Policy paper

towards phasing out of dental amalgam

to the ministry of health, the ministry of environment, the ministry of consumer protection and the parliament

the transition to mercury-free dentistry

According to the requirements of the EU Mercury Regulation 2017/852 of 17 May 2017 Article 10.3, dental amalgam:

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.

by

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Executive Summary

The use of dental amalgam should be considered outdated in modern dentistry, since mercury free alternatives are effective, available and affordable. Authorities should therefore initiate decisive steps towards the transition to mercury-free dentistry. All dental schools have been teaching dental students how to place mercury-free fillings for years, so dentists are prepared to stop the use of amalgam and increasingly expect amalgam will be phased out. The only consistent measure for a transition to mercury-free dentistry would be to start integrating these new materials into the national reimbursement schemes. The public health care system merely should adjust the reimbursement fees to the slightly higher material-costs of the alternative filing materials, always keeping in mind that the additional environmental costs for the use of dental amalgam will be significantly reduced.

Amalgam can already be replaced effectively and time-saving with alternative filling materials in most cases. Optimized restorative composites, extend the possibilities nowadays to bigger cavities. These bulk-fill composites can be placed and cured up to 4 mm deep and provide strength and low wear for durability.

In addition, the opinion has been consolidated that alternatives should be the material of choice, particularly in lesions that are suitable for other restorative materials. They help preventing healthy tooth structure where amalgam often requires the use of a retentive cavity as adhesion to the tooth does not occur.

Especially in small cavities, dental amalgam should no longer be used and the excessive removal of healthy tooth structure should stop.

In principle **all cavities** can be supplied time-saving with clinical-effective alternatives in few steps nowadays.

Therefore, we recommend to introduce new reimbursement fees for alternative materials preferably in 2020 and ban amalgam in a second step in 2022 (with more or less narrow exceptions).

As soon as all patients will have the free choice for a basic mercury free treatment without having extra costs, dental amalgam will become superfluous over time. In further steps it will be easy to reduce the use to narrow exceptional cases or to discourage the use of amalgam by cutting the subsidies for this material. According to the occasion of the mandatory national plans, the reimbursement system should be reconsidered thoroughly since examples from other countries have already proofed a fair distribution of the costs and lead to a better prevention of tooth decay.

The decision to phase out amalgam will be highly supported by the European public. When the European Commission launched an online public consultation on the Minamata Convention in 2014, fully 88% of the participating European public voted for "phase out amalgam" over "phase down amalgam".





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1. Introduction

The use of mercury in dental amalgam is the largest use of mercury in the Union and a significant source of pollution.

The EU Mercury Regulation 2017/852 confirms the decision towards phasing down and eventually phasing out the use of mercury added dental amalgam in the EU. The regulation beyond banning its use to children under the age of 15 and pregnant or breastfeeding women, further requests that Member states should set out a national plan based, in particular, upon the measures listed in Part II of Annex A to the Minamata Convention. Furthermore, the Commission should assess and report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans required by this regulation and whilst fully respecting Member States' competence for the organization and delivery of health services and medical care.

In principle the European Commission decided already to stop the use of dental amalgam. The only question is how and when to implement a ban considering the socio-economic conditions within the Member States. Since however the alternative materials are already effective, available and affordable, it is well possible that a dental amalgam ban could be decided sooner rather than later, at the EU level. Therefore, the national plans should be seen as an opportunity to effectively create the national conditions for a European ban of amalgam or to structure an individual phase out plan.

With this present document we would seek to assist Member States in this process. To that end we look and discuss the measures listed in Part II of Annex A to the Convention, **including recommendations for effective steps that Member states could take, incorporating those into their national plans**. In addition, you will find examples from other countries, suggestions on how to overcome difficulties and approaches for a realistic and detailed calculation of the costs and efforts for a ban on dental amalgam.

The list of measures under the Minamata convention are first assessed shortly. The high priority measures are then analysed and discussed. The elements provided in these sections would be helpful to our view when Member States are developing their National plans.







2. Overview of the provisions recommended by the Minamata Convention

In the present list you'll find the provisions recommended by the Minamata Convention with characterizations according to our analysis of effectiveness.

