An Roinn Sláinte
Department of Health

Ireland's National Plan for Phase-down to Phase-out of Amalgam towards 2030

1. Introduction

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This document sets out Ireland's approach to phasing out the use of dental amalgam. This is also an Action (Action 29: To progress preventive packages and outline measures, including the necessary research, to support the phase-down of amalgam in accordance with EU requirements) and a key priority within Ireland's National Oral Health Policy, Smile agus Sláinte. This national plan is part of a broader global, European Union and National environmental objective to phase down and phase out industrial mercury.

2. Background

Smile agus Sláinte, the National Oral Health Policy, was approved by the Government of Ireland in March 2019. This sets out the policy for oral health care for the next ten years and aims to ensure that all citizens achieve best oral health, regardless of personal circumstances. An integral part of that Policy is the phase-down of amalgam over the period of implementation of the policy. (Actions 11, 12 and 29).

The Minamata Convention on Mercury was ratified by Ireland in March 2019. It provides an international regulatory framework with the aim of protecting human health and the global environment from the harmful effects of mercury. The Minamata Convention addresses all aspects related to the use of mercury throughout its lifecycle and sets out measures such as banning mercury mining, restricting trade, manufacture of mercury-added products, and ensuring the safe storage and management of mercury waste.

EU Mercury Regulation (EU) 2017/852 was developed to ensure that all European countries are compliant with the expectations of the Convention and provides an ambitious roadmap towards the phase-out of industrial mercury. It provides for:

- An import and export ban on metallic mercury and certain mercury compounds
- A ban on the production and manufacture of specified mercury-added products
- Regulation of industries which use mercury in their processes
- Regulation of the safe storage and treatment of mercury waste

- Regulations on the use and environmentally-sound management of dental amalgam

The Regulation is enforced under SI 533 of 2018, which the Minister for Communications, Climate Action and the Environment signed in December 2018.

3. Phase down of Dental Amalgam under Regulation (EU) 2017/852

In relation to dental amalgam, the EU is currently assessing the feasibility of a total ban or phase-out of amalgam by 2030.

In the immediate term, Article 10 of the European Union Regulation sets out the rules relating to dental amalgam (Annex 1). Article 10 includes:

- From 1 July 2018, the prohibition on amalgam use for vulnerable populations (pregnant or breastfeeding women, children under 15 years old),
- From 1 January 2019, the obligation to use pre-dosed encapsulated amalgam to reduce emissions and exposure in dental facilities, and
- the requirement that dental facilities use amalgam separators to prevent amalgam waste being released into sewage systems and water bodies.
- the obligation to produce a National Plan by 1 July 2019, on the phase-down of Dental Amalgam.

The development of the National Plan is an integral part of Smile agus Sláinte, the National Oral Health Policy. The Policy supports the implementation of Regulation (EU) 2017/852 on the reduction in mercury use in dentistry, coupled with a reduction in the disposal of clinical and related waste, for environmental reasons. Actions 11, 12 and 29 of the Policy are directly relevant. They provide for progress in preventive packages for children and adults, supporting the phase-down of amalgam fillings.

4. Development of the National Plan

The following issues were considered by Ireland in the development of the National Plan:

1. Investment in public health promotion programmes across the life course
2. Public dental service provision across the life course to support the use of mercury-free materials and other approaches
3. Long-term monitoring of both environment and oral health
4. The fiscal impact of mercury-free dental materials
5. Investment in research to inform reduction in use of amalgam

Issues 1 to 4 were included as part of the development of the National Oral Health Policy; Smile agus Sláinte, which was approved by the Government in March 2019. This also included an analysis of various models of payment for dentists, considering the use of mercury-free alternatives as well as preventive approaches. In addition, separate research to inform the phase-down of amalgam was undertaken independently of Smile agus Sláinte research. This latter focused research was undertaken in two phases: firstly, projects were commissioned by the Environmental Protection Agency (EPA) to establish the baseline of amalgam use and challenges to its substitution in dentistry. It also commissioned work to examine the possible environmental impact of mercury-free alternatives. Both aspects of research were

undertaken by University College Cork. A second phase of research, which focused on measures to support phase out of amalgam and prevent and treat dental caries was commissioned by the Department of Health from the Health Research Board.

Both research phases were jointly steered by the Department of Communications, Climate Action and Environment (DCCAE) and the Department of Health.

