Our position on
Nanotechnology

What is the issue?

The term nanotechnology involves the engineering (i.e. deliberate manipulation, manufacture or selection) of materials at the atomic or molecular level. There is still no generally agreed definition of a "nanoparticle", its size or characteristics. Many organisations define one as a material with at least one primary dimension which is less than 100 nanometers (nm), while in the field of "nanomedicine" a mean particle size of up to 1000nm has been proposed.[i]

Having no internationally recognised definition or analytical method for measuring a nanomaterial makes it challenging to agree on their prevalence and value. The term "nano" can be applied inconsistently by different stakeholders. For the purposes of this paper, our position relates to deliberately engineered material with a mean particle diameter of 100nm or less in at least one dimension.

Nanomaterials may be incorporated into a broad range of products ranging from electronics and structural materials to pharmaceuticals. Applications include medical diagnostics, devices, medical imaging platforms and sun protection products. Benefits related to their use in the pharmaceutical field include enhanced drug delivery and improved bioavailability and absorption of drugs, which can help make medicines more effective.

While nanotechnology offers many potential benefits, concerns have been raised about possible hazards to human health, safety and the environment, arising from the novel properties of some materials engineered at the nano-scale. As a result, there are ongoing discussions about the need for tighter regulations to control the development and use of nanomaterials.

This paper sets out GSK's current use of nanotechnology, our approach to assessing and managing potential risks and our views on the adequacy of the existing regulatory environment.

What is GSK's view?

- GSK recognises the potential healthcare benefits of nanotechnology. But we also recognise that there are societal concerns about the potential human and environmental impact of engineered nanomaterials. We are fully committed to engaging in the public debate around addressing these issues and supporting ongoing research relevant to our field.
- Based on current scientific evidence, we share the consensus view held by the majority of regulatory authorities across the world that assessment of the use of nanomaterials should be undertaken within the existing regulatory framework for pharmaceuticals and vaccines.
- We believe the regulatory framework is robust and adequately provides for future risk assessment of products using nanomaterials. However, should evolving scientific evidence conclude that a more targeted regulatory approach is needed, we would support, and welcome the opportunity of contributing to, any review of regulations governing the development and marketing of nanoproducts.
- In common with many other vaccine manufacturers, GSK is using nanotechnology in our development programmes to explore ways of enhancing the effectiveness of new antigens or to potentially expand the uses of existing commercial vaccines. Specifically, we use nanoparticles

and liposomes to improve the solubility, bioavailability, safety and effectiveness of our vaccines or to enhance their stability.

- GSK's Environment, Health and Safety (EHS) policies and procedures provide a high level of protection for those working in the development, manufacture, transportation and disposal of all our proprietary materials in accordance with applicable laws and regulations. These are modified as necessary to address any unusual risks for the environment, health or safety identified as related to nanomaterials.
- Recognising concerns about the potential health risks presented by nano-engineered materials, if hazard data are insufficient to quantify the level of risk, GSK adopts a precautionary approach during the development of new products that include or involve the use of nanomaterials. This means that until risks are quantified, strict exposure controls are used for novel engineered nanomaterials so that substances are rigorously contained by physical means while in GSK control.
- GSK is committed to reducing the environmental impact of our operations and our products. This commitment extends beyond our direct operations to include our entire value chain, which is why we work closely with Third Parties on identifying ways we can reduce our collective environmental impact and why we audit contract manufacturers against stringent standards for quality and EHS. Our policy on Working with Third Parties can be found on GSK.com.
- As our own internal experience with the control of the EHS hazards and risks of nanomaterials develops, we will share this at relevant public meetings so that others benefit from this knowledge. As new information comes to light, we will also communicate guidance to customers, contract manufacturing partners and onward users on the safe processing, usage, transportation and disposal of any nanomaterial intermediates or products derived from nanomaterials.

Background

Nanotechnology is rapidly developing and expected to transform many areas of healthcare. The potential benefits of nanomaterials are associated with their increased solubility, enhanced bioavailability, improved targeting ability, better side effect profiles and more convenient dosage forms.

Investment in the area is significant as governments and industry see opportunities to advance old technologies and to create new ones from the use of engineered nanomaterials. Investment is also being directed towards the potential environment, health and safety risks associated with nanomaterials. Issues under review include assessing the impact of nanoparticles gaining access to tissues and cells that would normally be bypassed by larger particles; the length of time they may then remain in the body; how they are cleared from tissues and blood; impact on cellular functions; and environmental impact of nanoparticles on other species.

Regulatory environment

While it will differ from material to material, the physical properties and behaviour of nanomaterials may be different to those of the same material of larger particle sizes, or simply be more efficient at providing the same benefit. For the purposes of effective oversight and regulation of biomedical products, the critical issue is whether a nano-engineered particle alters the benefit/risk profile of a specific product and its intended use. For example, regulators will need to know if the nano-engineered material changes the

absorption, distribution, metabolism and excretion or toxicology profile of the compound; and if so, does this adversely impact the safety profile or benefit/risk profile.

The consensus view is that the necessary safety profile of biomedical product containing nanomaterials can be evaluated within the existing regulatory frameworks, and on a product-by-product basis. Regulators have acknowledged, though, that further research and pooling of knowledge and expertise will continue to be needed at a global level and across disciplines. This is due to our evolving understanding of this specific science, as well as the associated challenges that the application of nanotechnologies may present.

EU

This view was reconfirmed by the European Commission in its October 2012 Communication on Nanotechnology, which concluded that nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. The Commission has now implemented regulation requiring registration of defined nanoform materials.[ii]

For example, also in 2017, the Medical Device Regulation was adopted and includes new rules to ensure a high level of health protection for devices presenting a high or medium potential for nanomaterials to be in contact with the membranes inside the body. For other biomedical products, the EU is currently comfortable for any claims made relating to the safety and efficacy of nanomaterials to be assessed as part of the existing regulatory framework.

US

In the US, while the FDA acknowledges that nanomedicine holds great promise, it supports continued research - as sponsors move from pre-clinical through clinical phases of product development - to assess any potential safety and efficacy concerns of such products.US agencies including OSHA and NIOSH have issued Nanomaterial guidance for workplaces.

Engaging in public debate

As current research projects mature it is anticipated that there will be continued growth in the applications, production and use of nanomaterials.

Against this background, several groups have called for caution and greater understanding of potential risks. Companies developing nanotechnology-based products support additional research to characterise the hazards, and any potential risks in use, of novel materials. If the science is to flourish so that the benefit of these materials can be assessed and then realised, then companies need to continue to be open and transparent about uncertainties and committed to working to address them.

Industry, including GSK, actively participates in various consortia around the world with a view to producing Codes of Practice for developing nanomaterials. These codes are also supported, or sponsored, by governments recognising the potential risks to health and the environment.

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[i] Nanomaterials - ECHA (europa.eu)
[ii] Nanomaterials in REACH and CLP - Environment - European Commission (europa.eu)