Measures listed in Part II of Annex A to the Minamata Convention

	Provisions
i.	Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;
ii.	Setting national objectives aiming at minimizing its use;
iii.	$\sqrt{\rm Promoting}$ the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
iv.	\checkmark Promoting research and development of quality mercury-free materials for dental restoration;
V.	Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and or promoting best management practices;
vi.	Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;
vii.	Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;
viii.	X Restricting the use of dental amalgam to its encapsulated form;
ix.	X Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

$\sqrt{\text{Effective measures for a final transition to a mercury-free dentistry}}$

ii. Since the EU has adopted the ban to use amalgam for to children under the age of 15 and pregnant or breastfeeding women **national objectives** should go beyond. This could be for example be an extension of the ban of amalgam for the vulnerable population **to all women in childbearing age (up to 45 years) or to children up to the age of 18**.

But as soon as further restrictions would entail the introduction of durable filling materials, amalgam should be possible to be replaced **for all patients**. (For the ban of amalgam for children up to 15 years and pregnant and breastfeeding women it was still possible to bridge the time with temporary fillings like glass ionomers).

iii. A new generation of cost and clinical-effective alternatives for permanent treatments are already available. Therefore, we recommend to aim at a general phase out of dental amalgam.

This could include exceptions in a first step like in the Danish role model or more narrow exceptions like in Sweden. In Denmark amalgam was banned in 2008 with exceptions for particularly large cavities or where the distance to the proximate tooth are too great.

vi., vii. For a transition to mercury-free dentistry, it will be essential to introduce **new reimbursement** fees for alternative filling materials in the public health care system.





$\sqrt{\rm Already\ implemented\ measure\ in\ European\ countries\ at\ least\ since\ amalgam\ is\ banned\ for\ the\ vulnerable\ population$

v. Dental school curricula are already updated since the prohibition to use amalgam for vulnerable populations exists in all EU countries. The expansion of using mercury-free alternatives to other patient groups, from technical point of view, should not pose a problem.

$\sqrt{\text{Less effective}}$ measures towards amalgam phase out, since they will not effectively reduce the use of dental amalgam per se or in comparison to alternative filling materials

i. The dental caries prevention for example would promote the oral health but not be effective to reduce the use of dental amalgam in comparison to alternative filling materials.

iv. The promotion of research and development of quality mercury-free materials for dental restoration is covered by the EU Program Horizon 2020.

X Already covered measures by the EU-Mercury regulation

Restricting the use of dental amalgam to its encapsulated form and the mandatory installation of separators to reduce releases of mercury and mercury compounds to water and land had already been adopted by the EU.

3. Setting national objectives aiming at minimizing amalgam use

For setting national objectives aiming at minimizing its use, the EU has already adopted the ban to children under the age of 15 and pregnant or breastfeeding women, which entered into force on 1st July 2018. Taking this as the first step, it now has to be examined how the use could be minimised further.

National measures can go beyond the EU regulation. Therefore, it is a question of political will and ambition.

Taking into account the information we already have, national objectives could already be set to ban amalgam use for all population, potentially with some exemptions.

As one example - a general ban could be adopted including certain exceptions:

In Denmark amalgam is banned since 2008 except where:

- it is not possible to keep the area dry;
- it is difficult to access the cavity;
- there is a particularly large cavity; or
- the distance to the proximate tooth is too great.

Dental amalgam can already be replaced effectively and time-saving with alternative filling materials in smaller and medium sized indications. Only in rare cases of bigger cavities it would take more time with alternative filling materials. The use of alternatives should actually be preferred in smaller cavities, since the excessive removal of healthy tooth structure to place amalgam should be avoided. Therefore, a ban on the use of amalgam in cases that are suitable for alternatives, which are the majority, would be easy to implement and therefore recommended.

A phase out of amalgam for small cavities, would also comply with the recommendations of the World Dental Federation which recommended in September 2018 to reduce and if possible, avoid the use of amalgam particularly in lesions that are suitable for other restorative materials, especially in first restorative treatment and young patients.¹





The phase out of amalgam would also reduce the emergence of excessive cavities (due to initially placed amalgam fillings). As a result, difficult and time-consuming future replacements would be avoided.

As soon as the emergence of excessive cavities will be reduced, the transition to stricter measures would be even easier to implement.