5. Key Actions for Ireland towards 2030 - The National Plan

The National Plan is the mechanism for each country to reduce amalgam use across different age groups and circumstances, in a phased way, depending on each country's circumstances. Ireland is now able to take this step towards phase-out in view of:

- the policy outlined in Smile agus Sláinte;
- the research and evidence separately commissioned to assess the feasibility of phase-down to phase-out in Ireland; and
- the support of key stakeholders

Ireland is not alone in this approach. Scandinavia and the Netherlands already have a ban in place on amalgam use.

Ireland supports a phase down towards phase out/ban of amalgam across all age groups by 2030, as outlined in the National Oral Health Policy, Smile agus Sláinte.

Under the National Plan, Ireland commits to the following:

- The use of amalgam will be allowed only in exceptional clinical circumstances. Examples of such clinical exemptions are outlined in Annex 2.
- The ongoing need for clinical exemptions will be reviewed periodically.

The following actions will support the Plan:

- The revision of the public payment system to support mercury-free alternatives for eligible persons across all age groups. The payment system will be revised in line with the framework outlined in Smile agus Sláinte.
- A supporting infrastructure of health promotion programmes and individual prevention packages in line with Smile agus Sláinte will be put in place.
- Reduction of amalgam use in Ireland will be monitored by the changes in the proportion of mercury-free restorative use within the adult Dental Treatment Services System. This will be coordinated by the Department of Health.

6. The National Oral Health Policy of Ireland: Smile agus Sláinte

6.1 Overview

Smile agus Sláinte, the National Oral Health Policy, was published in April 2019. An integral part of that policy is the phase down of amalgam over the period of implementation of the policy which spans over eight years.

The Policy has two principal goals:

1. To provide such support as will enable every individual to achieve their personal best oral health. This will be accomplished by ensuring that an accessible and adaptable service is available throughout a person's life.

2. To reduce oral health inequalities. This will be achieved by enabling vulnerable groups to access oral healthcare and improve their oral health. Appropriate additional support for persons with moderate and profound disabilities; those who are less ambulatory and are living in residential care; those who are socially excluded due to life circumstances; and those at any stage of life who may undergo an episode of vulnerability is provided for in the Policy.

The Policy adopts a 'primary care approach', where most of the oral healthcare is provided by a local oral healthcare professional of an individual's choosing. This approach emphasises prevention, local access, person-centred and family-centred care, and facilitation of choice for the public. Empowering the public to maintain good oral health and access services is in step with the 'Healthy Ireland' framework and modern public health tenets.

The other philosophies that informed the National Oral Health Policy included the 'life-course' approach, ensuring oral healthcare services are available from birth to old age. Also, the 'common risk factor' approach was integrated into the Policy. This approach recognises that risk factors for poor oral health are like those for poor general health – mainly smoking, alcohol and diet.

People with disabilities and other vulnerable people need to have easy access to primary care oral healthcare services. In line with current healthcare philosophies, people with disabilities should be able to access primary oral healthcare services on the same basis as the rest of the population, and with additional specialist support as necessary.

6.2 Strategic Strands

The policy delivery has three strategic strands:

- Health and oral health promotion and protection programmes;
- Service provision, and;
- An evaluation of the public's oral health needs (a clinical surveillance programme)

The **first strand** - (oral) health promotion and protection, reflects the Healthy Ireland framework, which embraces population health promotion programmes and the mandatory water fluoridation policy.

The **second strand**, the delivery of services, is divided into three components

Primary oral healthcare service providers (local dental practices) will be responsible for the delivery of both prevention and 'packages of care', from birth to old age. Evaluation of oral health will also be undertaken in practice.

1. The reoriented HSE Public Dental Service (PDS), the current salaried school–service, will have a broader community oral healthcare services focus. It will focus on services to vulnerable people referred from their local dentist for episodic care. The reoriented PDS, community oral healthcare services, will also provide more long-term care for some people in residential care settings. The community oral healthcare services will have a key role in oral health promotion and in assessing oral health needs of the most vulnerable.
2. Advanced oral healthcare centres in dental hospitals, other hospitals and designated centres will provide complex care that is not available in a primary care setting.

The **third strand** - the evaluation of the public's oral health needs (the clinical surveillance programme), will target key age cohorts across the life course to monitor their oral health status, signpost them to services and assess the success of policy initiatives, including phase down in use of amalgam.
A fundamental principle in the development of the National Oral Health Policy was to ensure it was evidence-informed. For the future, a research infrastructure will be developed that will enable evidence to be readily available to the oral healthcare profession and policymakers.

