

free of charge medical device nomenclature available for interaction with Eudamed, and stricter requirements for clinical investigations.

MedTech Europe, the alliance of Eucomed and the European Diagnostic Manufacturers Association, has ‘welcomed the fact that the Council has opted to move forward with its proposal’ but ‘recognises a number of areas that still raise concern and thus warrant further work’. With respect to the proposal for medical devices, MedTech Europe believes that, as a minimum, the following two issues require attention if Europe is serious about providing equal levels of patient safety and treatment across its Member States:

- the scrutiny mechanism, which is still too complex and too slow;
- the reprocessing of single-use devices, which has different levels of safety depending on who the reprocessor is (original manufacturer, commercial reprocessor, hospital).

Other important areas that require additional attention include provisions on clinical evidence, hazardous substances and unnecessary bureaucratic burden.

With regard to the proposal for IVDs, the five-year transition period is in line with the initial proposal from the Commission and with other countries that have made similar changes to their IVD legislation. There are, however, still problems with the requirements concerning:

- clinical evidence: the Council’s proposal greatly increases the burden of the new clinical evidence requirement for IVDs with unclear benefits for patients, while at the same time breaking the alignment with the international consensus which would have mitigated the impact of the clinical evidence requirements; *and*
- companion diagnostics: the proposed definition is too broad to be functional as too many assays (e.g. simple cholesterol tests) fall under the new definition.

Technical experts from the Council are scheduled to meet on 8–9 September 2015 to study the differences between the Council’s text and the text from the European Parliament. This will pave the way for the dialogue discussions that will begin, at the earliest, at the beginning of October 2015.

References

1. <http://data.consilium.europa.eu/doc/document/ST-9769-2015-INIT/en/pdf>.
2. <http://data.consilium.europa.eu/doc/document/ST-9769-2015-ADD-1/en/pdf>.
3. <http://data.consilium.europa.eu/doc/document/ST-9770-2015-INIT/en/pdf>.
4. <http://data.consilium.europa.eu/doc/document/ST-9770-2015-ADD-1/en/pdf>.
5. <http://www.consilium.europa.eu/en/press/press-releases/2015/06/19-medical-devices-council-ready-talk-with-ep/>.



Safety of dental amalgam and its alternatives: SCENIHR publishes final Opinion

A final Opinion on the safety of dental amalgam and alternative dental restoration materials has been published by the European Commission and its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)¹. This Opinion, which updates SCENIHR’s previous Opinion from 2008, assesses the safety and effectiveness of both dental amalgam and its possible alternatives by evaluating the scientific

evidence on the potential association between amalgam and its alternatives, and allergies, neurological disorders, or other adverse health effects.

A public consultation on the preliminary opinion was held in 2014. In total, there were 25 contributors (representing industry associations, universities, professional organisations, national authorities, non-governmental organisations and individuals) who participated in the public consultation, submitting a total of 102 comments.

The SCENIHR has concluded that current evidence does not preclude the use of either amalgam or alternative materials in dental restorative treatment. However, the choice of material should be based on patient characteristics such as primary or permanent teeth, pregnancy, the presence of allergies to mercury or other components of restorative materials, and the presence of impaired renal clearance. The clinical trend towards the use of adhesive alternatives is considered advantageous as it implies that a sustained reduction in the use of dental amalgam in clinical practice will continue across the European Union.

The SCENIHR has recognised that there is a need for further research, particularly to evaluate the potential neurotoxicity of mercury from dental amalgam and the effect of genetic polymorphisms on mercury toxicity, and to expand knowledge of the toxicity profile of alternative dental restorative materials. Furthermore, there is a need for the development of new alternative materials with a high degree of biocompatibility.

To reduce the use of mercury-containing products in line with the intentions of the Minamata Convention, the Opinion recommends that for primary teeth, and in pregnant patients, alternative materials to amalgam should be the first choice.

In light of the above, the SCENIHR has concluded that existing dental amalgam is not a health risk for the general population. Consequently, pre-existing amalgam restorations should not be removed as a preventive measure. As far as dental personnel are concerned, it is recognised that they may be at greater risk with respect to higher mercury exposure from dental amalgam than the general population, although the incidence of reported adverse effects seems to be in the same order of magnitude.

Information on exposure, toxicity and clinical outcomes for alternative materials is much scarcer than for dental amalgam. There is some evidence that some of the low molecular weight substances used in their preparation are associated with local allergic reactions. There are insufficient data to draw firm conclusions about associations between these alternative materials and neurological or other health disorders. The continuing evolution of these materials suggests that caution should be exercised before new variations are introduced into the market. As far as dental personnel are concerned, there are reports of small numbers of cases of induced allergies to these materials. Their volatile organic solvent species that are pervasive in dental clinics should be identified and quantified to enable proper risk assessment.

The SCENIHR has concluded that dental restorative treatment can be adequately ensured by amalgam and alternative types of restorative material. The longevity of restorations of alternative materials in posterior teeth has improved with the continuing development of these materials and the practitioner's familiarity with effective placement techniques but is, in certain clinical situations (e.g. large cavities and high caries rates), still inferior to amalgam.

Reference

1. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf.



Final Opinion from the SCENIHR on the safety of medical devices containing phthalates (DEHP)

In July 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published its final Opinion¹ on the safety of medical devices containing di(2-ethylhexyl)phthalate (DEHP) plasticised polyvinyl chloride (PVC) or other plasticisers on neonates and other groups possibly at risk. Following an assessment of all available scientific evidence, the SCENIHR has concluded that:

- With respect to adult patients, those undergoing haemodialysis have the highest exposure due to the chronic nature of the treatment.
- Children are potentially at a higher risk than adults, particularly neonates and infants, because of their low body weight.
- There is evidence suggesting that DEHP causes the most severe reproductive toxicity in animal studies when compared to other alternative plasticisers. There is, therefore, a strong need to develop and collect data on exposure of alternative materials in the actual conditions of use in order to refine the knowledge of their toxicological profile. The possibility of replacing DEHP with these products could then be considered, taking account of the efficacy of the treatment as well as the toxicological profile and leaching properties of the alternative materials.

