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European Commission Launches Public Consultation on Health Risk Assessment for Nanomaterials in Medical Devices

On 18 July 2014, the European Commission and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) launched a public consultation on a preliminary opinion entitled 'Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices'. Comments may be submitted through the consultation website until 3 October 2014. If this guidance is adopted substantially 'as is', it would mean additional testing requirements for some, but not all, medical devices containing nanomaterials, as well as possible restrictions and bans if devices are found to pose unacceptable risks.

New Stakeholder Dialogue Procedure

This consultation is conducted pursuant to the new Stakeholder Dialogue Procedures as laid down in Annex IV to the Rules of Procedures of three key scientific committees, including SCENIHR. Under these rules, consultation is not mandatory but is encouraged on "issues that are of potentially high importance for human health and/or environmental protection".

The objective is for public comments to contribute to the quality of the scientific opinions of the committees without interfering with the committees' work. In this case, scientific input is solicited during the preparation of a committee opinion. The rules contemplate that public hearings may be organized in addition to public consultations.

The Draft Opinion

On 17 July 2014, the SCENIHR adopted, by written procedure, a preliminary opinion on the determination of health effects of nanomaterials used in medical devices. In light of the increased use of nanomaterials in medical devices and the proposed new EU medical device legislation, the SCENIHR has been requested to provide guidance to risk assessors on specific aspects to be considered in safety evaluation.

The preliminary opinion recognizes that "nanomedicine" is a promising technology, but poses a challenge for risk assessment and safety evaluation. As uses of nanomaterials in medical devices can vary considerably, the draft guidance recommends a phased approach based on the potential release and characteristics of nanomaterials. Thus, the draft guidance reflects a case-by-case approach for risk evaluation of medical devices containing nanomaterials.

Release and exposure

According to the SCENIHR, the potential risks arising from nanomaterials in medical devices depend chiefly on two factors: (i) potential release of free nanoparticles from the device and (ii) the duration of exposure. Potential release depends on how nanomaterials are used; such use could be as free nanomaterial, nanomaterials fixed on surfaces, or nanomaterials embedded in a matrix. In addition to particle releases and their potential effects, possible local effects at the site of application should also be considered. Even where a device does not contain nanomaterials, the draft opinion states, wear and tear of a medical device may result in the generation of nano-size particles.

Phased testing

To avoid unnecessary testing, a phased approach is recommended. Phase 1 involves an evaluation of the device's potential to release nanoparticles either directly or due to wear and tear during use. In phase 2 the distribution of the nanoparticles released and their persistence potential is determined. Here, a distinction is made between non-invasive (e.g. devices coming into contact with the intact skin) and invasive medical devices (wound care materials, implantable devices, dental and bone fillings and cements, injectable materials). While for non-invasive devices the analysis focuses on the potential of nanoparticles to enter the systemic circulation, toxicokinetic studies of the potential of the nanoparticles to access and remain in specific tissues are necessary for invasive devices; depending on results, further toxicological testing may be required. Phase 3 involves hazard assessment through toxicity tests selected based on observed exposure and potential persistence patterns. Phase 4 is the final risk characterization, in which the estimated risk is compared to the risks of comparable devices. In the final risk assessment, the potential benefit for the patient should be considered as well.

Implications of guidance

The SCENIHR guidance could have significant implications. Manufacturers and importers of medical devices containing nanomaterials would be required to assess the specific risks associated with nanoparticles. Specifically, if the guidance is adopted substantially as set forth in the preliminary opinion, it would imply additional testing requirements for some, but not all, medical devices containing nanomaterials. In addition, based on the outcome of the risk assessment, restrictions and bans may be imposed with respect to devices that are found to pose unacceptable risks.

Submitting Comments

All interested parties are invited to submit written comments on the preliminary opinion by 3 October 2014. Any comments should be submitted in the electronic format provided on the consultation website at http://ec.europa.eu/eusurvey/runner/nano_medical_devices. Comments should relate to the scientific basis of the preliminary opinion and any other relevant scientific information regarding the questions addressed in the opinion. The consultation does not deal with risk management measures and related policy issues, which will be addressed in further procedures.

How Hunton & Williams Can Help

Hunton & Williams LLP has extensive experience in assisting clients with all areas of law that affect the medical device industry. We advise clients on a wide range of regulatory matters, including compliance management, liability assessment, inspections and enforcement, and legal remedies. Working closely with our clients and with regulatory and technical experts, we ensure that our clients' interests are effectively protected.

Hunton & Williams is a global law firm with a strong focus on regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels and Washington, DC.

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