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Your ref.: DSC 27/24
Our ref.: EO10/12/101/0000009

20 March 2024

Dear Marie

Regulation (EU) 2017/852 on mercury

I refer to your letter dated 7 March seeking views from the Department of Health on the impact of Regulation (EU) 2017/842 for the dental industry and wider society, along with details of any representations that have been made to the Department (other than by the BDA); and the impact on Department for Agriculture, Environment and Rural Affairs in relation to its area of responsibility.

Please note the input received from Health colleagues at Annex A; and those from DAERA attached at Annex B.

With my regards

S Hamilton-Shields

Stephen Hamilton-Shields
Assistant Director, Post EU Exit Coordination Group

DEPARTMENT OF HEALTH INPUT

BACKGROUND

1. The Minamata Treaty is a global environmental treaty aimed at reducing the release of mercury into the environment and prescribes a phase-down of the use of dental amalgam for environmental reasons. The Treaty advocates a phase-down of the use of dental amalgam, in line with the domestic circumstances of each country and in tandem with recommendations for prevention programmes and increased research into alternative materials.

2. The current position in the UK is that the four UK Chief Dental Officers and their respective Health Departments have incorporated measures to phase down the use of dental amalgam, rather than phase out. These include factors to minimise environmental discharge, improve collection of amalgam waste and changes in service delivery and support for alternative materials. This remains the policy position and preference of the Department.

3. In July 2018, EU Mercury regulations were implemented that restricted the use of amalgam in children under 15 years and pregnant and breastfeeding women. The most recent regulatory change in respect to mercury in dental amalgam was a requirement for all Member States to have plans to phase down its use. Northern Ireland published its action plan in July 2019 and remains in compliance. The UK CDO's still advocate the use of amalgam fillings for reasons of clinical suitability, practicality and cost; also recognising key barriers in terms of disease patterns in their populations and the lack of an ideal, universal replacement material.

4. In July 2023, the European Commission published a proposal to amend Regulation (EU) 2017/852 of the European Parliament and of the Council on Mercury (the EU Mercury Regulation). The main impact of the amendment would be to prohibit the use of, and sale of, dental amalgam from January 2025, save on grounds of medical need. This would cause undesirable and problematic

divergence in law from January 2025, between NI and the rest of the UK, until such time as the UK Government phase out the use of dental amalgam, or the Minamata Treaty is amended to phase out rather than phase down.

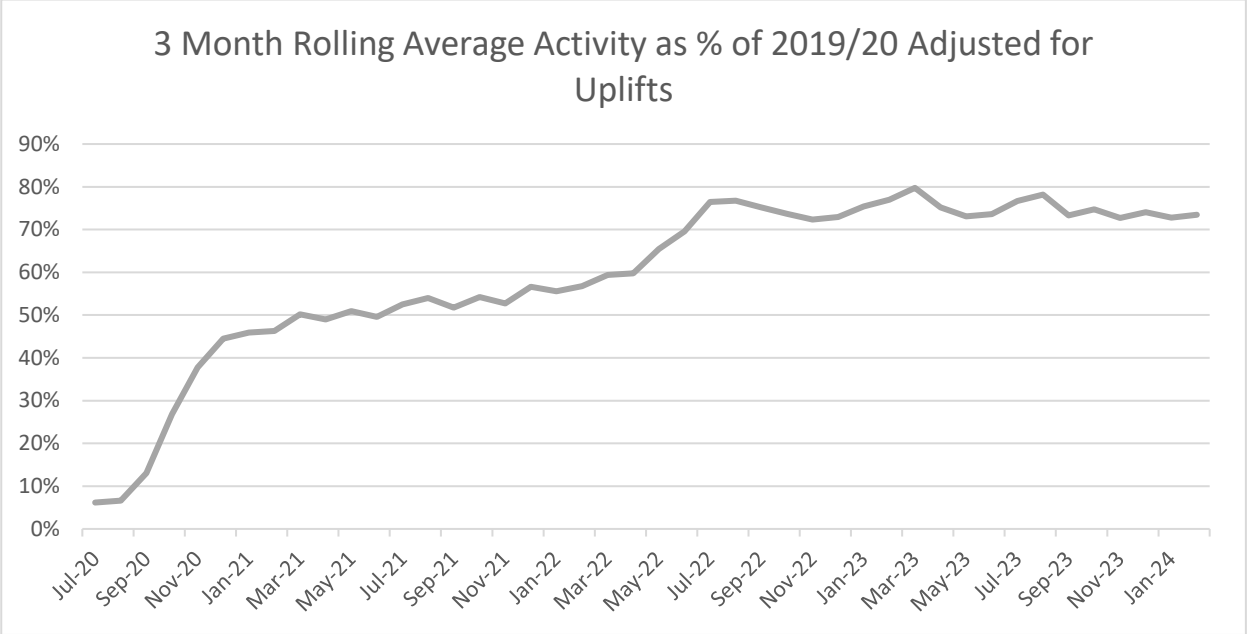
5. It is understood that amendments to the EU Mercury Regulations will apply directly in Northern Ireland under the terms of the Windsor Framework, unless the Stormont Brake process is initiated by Members of the Assembly and considered by the Secretary of State.