6.3 Key Actions contained in the Policy

The Policy contains 41 actions which are designed to achieve its core goals. The timeframe for the implementation of the Policy is 2019 to 2026. In the first phase, 2019-2021, the areas that will be targeted include governance and management, maintaining water fluoridation, oral health promotion programmes, development of prevention and primary care packages, education and training and regulation.

However, the following actions will be afforded immediate priority:

1. The development of preventive and primary care packages for children from their local dentist (starting with a roll-out to under 6-year olds)
2. To conduct needs assessments and develop care plans for vulnerable populations (commencing with older patients and people with intellectual disabilities in residential settings)
3. The development of preventive packages for adults from their local dentist (starting with a rollout to 16-25-year olds and 65+ year olds)

For the first time, children from birth to six years of age will be able to access fully comprehensive care from their local dentist without cost. Introducing prevention and advice to this age group reduces the likelihood of decay in baby teeth often only treatable under general anaesthetic. In line with Healthy Ireland, it gives the best start for children's oral health.

Neglected vulnerable groups in residential settings will have oral healthcare needs assessments to plan and co-ordinate their care. This will determine whether they can attend their local dentist for services or require the additional support of the community oral healthcare services. This cohort has some of the poorest oral health and the highest levels of tooth loss.

Preventive packages (including cleaning and polishing of teeth, fluoride therapies, fissure sealants and preventive advice) will be introduced for adults. This is in line with modern approaches to care and will

change the emphasis from a curative service to supporting retention of teeth and self-maintenance. The development of preventive packages for adults will be facilitated across all the age groups on a phased basis.

The proposed review of undergraduate education and graduate mentoring in line with policy actions will also support the use of mercury-free materials.

7. Research

7.1 Environmental Protection Agency Research

The Environmental Protection Agency (EPA) commissioned research in 2017 which was completed in June 2019. The aim of the project was to determine the current level of usage, and waste management practices, of dental amalgam and mercury-free alternatives in Ireland among general dental practitioners and HSE salaried practitioners. The main objectives of the study were to:

- Determine the approximate number of restorations placed by dentists in Ireland
- Quantify the proportion of which were dental amalgam versus mercury-free alternatives
- Identify key waste management practices and policies for amalgam and mercury-free alternatives
- Assess current knowledge among registered dental practitioners regarding national and international legislation in disposal of both dental amalgam and mercury-free alternatives

The response rate to the study was low, 12% (n=286). The study found that participants most commonly place resin composite as a restorative material (71%), followed by dental amalgam (20%), and a small percentage of glass ionomer and resin-modified glass ionomer cements. In relation to the Minamata Convention on Mercury, 96% of respondents reported being aware of guidelines and were compliant with measures outlined by it. The proportion of dentists who reported having an amalgam separator fitted was 87% with 94% reporting having a waste management policy in relation to the disposal of waste amalgam.

Generally, it was found that dentists who participated were compliant with the Minamata Convention on Mercury. The main limitation of the study was the low response and the results should be interpreted with caution.

However, this work informed both Departments of the challenges they will face when reducing the use of amalgam. A key factor that is preventing reduction in the use of amalgam, is the current non-availability of mercury-free alternatives in the Dental Treatment Services Scheme (DTSS), the scheme that provides dental services in general practice for eligible adult patients ie those with a medical card.

The low response rate in the EPA study meant that the baseline measure of amalgam use in Ireland could not be reliably assessed from this research.

The Government-funded Dental Treatment Services Scheme (DTSS) is restricted to adults with reduced means or with specific medical or other needs. The EPA research suggested that the current government dental contracts are a substantial barrier to reducing amalgam. Education and skills were not perceived as a major barrier, especially in the age group of dentists qualified since the mid-90s who had greater access to training as undergraduates.

The EPA also commissioned further research to assess the possible environmental impact of mercury-free alternatives to amalgam. From the literature examined there was no evidence to date of adverse impacts from mercury-free alternatives to the environment. This literature review is ongoing and will also review the health impacts.

7.2 Health Research Board Research

To further inform the national plan and the feasibility of phase out of amalgam in Ireland further research was commissioned in 2018 by the Department of Health from the Health Research Board.

Four questions were considered by the Department of Health:

1. Were there clinical cases where only amalgam could be used?
2. What was the experience of other countries who phased out amalgam?
3. What are the alternatives to amalgam in children and adolescents, including prevention?
4. What are the alternatives to amalgam in adults, including prevention?

