SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

Request for a scientific opinion on

The safety of dental amalgam and alternative dental restoration materials for patients and users

1. Background

Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used, in particular in large cavities due to its excellent mechanical properties and durability. Dental amalgam is a combination of alloy particles and mercury that contains about 50% of mercury in the elemental form.

Overall, the use of alternative materials such as composite resins, glass ionomer cements, ceramics, and gold alloys, is increasing, either due to their aesthetic properties or alleged health concerns related to the use of dental amalgam.

Whereas the toxicity of mercury has been extensively researched, relatively little is known about the safety of alternative materials, possibly because some alternatives are relatively new materials.

In January 2005, the Commission adopted a proposal for a Community Strategy concerning Mercury[1] in order to reduce mercury levels in the environment and human exposure. Pursuant to Action 6 of the Strategy, the use of dental amalgam should be evaluated with a view to considering whether additional regulatory measures are appropriate.

Dental amalgam and its substitutes are regulated under Council Directive 93/42/EEC[2] concerning medical devices, according to which they must comply with the essential requirements laid out in the directive, in particular in relation to the health and safety of the patients.

An Expert Report mandated by the European Commission's DG III and published in 1998[3] concluded that no proven adverse effects could be associated with the presence, placement or removal of dental amalgam fillings in patients and users, based on available science and when used according to manufacturer's instructions.

Subsequently, several Member States have adopted recommendations according to which dental amalgam should not be used in certain patient groups such as pregnant women or young children.

In view of the above and in order to reconcile patients' oral health and the global aim of the Community Strategy concerning mercury, it is necessary to review the safety and performance of dental amalgam and of their substitutes for the treatment of dental cavities.

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[1] COM (2005) 20 final
[2] OJ L 00042, 20.11.2003, p.2
[3] Dental Amalgam. A report with reference to the Medical Devices Directive 93/42/EEC from an AD Hoc Working Group mandated by DG III of the European Commission. 1998.

2. Terms of reference

2.1 Human safety

2.1.1 Dental amalgam

In view of mercury exposure level due to the presence, the placing or the removal of dental amalgam, the Scientific Committee is requested to consider the following questions:

1. is there scientific evidence that supports a link between amalgam and allergic reactions, neurological disorders or other health disorders?

2. in view of the above, is the use of dental amalgam safe for patients and users, i.e. dental health professionals? Are certain populations particularly at risk, e.g. pregnant women or children?

2.1.2 Alternative materials

Overall, alternative materials such as composite resins, glass ionomer cements, ceramics and gold alloys, are increasingly used for the restorative treatment of dental cavities. The Scientific Committee is requested to evaluate the safety of these materials when used for dental restorative treatment and to consider the following questions:

1. is there scientific evidence that supports a link between alternative materials and allergic reactions, neurological disorders or other health disorders?

2. in view of the above, is the use of alternative dental restoration treatment safe for patients and dental health professionals? Are certain populations particularly at risk, e.g. pregnant women or children?

2.2 Oral health and safety.

In view of the specific properties of dental amalgam and alternatives when used for dental restorative treatment, is dental health equally ensured by dental amalgam and alternatives?

3. Deadline

A scientific opinion on the above-mentioned issues by the end of December 2007 would be appreciated.