6. The most recent update from the Office of the NI Executive in Brussels is that ENVI Committee, of the EU Parliament, has voted in favour of the provisional agreement resulting from interinstitutional negotiations. The file is expected to be tabled for a vote in the April plenary.

7. Current expectations are that the new regulations will be published between late April and June, at which point they could be notified to the NI Assembly by the UK Government.

8. DAERA and DOH have established a NI Mercury Working Group (NIMWG) to monitor the progress of the legislation, identify the arising impacts and risks and agree actions to mitigate said impacts and risks.

9. Access to GDS and dental activity has still not returned to pre-covid levels. In the last 6 months, activity within GDS has been relatively stable. This equates to approximately 73% of average activity over the same 6 months in 2019/20 adjusted for fee uplifts. The table below shows the ongoing impact on activity following the pandemic and showing a plateauing at around the 73% level.



DETAIL

10. In short, if implemented in NI, General Dental Practitioners (GDPs) would only be permitted to use amalgam fillings when there is a specific medical need. Alternative materials would need to be used in the vast majority of cases, such as composites and glass ionomers.

11. The impact would also be felt in Community Dental Services who manage many high needs and vulnerable patient groups.

Materials

12. Composite fillings are frequently used in NI and are already listed in the NI GDS Statement of Dental Remuneration, the list of permitted Health Services treatments. However amalgam is still a very popular, common and appropriate treatment used by GDPs.

13. In 2022/23, GDPs undertook approximately 201k treatments with amalgam and 437k using non-amalgam materials. However, a significant number of the non-amalgam fillings would be small fillings, in anterior (front) teeth, compared to larger amalgam fillings in posterior (back) teeth. This is a very important distinction in terms of the amount of material being used, and associated costs. Chart 2 below attempts to estimate, as far as possible, the ratio in relation to material use in back teeth.