The research indicated that there were a variety of mercury-free alternatives available. Also, the review suggested that there were few clinical situations where amalgam only could be used. In general, from the experience of other countries, clinical exemptions to facilitate the use of amalgam were only necessary when phase out (ban) was initially introduced. Over time, the research indicated that after a period of adjustment clinical situations that allowed amalgam use could be reduced or removed entirely.

The HRB evidence supported the preventive strategies and the emphasis on prevention in Smile agus Sláinte. A detailed review of amalgam free alternatives was also undertaken at early and late caries (decay) stages in young and adult age cohorts. This research indicated that there were many mercury-free alternatives that could be used instead of amalgam across all age groups. Countries that had banned amalgam in the 1990s and 2000s, allowed amalgam use in some exceptional clinical situations when the ban was first introduced. These clinical exemptions are reviewed and presented in Annex 2.

8. Stakeholder views

There were two stakeholder consultation sessions held by the Department of Health in 2018 and 2019 conjointly with colleagues in the Department of Communications, Climate Action and the Environment. One was held prior to the introduction of the EU regulation and the second prior to the finalisation of the National Plan. The stakeholders represented included:

- Dental Council
- Health Service Executive
- Irish Dental Association
- Irish Dental Nurses Association
- Irish Dental Hygienists Association
- Dublin Dental Hospital
- Cork University Dental School
- Royal College of Surgeons of Ireland
- Health Products Regulatory Agency

- Environmental Protection Agency

Local authorities were also briefed on the proposal to phase out amalgam by 2030.

In addition, there were several separate engagements with the regulator, the Dental Council, regarding the National Plan.

There was expressed support from the stakeholders, with the caveat that it would be contingent on preventive programmes being in place and the public payment system being revised to support the availability of mercury-free alternatives.

The public response since the implementation of the regulation suggests that the public has accepted the use of mercury-free alternatives.

9. Phase-out of amalgam across all age cohorts in Ireland

The research undertaken indicated that the implementation of Smile agus Sláinte is essential to support the phase-out of amalgam over a period of ten years (up to 2030). After the implementation of Smile agus Sláinte, clinical situations where the use of amalgam is justified will remain in place and will be reviewed periodically. Examples of these clinical exemptions are outlined in Annex 2.

Annex 1 - Article 10 of Regulation (EU) 2017/852 - Dental Amalgam

1. From 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form. The use of mercury in bulk form by dental practitioners shall be prohibited.

2. From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

3. By 1 July 2019, each Member State shall set out a national plan concerning the measures it intends to implement to phase down the use of dental amalgam.

   Member States shall make their national plans publicly available on the internet and shall transmit them to the Commission within one month of their adoption.

4. From 1 January 2019, operators of dental facilities in which dental amalgam is used or dental amalgam fillings or teeth containing such fillings are removed, shall ensure that their facilities are equipped with amalgam separators for the retention and collection of amalgam particles, including those contained in used water.

   Such operators shall ensure that:

   (a) amalgam separators put into service from 1 January 2018 provide a retention level of at least 95 % of amalgam particles; and
   (b) from 1 January 2021, all amalgam separators in use provide the retention level specified in point (a).

Amalgam separators shall be maintained in accordance with the manufacturer's instructions to ensure the highest practicable level of retention.

5. Capsules and amalgam separators complying with European standards, or with other national or international standards that provide an equivalent level of quality and retention, shall be presumed to satisfy the requirements set out in paragraphs 1 and 4.

6. Dental practitioners shall ensure that their amalgam waste, including amalgam residues, particles and fillings, and teeth, or parts thereof, contaminated by dental amalgam, is handled and collected by an authorised waste management establishment or undertaking. Dental practitioners shall not release directly or indirectly such amalgam waste into the environment under any circumstances.

Annex 2 - Examples of clinical exemptions that allow the use of amalgam are (or were):

- Inability to keep the area dry (Denmark, Norway, UK)
- Too difficult to access the cavity (Denmark)
- A very large dental cavity (Denmark)
- Too long a distance from affected tooth to proximate tooth (Denmark)
- Restoration requires general anaesthesia (Denmark, Norway)
- Allergy to components of mercury-free fillings (Norway, UK)
- Specific medical condition (Sweden)
- Amalgam can be used when other dental filling materials cannot be used or cannot provide adequate restoration (Finland and Sweden)
- Amalgam can be used in the best interests of the patient based on the patient's specific dental needs (UK)

Two countries ceased their exemptions: Norway (1 January 2011) & Sweden (31 December 2011).

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