediates, surfactants, biocides, colours, flavourings and 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.

This paper focuses on GSK's use 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.

What is GSK's view?

- We recognise that hazardous chemicals must be used in a way that minimises any potential adverse effects on human health, safety, and the environment. Their use must be based on both an understanding of the hazards they present and on the corresponding controls aimed at managing the risk of exposure in accordance with applicable laws and regulations.
- 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 applicable national and regional regulatory requirements.
- We constantly monitor for chemicals of particular concern or high risk, so they can, if necessary, be removed from our manufacturing processes and products. Where elimination or substitution is not possible, appropriate and responsible risk management approaches are adopted.
- As governments look to regulate large scale use of hazardous chemicals, we urge them to consider an approach based on the EU's REACH framework. It has evolved well over the years, responding to both environmental and industrial concerns, as well as patient access challenges. The result is a framework that simultaneously imposes robust standards, protects the environment, provides certainty for industry and contains processes that safeguard patients' access to life saving medicines.
- 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 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. GSK's public policy position on Working with Third Parties, available on gsk.com, outlines our expectations of compliance with our standards on quality, patient safety, health and safety and the environment.
- We recognise the potential of 'green' or sustainable chemistry and we seek to embed new methodologies aimed at minimising 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 appropriate management of chemicals. We identify the key environmental and workplace health and safety (EHS) hazards and risks associated with all GSK proprietary chemicals and products.

For non-proprietary chemicals, we have robust processes in place to obtain and assess 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

Our global EHS Standards set out our expectations and requirements for managing EHS risks. Through their implementation, we comply with applicable laws and regulations.

The EU's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is generally regarded as the benchmark worldwide for regulating chemicals. The entire system, or elements of it, have been replicated by the UK and US and by other countries. This alignment – and resulting consistency of standards and approach – is welcome.

REACH 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).

GSK is subject to REACH because we manufacture and use chemicals to produce our medicine and vaccine products in the EU. We also have REACH obligations due to chemicals in the packaging materials we use.

Medicinal products and APIs are exempt from REACH. This reflects the fact that they are already subject to extensive regulatory requirements. However, other substances designated as SVHCs by the

European Chemicals Agency (ECHA), such as processing solvents and intermediates used in API manufacturing, are not exempt.

Authorities can manage use of these 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, however, strict regulatory and quality requirements, designed to ensure that any changes in manufacturing do not adversely affect the safety or efficacy of a medicine, mean that substitution is not always technically feasible within the established timelines for an Authorisation, if at all.

Embracing green chemistry

We seek to minimise the potential environmental impact of our science throughout our pipeline. In this context, 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 substance. We have invested in academic collaborations exploring different aspects of green chemistry around the world.