

NOVEMBER 2013

// CED RESOLUTION

DENTAL AMALGAM: 2013 UPDATE

// INTRODUCTION

The Council of European Dentists (CED) is the representative organisation for the dental profession in the EU, representing over 340,000 practising dentists through 32 national dental associations. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED promotes high standards of oral healthcare and effective patient-safety centred and evidenced-based professional practice across Europe.

// HEALTH CONSIDERATIONS

The safety and importance of the continued use of amalgam is supported by the World Dental Federation (FDI) (Resolution on the use of dental amalgam adopted in 2010) and by the 2010 World Health Organisation (WHO) report on Future Use of Materials for Dental Restoration. The effectiveness and safety of dental amalgam in the restoration of decayed teeth has been demonstrated through long usage.

Research over many decades has failed to show any significant health risk posed by dental amalgam either to patients, dental staff or the public.

The CED welcomed the adoption, in May 2008 after public consultation, of the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risk) scientific opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users. The opinion confirmed the stance of the CED in regard to dental amalgam and its alternatives concluding that, "dental health can be adequately ensured by both types of material. All the materials are considered safe to use and they are all associated with very low rates of local adverse effects with no evidence of systemic disease."

In August 2012, the European Commission (EC) requested SCENIHR to update its opinion on dental amalgam on the basis of new information made available. This opinion was expected by February 2013 but has been deferred until December 2013.

// ENVIRONMENTAL CONSIDERATIONS

The CED also welcomed the adoption, in May 2008, of the SCHER (Scientific Committee on Health and Environmental Risks) scientific opinion on the environmental risks and indirect health effects of mercury in dental amalgam, noting that the opinion stated that, "the information presently available does not allow to comprehensively assessing the environmental risks and indirect health effects from use of dental amalgam in the Member States of the EU 25/27."

BIO Investigative Services (BIOIS) was commissioned by the European Commission to "fill the gap" identified by SCHER, publishing their final report on 12 July 2012. The CED flagged up the significant flaws of the study, revealing a number of inaccurate data and statements. The CED noted that the continued absence of hard and accurate environmental data in Europe meant that the findings and recommendations of the BIOIS report were based on assumptions and extrapolations of those assumptions, bearing no scientific value or established evidence.

The CED acknowledges with appreciation the conclusions of the SCHER preliminary opinion on the environmental risks and indirect health effects of mercury from dental amalgam adopted on 28 June 2013. The preliminary opinion notes that: "the information available on the Hg-free alternatives does not allow a sound risk assessment to be performed. For the human health, [...] the conclusions of the 2008-opinion are still valid, except for alternative materials containing bisphenol A-glycidyl methacrylate (Bis-GMA). For these [...] refer to an on-going SCENIHR mandate on the use of bisphenol A in medical devices [...]. For the environment, considering the probably low level of emissions and the relatively low toxicity of the chemicals involved, it is reasonable to assume that the ecological risk is low. However, it is the opinion of the SCHER that, at present, there is no scientific

(E)

evidence for supporting and endorsing these statements. Therefore, more research on alternative materials is recommended."

The dental profession takes seriously the environmental impact of its activities and the CED emphasises that the dental professional has an obligation to work within the legal framework governing mercury containing products. The CED calls on Member States to ensure the full implementation and enforcement of EU waste laws, and fully supports examination into whether this is happening. In most Member States amalgam separators are used and in many they are obligatory. Amalgam separators are an effective way of reducing harmful waste and remove a further 95% from the dental units' existing filtration systems resulting in a total capture of 99%, so preventing waste amalgam entering the waste stream.

The CED also encourages national dental associations to share best practice on waste management and to support their members regarding compliance with waste management obligations.

The CED also encourages due regard and reduction of the health and environmental impacts of its use of dental amalgam through its <u>Resolution on responsible practice</u> from November 2011.

// ECONOMIC CONSIDERATIONS

For countries with high disease rate, state systems will not always be able to afford the use of alternative materials. The evolution of health systems to accommodate the changes in support of the Minamata Convention must be balanced by the need for domestic stability of healthcare provision. An abrupt change can deeply destabilise health economies and may contribute to create an unintended consequence of increased untreated disease levels or the unintended consequence of the choice by the patient of extraction rather than restoration. Financial and operational issues are key factors driving the pace of change in individual European countries. This has duly been acknowledged by the Minamata Convention in the heading of Annex A part II. There it is stated that domestic circumstances have to be taken into account when considering measures to phase down the use of dental amalgam.

// USE OF AMALGAM

The worldwide consensus of the dental profession is that amalgam should remain part of the dentist's armoury in order to best meet the needs of patients. It is important that patients must not be denied freedom of choice in respect of how to be treated.

As one of the tools of dentists' armoury, dental amalgam continues to be an appropriate filling material for many restorations, due to its ease of use, durability and cost-effectiveness. Dentists are best placed to identify patients' oral health needs, offer choices of a range of options to their patients and seek valid consent for the treatment they provide.

// IMPORTANCE OF PREVENTION

CED, as the authoritative and independent voice of dental profession in Europe, calls on governments to foster and ensure the phase up of effective dental caries prevention and health promotion programmes. This should be linked to preventive disease management, which will result in the phase down of use of current restorative materials, including dental amalgam. The pace of improvement of oral health will vary from country to country depending on factors such as the level of existing disease, particularly in disadvantaged communities, and the investment of national governments in supporting health promotion.

Amalgam is a safe and highly effective restorative material. To maintain and protect public health, the phase down of amalgam needs to be accompanied by the development of an alternative and suitable replacement restorative material.

(E)

// MINAMATA CONVENTION

The CED believes that the signing of a globally-binding treaty on the use of mercury is a sensible outcome that recognises the practicalities of improving oral health. For many years, the CED has stressed the importance of avoiding a complete phase-out of the use of mercury in dentistry, particularly in a short timeframe.

The CED welcomes the flexible approach adopted to take into account countries domestic circumstances. The treaty encourages governments to phase down dental amalgam alongside investment in prevention, appropriately funded healthcare systems, promoting research and accurate information on the efficacy of all dental materials. It reaches a good balance between the use of amalgam and non-mercury based materials.

Unanimously adopted by the CED General Meeting on 22 November 2013