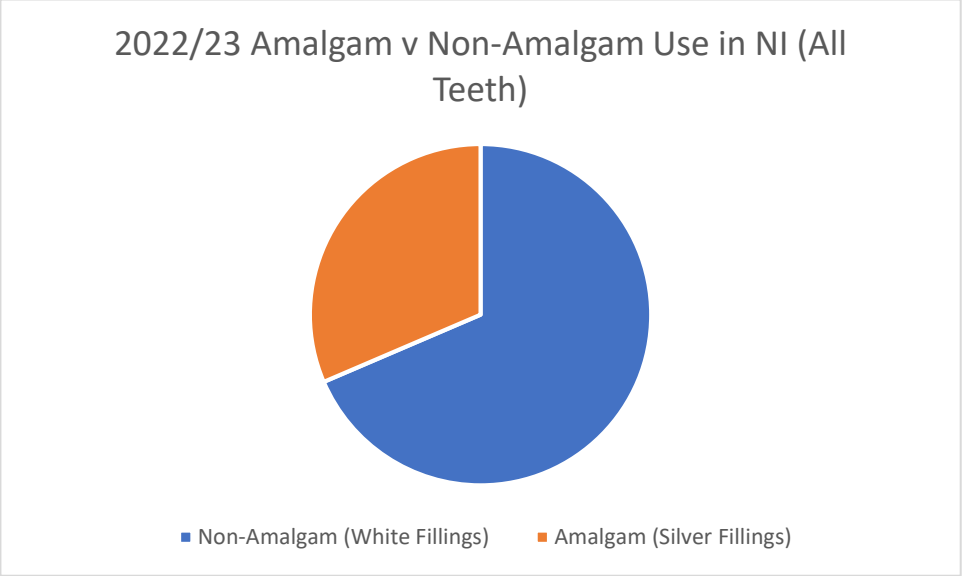


Chart 1

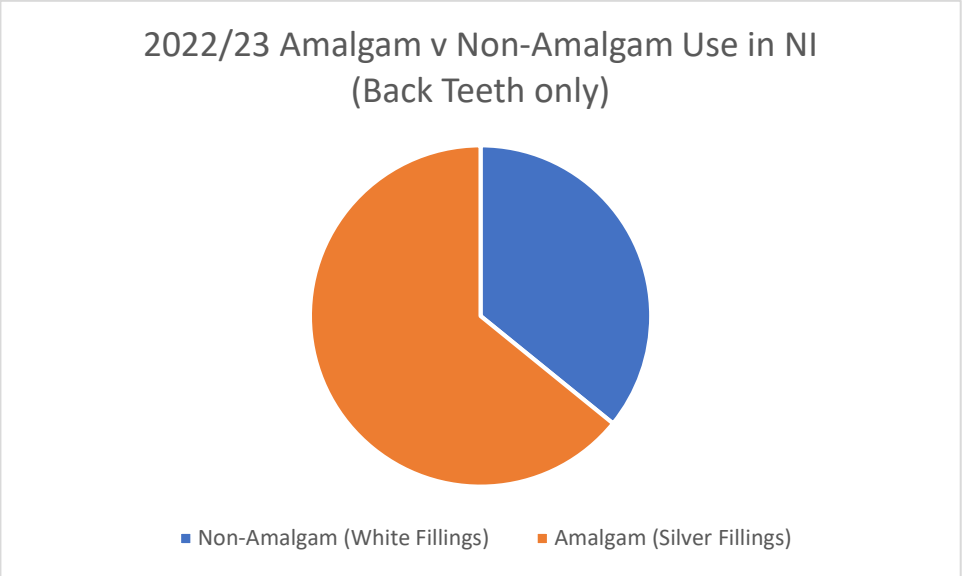


Chart 2

14. The key clinical impact, then, relates to how GDPs treat caries in back teeth.

Costs

15. It is estimated that replacing the 201k amalgam fillings with non-amalgam alternatives would cost in the region of £3.6m to the Department per annum, based on 2022/23 activity levels. However, there is also a notable increase in clinical time for non-amalgam fillings to be placed. The Department is concerned that both the increase in costs and in clinical time will erode the already reduced dental

capacity in NI. The £3.6m is only to the to the Department; patients that are not exempt will also have to pay for the more expensive treatments, as alternatives are more expensive and have reduced longevity, so need to be replaced more often. The increased cost implication represents a 4% increase in the Department of Health's (DoH) dental budget at a time of post-COVID pressure on the dental health system and significant pressure on public finances.

16. There are also likely to be impacts to the price of dental amalgam, increased in line with reduced availability, and in relation to the price of alternative materials, with demand increasing sharply across the EU. These impacts will be felt not only in NI but across the UK and discussions are ongoing with the Department of Health and Social Care (DHSC) in relation to better examining these impacts. So whilst the costs can be estimated, there are a range of variables at play.

17. We would also want to explore any additional training requirements, to offer dental professionals across all sectors refresher training on the use on non-amalgam restorations.. Upskilling and postgraduate training adjustments would also be required to accommodate higher rates of non-amalgam restoration. This will lead to some less significant resourcing pressures across the GDS and HSC Trust dental services

18. There is an extant process in place to bid to Treasury for such EU Exit Divergence cost pressures, and the Department intends to develop a robust case to seek to recover any additional costs.

19. DHSC have already taken the view that it is very unlikely that there will be an effect on the EU Single Market if the updated regulation does not apply in Northern Ireland. So the impact of deploying the Stormont Brake is regarded to have very little impact on the achievement of EU policy goals.

<u>Levels of disease</u>

20. NI has the highest rates of tooth filling in the UK at 47,000 per 100,000 in 2019/20, compared with 22,000 per 100,000 in England, reflecting higher reliance on dental amalgam and poorer oral health. In terms of losing further capacity in GDS, we are concerned that this will impact low-income patients and families the most,

further increasing already evidenced health inequalities. Dental decay disproportionally affects those living in areas of deprivation and least able to pay for dental care and treatment.

21. Dental amalgam is still widely considered as the material of choice for specific procedures, such as the replacement of existing amalgam restorations in complex cavities and in deep cavities where moisture control is challenging. Vulnerable patient groups, including older people, will have had amalgam fillings placed and replaced over many years and would be most affected by a ban.