This final Opinion updates the SCENIHR Opinion from 2008. It focuses on the potential risks for patients exposed to DEHP or similar plasticising compounds leaching from medical devices. Exposure of the general population to plasticisers has also been considered. The assessment includes information on currently-available plasticisers, as well as some proposed alternatives to DEHP in medical devices for neonates and for other patient groups.

Reference

1. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_047.pdf.



SCENIHR issues preliminary Opinion on safety of surgical meshes used in urogynaecological surgery

A public consultation on the preliminary Opinion on the safety of surgical meshes used in urogynaecological surgery has been held by the European Commission and its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)¹. This Opinion focuses on the health risks of meshes used in urogynaecological surgery, how to identify high risk patient groups, and what the assessment needs are. In its Opinion, SCENIHR was asked to address, in particular, the following:

- Are specific meshes, in terms of designs and/or materials, considered to be of a higher risk? If possible, list and describe the risks.
- Are certain surgical techniques of higher risk? If possible list, and describe the risks.
- Are any combinations of the above (designs/materials and surgical techniques) of a higher risk?
- Are there specific limitations (e.g. clinical, designs/materials, surgical techniques) with the use of

meshes in urogynaecological surgery?

- What are the risks of surgical interventions using mesh compared to classic surgical interventions?
- What factors could affect the outcome of the surgical interventions?
- Are there patients groups (e.g. in relation to age, weight or other co-morbidities) for which the use of meshes would carry a specific risk?
- In light of the above, identify risks associated with use(s) of meshes other than for urogynaecological surgery and advise if further assessment in this field(s) is needed.

Based on the available scientific evidence, SCENIHR has recommended that:

- Aspects such as material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience should be taken into consideration when choosing an appropriate therapy.
- In assessing the risk associated with mesh application, consideration should be given to the overall surface area of material used, the product design and the properties of the material used. The available evidence suggests a higher morbidity in treating pelvic organ prolapse (POP), which uses a much larger amount of mesh compared to stress urinary incontinence (SUI).
- When assessing synthetic mesh risks there is a need to separate clearly the smaller risks associated with SUI sling surgery from those of POP mesh surgery.
- The implantation of any mesh for the treatment of POP via the vaginal route should only be considered in complex cases, in particular after failed primary repair surgery.
- Synthetic sling SUI surgery should only be carried out by appropriately trained surgeons after thoroughly counselling patients on the associated risk/benefits.
- Use of synthetic mesh for POP repair via a trans-vaginal route should only be used when other surgical procedures have already failed or are expected to fail.
- The amount of mesh should be limited for all procedures, where possible.
- A certification system for surgeons should be introduced based on existing international guidelines and established in co-operation with the relevant European Surgical Associations.

SCENIHR has also recommended the following actions:

- Ensure the patients are correctly and comprehensively informed on the benefits and risks associated with the use of synthetic non-absorbable meshes.
- Establish European implant registries.
- Establish scientific studies to assess the long-term (at least five years) safety and performance of synthetic non-absorbable meshes.
- Encourage further research into novel design and materials, in particular absorbable meshes, and improved technologies for manufacturing meshes, such as electrospinning.
- Encourage further research into the application of regenerative medicine technology, such as the cellular seeding of graft materials.

- Establish evidence-based European Guidelines.
- Develop training programmes for surgeons in association with European medical associations.

Consultation on the preliminary Opinion closed on 19 July 2015.

Reference

1. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf.



Harmonised European standards

Updated lists of standards harmonised under the Active Implantable Medical Device Directive (90/385/EEC), the Medical Device Directive (93/42/EEC) and the *In Vitro* Diagnostic Directive (98/79/EC) have been published in the Official Journal in the form of three Commission Communications¹⁻³.

References

1. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.226.01.0001.01.ENG.
2. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.226.01.0009.01.ENG.
3. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.226.01.0043.01.ENG.



European Committee for Standardization, CEN, elects new President

Vincent Laflèche from France has been elected as the new President of the European Committee for Standardization (CEN)¹. He will serve for 12 months as President-Elect of CEN, starting in January 2016, before taking over from Friedrich Smaxwil as President on 1 January 2017. Mr Laflèche, who will serve as CEN President for a term of three years from 2017 to 2019, will be responsible for:

- chairing the CEN Administrative Board and the CEN General Assembly;
- participating in the Presidential Committee of CEN and CENELEC (the European Committee for Electrotechnical Standardization), as well as the Joint Presidents' Group of CEN, CENELEC and ETSI (European Telecommunications Standards Institute);
- representing CEN in dealings with the European institutions, international standardisation organisations (notably the International Organization for Standardization, ISO) and other key partners.

Reference

1. <http://www.cen.eu/news/brief-news/Pages/NEWS-2015-011.aspx>.



Germany adopts benefit assessment regulation for medical devices

On 1 August 2015, the *Act to Strengthen Care Provision in the Statutory Health Insurance system* (GKV-VSG)¹ came into effect in Germany. This Act has introduced numerous new provisions for both the outpatient and the inpatient sector. For the medical technology industry, the most important aspect of this Act is the regulation on benefit assessment procedures for new methods and medical technologies. The final regulation in the Act provides the following improvements compared with the draft version: