



European Commission
DG Health and Consumer Protection
Scientific Committee on Emerging and Newly Identified Health Risks

Consultation Response to SCENIHR preliminary report on "The safety of dental amalgam and alternative dental restoration materials for patients and users"

The International Federation of Anthroposophic Medical Associations (IVAA) has carefully assessed the preliminary report "The safety of dental amalgam and alternative dental restoration materials for patients and users" (SCENIHR report) prepared by the Scientific Committee on Emerging and Newly Identified Health Risks on behalf of the European Commission. The IVAA cannot agree with or endorse the content, opinions and conclusions expressed in this report, for the following reasons:

The SCENIHR report does not present the existing scientific data on the safety of amalgam and alternative dental restoration materials in a systematic and transparent form. Instead, the SCENIHR report presents a highly selective compilation of singular studies and is based on personal opinions. The report does not enable readers to trace and evaluate this subjective and selective process. This deficiency could be demonstrated regarding a number of issues raised in the SCENIHR report; for the sake of brevity we will discuss only one:

The SCENIHR report, Section 3.3.6 deals with 'Adverse effects in individuals with amalgam restorations'. One relevant source of scientific information on this topic is studies of amalgam removal in subjects with suspected adverse reactions from amalgam restorations. Hence, in the subsection 'Localized mucosal reactions' (3.3.6.1, approximately 1½ pages long), the report cites five studies [1-5] reporting clinical outcomes after amalgam removal (but regrettably omits a corresponding systematic review by the first author of one of these studies [6]). In the following subsection 'Systemic reactions' (3.3.6.2, approximately 5½ pages), the report cites only one study of amalgam removal in subjects with suspected systematic adverse reactions from amalgam restorations [7]. However, the IVAA is at present aware of at least 35 studies published on this subject! Even after exclusion of grey publications and retrospective reports, 12 prospective studies published in dental journals or non-dental

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Medline-indexed journals remain [7-18]. Thus, the SCENIHR report does not enable readers to verify whether the highly selective information conveyed on clinical outcomes after amalgam removal is representative for the available scientific data on this subject.

As this example demonstrates, the SCENIHR report does not contain a systematic information synthesis but is instead a narrative and highly selective product.

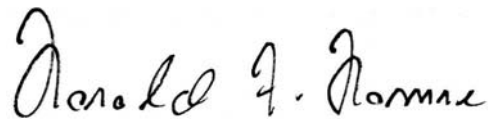
Similar deficiencies can be found in other parts of the SCENIHR report such as the abstract and the sections on exposure to mercury and psychological conditions.

Notably, studies, reviews and opinions supporting a more restrictive position on the use of dental amalgam are underrepresented or absent in the SCENIHR report. In order to assess the safety of amalgam and alternative dental restoration materials in a systematic, transparent and balanced fashion, the report would need to be completely rewritten. Summarizing, the SCENIHR report "The safety of dental amalgam and alternative dental restoration materials for patients and users" does not offer a sufficient basis for regulatory or political decisions on dental restorative materials.

Hollola, Finland, 17 February 2008



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