The British Dental Association

22. The British Dental Association (BDA) have also warned that the introduction of a dental amalgam phase-out by 2025 could have significant contractual and financial implications for dental practices across the UK, with increasing costs borne by dentists, patients or the NHS, risking the destabilisation of a healthcare system already under excessive strain. Further detail has been provided to the Committee in their briefing paper.

23. A December 2023 survey undertaken by them revealed that 41% of practice owners and 38% of associate dentists in Northern Ireland would like to 'leave NHS dentistry as soon as possible'. There is an ongoing concern, therefore, that the impact of the additional cost and time burden of these proposals could further negatively impact on reduced commitment rates of GDPs from HS dentistry.

ANNEX B

DEPARTMENT FOR AGRICULTURE, ENVIRONMENT AND RURAL AFFAIRS INPUT

1. Regulation (EU) 2017/852 on mercury implements the 2013 Minimata Convention on mercury which is an international convention to which the EU and UK are both signatories. The regulation seeks to protect human health and the environment from exposure to mercury and mercury compounds. It applies directly and in full in Northern Ireland (NI) due to the Windsor Framework, whereas an amended version is retained in Great Britain (GB). DAERA is the Competent Authority for the Regulation in NI. The Northern Ireland Environment Agency (NIEA), an agency of the Department, is the Enforcing Authority.

2. An EU proposal to amend the regulation is expected to be adopted by June 2024. The amendments include a prohibition on the use, manufacture and export of dental amalgam and the addition of six mercury-added products (MAPs) (mercury-containing lamps) to Annex II of the regulation, prohibiting the export, import and manufacture of four from 1 January 2025 and the remaining two from 1 January 2027. The Department of Health is the policy lead for dental amalgam, DAERA is the policy lead for MAPs.

3. The MAPs included in the proposal are:
    - Compact fluorescent lamps not already included;
    - Triband phosphor lamps for general lighting purposes not already included;
    - Halophosphate phosphor lamps not already included;
    - Non-linear triband phosphor lamps;
    - Non-linear halophosphate phosphor lamps; and
    - High pressure sodium vapour lamps.

4. Prohibitions on the first three were adopted by the Minimata Convention in November 2023. This means that the EU and UK will align in respect of these MAPs. GB is not obliged to follow the EU prohibitions on the second group of MAPs. This means that divergence is possible in respect of this latter group.

5. The impact of these prohibitions and any potential divergence is expected to be minimal. There are only four manufacturers of mercury-containing lamps in the EU, none at all in the British Isles. Due to the hazardous nature of mercury and its compounds, MAPs have been the subject of restrictions for a long time, as viable alternatives become technically and economically feasible.

6. EU Directive 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), transposed in the UK by The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 have prohibited the import and placing on the market of many mercury-containing lamps. Any exemptions granted for the above MAPs are expiring and regulators are not coming under pressure to renew them due to the availability of alternatives.

7. Although there is potential divergence between NI and GB in relation to three mercury containing lamps, as mercury free alternatives are now widely available, this divergence should have minimal impact to NI.

Northern Ireland Assembly

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Ref: DSC 27/24

7 March 2024

Stephen Hamilton-Shields
Assistant Director
Post EU-Exit Coordination Group
The Executive Office

Issued via email to: stephen.hamilton-shields@executiveoffice-ni.gov.uk

Dear Stephen

Regulation (EU) 2017/852 on mercury

At its meeting on 7 March 2024, the Windsor Framework Democratic Scrutiny Committee (DSC) considered correspondence from the British Dental Association (BDA) regarding Regulation (EU) 2017/852 on mercury.

The proposed EU act amends an existing EU regulation, which applies here under the Windsor Framework, and is expected to be formally adopted by the EU in the near future. Therefore, the Committee is anticipating that it will be formally notified of the EU act once it is published in the EU Official Journal.

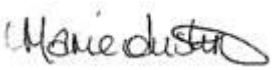
Given the anticipated notification, the DSC agreed to commence an **evidence gathering exercise** in relation to the proposed EU act. As part of the exercise, it agreed to request information from both the Department of Health and the Department of Agriculture, Environment and Rural Affairs.

Specifically, views are requested from the Department of Health on the impact of the proposed EU act for the dental industry and wider society, and details of any representations that have been made to the Department, other than by the BDA.

In relation to the Department of Agriculture, Environment and Rural Affairs, views are requested on the impact of the proposed EU act in relation to its area of responsibility.

I would appreciate a response by 22 March 2024.

Yours sincerely



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