GSK Public policy positions

Nanotechnology

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 characterisation. Many organisations define one as a material with a mean particle diameter of less than 100 nanometers (nm), while in the field of “nanomedicine” a mean particle size of up to 1000nm has been proposed.

The lack of an internationally recognised definition or characterisation of nanomaterials frustrates much of the debate around their prevalence and value. It means that the term “nano” can be applied broadly by different stakeholders. For the purposes of this paper, GSK’s position relates to material with a particle diameter of 100nm or less.

Nanomaterials may be incorporated into a broad range of products ranging from electronics, structural materials and biomedical products. Medical applications include incorporation into medical diagnostics, device and medical imaging platforms and quantitative analysis. Benefits related to their use in the biomedical field include enhanced drug delivery, improved bioavailability and absorption of drugs, as well as reduced toxicity.

While nanotechnology offers many potential benefits, there are emerging concerns 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 regarding the need for new 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. As knowledge and experience of the science increases, we would anticipate amending this statement to reflect new developments.

GSK’s Position

– GSK recognises the biomedical potential of nanotechnology; however, we also accept that there are numerous 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 where we can.

– Based on current scientific evidence, GSK shares the consensus view held by major regulatory authorities across the world that assessment of the use of nanomaterials should be undertaken within the existing regulatory framework for pharmaceuticals and consumer healthcare products. We believe the framework is robust and should sufficiently provide for future risk assessment of products using nanomaterials. However, should evolving scientific evidence conclude a more targeted regulatory approach is needed, we would support revision of regulations governing the development and marketing of nanoproducts.

– GSK’s Consumer Healthcare business currently markets a few sunscreen products containing nanosized titanium dioxide. This ingredient is used for its capacity to reflect and scatter UV light thus offering protection against the adverse effects of UV radiation.

– In common with many other vaccine manufacturers, GSK is using nanotechnology to enhance the effectiveness of new compounds or to expand the uses of products already on the market. Specifically we use nanoliposomes and nanoemulsions to improve the solubility, bioavailability, safety and effectiveness of our vaccines or to enhance their stability.

– There are currently no GSK pharmaceutical products on the market that contain deliberately engineered nanomaterials. However, we are actively investigating a number of opportunities that use nanomaterials in our R&D programmes.

– GSK is committed to ensuring that we control the risks to employees developing and manufacturing products that involve nanomaterials. 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. These will be modified as necessary to address any unusual risks for the environment, health or safety identified as related to nanomaterials.

– Recognising that nanotechnology is a relatively new area of scientific research and fully acknowledging 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 the control of environmental, health and safety risks throughout our entire manufacturing supply chain. We therefore expect our suppliers to meet equivalent standards for quality and EHS to those expected from our own factories and we audit contract manufacturers against them.

– GSK is committed to openness and transparency about how we manage risks associated with our use of nanomaterials. We regularly engage with stakeholders on the issue and we are, along with other groups, a member of the International Standards Organisation's Nanotechnologies Committee, Cosmetics Europe Expert team on Nanotechnology and the US Consumer Healthcare Products Association Nanotechnology Committee. We fully endorse the Responsible Nano Code and financially support the engagement activities of "nano & me"[1]

– As our own internal experience with the control 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, GSK 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

Growing Investment in Nanotechnology

Nanotechnology is rapidly developing and expected to transform many areas of healthcare. The potential benefits of nanoparticles are associated with their increased solubility, enhanced bioavailablity, improved targeting ability, better side effect profiles and more convenient dosage forms. The global nanomedicine market reached $63.8 billion in 2010 and $72.8 billion in 2011. It is expected to grow to $130.9 billion by 2016.

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. In the US, the cumulative investment since 2001 in the National Nanotechnology Initiative (NNI) now totals almost $18 billion. Government funding in the EU is not on the same scale; however, there is a concerted public policy effort centred around a European Technology Platform dedicated to nanomedicine and to ensuring European countries remain competitive in the area.

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 tissues and blood; how they are cleared from tissues and blood; their impact on cellular functions (transient and/or permanent?): and the environmental impact of nanoparticles on other species.

[1] http://www.nanoandme.org/social-and-ethical/corporate-responsibility/responsible-nano-code/

The Regulatory Environment

While it will differ from material to material, the physical properties and behaviour of nanomaterials will often be different to those of the same material of larger particle sizes. For the purposes of effective oversight and regulation, the critical issue, however, 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.

Currently no regulatory authority categorically judges products containing nanomaterials (or otherwise involving the application of nanotechnology) to be either inherently benign or inherently harmful. The consensus view is that the necessary benefit/risk profiles associated with nanomaterials can be evaluated within the existing regulatory framework, and on a product-by-product basis. Regulators have acknowledged, however, that further research and pooling of knowledge and expertise may be needed at a global level and across disciplines given the scientific challenges that the application of nanotechnologies may present.

The 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. Its decision to create a web platform with references to all relevant information on nanomaterials and to launch an impact assessment to ensure appropriate regulatory oversight may yet precipitate a change in approach. For now, however, the EU is comfortable for any claims made relating to the safety and efficacy of nanomaterials to be assessed as part of the existing regulatory framework for biomedical and consumer healthcare products. Acknowledging limited regulatory experience to date in the nanotechnology area, the EMA also encourages dialogue with sponsors at an early stage of development.

The US

In the US, while the FDA acknowledges that nanomedicine holds great promise, it concedes that more research is needed - as sponsors move from pre-clinical through clinical phases of product development - to assess the potential safety and efficacy concerns of such products. In addition to its internal research, FDA is working with other stakeholders to develop evaluative and predictive tools that will facilitate the development of safe products and mitigate potential risks. The FDA is also working closely with standard-setting organisations, Federal and State bodies, academia, industry and other stakeholders to help advance the field of nanotechnology and nanomedicine.

International

At the international level, after a six year study, the Organisation for Economic Co-operation and Development (OECD) concluded in 2012 that:

> *"approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. As with other chemicals, it is clear that each nanomaterial may pose specific challenges, but in most instances, they can be addressed with existing test methods and assessment approaches".*

Commitment to Transparency

Hundreds of competitor consumer products, including skin care, sunscreen and toothpaste products, are already on the market, which claim enhanced performance from the use of nanomaterials. As current research projects mature it is anticipated that there will be a massive growth in the production and use of these materials.

It is against this background that several groups have called for caution until the risks are better understood. Companies developing nanotechnology-based products recognise that new research is required to characterise the hazards 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, therefore actively participates in various consortia in several parts of the world with a view to producing Codes of Practice for developing nanomaterials. These codes are also supported, or sponsored by governments, recognising potential risks to health and the environment and some have developed initiatives such as the UK voluntary scheme for reporting risk assessments of nanomaterials.

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