In Sweden amalgam is banned since 2009 except when: deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient. The exceptional use of amalgam is only allowed in dental clinics. (less than 10 cases a year)

4. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration

Alternatives to mercury for dentistry like composite fillings exist since the 1960s. Technology has advanced a lot and new materials with much better qualities are available. Furthermore a few additional elements need to be kept in mind:

- Alternatives to amalgam are not only bearing a lower risk for health and environment, they are
 preventing healthy tooth structure. The ability of alternative materials to bond chemically to
 the dentin ensures less invasive preparations which is a major advantage over conventional
 amalgam placement. In smaller restorations, amalgam often requires the use of a retentive
 cavity as adhesion to the tooth does not occur.
- If amalgam is not laid properly, it can even potentially **increase the risk** of cracks and **tooth fractures**, since the access of moisture during mixing and condensation can lead to increased expansion and corrosion of the filling.²
- To properly place an amalgam filling, a suitable pulp/dentine protection underneath and **two** visits to the dentist are required (one to place the filling and a second one to polish), making it the less efficient procedure.³ If left unpolished, amalgam restorations will have a lower lifetime due to an elevated corrosion surface.

Alternatives to dental amalgam are effective, available and affordable.

- **Small cavities** can be fast and easily filled with composites, composer or glass ionomers. Since the use of these materials is less invasive and allows a longer survival of the tooth, they should be **the first choice for small cavities.**
- For big cavities dentist have nowadays the choice between several modern non-metallic alternatives with a comparable lifetime to amalgam. Ceramic inlays prepared with the CAD/CAM System⁴, composites and the new generation of optimized bulk fill composites. Given that these new composites are placed in-bulk, restoring the complete cavity or most of it, depending on the type of bulk-fill composite, the placement is time-saving and therefore cost-effective.

The amount of time needed for treatment of big cavities may vary depending on whether the tooth structure has already been damaged by amalgam, or not. Composite is often used to replace a previous amalgam restoration. As explained in the BIOIS 2012 report, "**the time required for a composite to replace a previous amalgam restoration is higher than for replacing a composite filling**: a cavity originally prepared to receive an amalgam filling is typically larger and distinguished by various angles that would never be prepared for a composite, rendering the placement of a composite more difficult and time-consuming than it would otherwise have been."⁵

Modern glass ionomer restoratives are strong, radiopaque, for long-term Class I (1 surface) and Class II (multiple surfaces) restorations with restrictions.⁶ They are available in both capsule or hand mix format and are used as a bulk placed restorative. Modern glass ionomers provide an excellent seal on the margins of fillings and can be applied without the need of a liner, cavity conditioner or final glaze for protection.





Bulk fill restoratives are visible-light activated, restorative composites optimized to create fast and easy restorations and provide excellent strength and low wear for durability. The material can be placed and cured up to 4 mm deep, enabled by a stress-relieving resin system and optimized optical properties. **"Dentists get composite restoratives materials with strong physical properties which guarantee a permanent yet economical solution. It can be cured within 10 seconds."**⁷

Scientific evidence of clinical-effective new alternatives

In many European countries new bulk-fill composites have already been used for years and are well established. Scientific studies have now confirmed the quality of this material:

- The 4 mm bulk-fill technique with the flowable resin composite showed highly clinical effectiveness, which was comparable during the 3-year follow-up with the 2mm resin composite layering technique.⁸
- Bulk-fill composite resin is superior to layered composite resin in respect to retention and marginal adaptation in class I (one surface) restorations of permanent molar teeth.⁹

New standards for polymer-based restorative materials

Composites are misleadingly referred to as 'plastic fillings'. However, the basic components are resin and fillers such as glass, ceramics or quartz. The standard composites which can be placed in 2mm layers, consist of 80-90% filler; whereas the bulk fill composites which can be placed to layers of 4-5 mm, consist of 65-85% filler.

Indirect health effects or environmental impacts of these materials are considered to be **very low**:¹⁰ ¹¹ Mercury as the main component of amalgam fillings is 100-800 times more toxic than the most toxic components of composites.¹² ¹³

For additional safety of polymer-based restorative materials, the licensing requirements for new products will be updated in 2019, and producers will have to publish the main composition of their products:

Indications become mandatory for general ingredients with a minimum of 1% of the shares and for toxic ingredients (CMR) with a minimum of 0,1 % of the shares. ¹⁴

5. Promoting research and development of quality mercury-free materials for dental restoration

The available information concerning mercury free materials for dental restorations, is already sufficient for policy decisions to be taken. The promotion and investment in research and development of effective substitute materials should therefore not prevent such decisions.

Research is being carried out at EU level under the EU research program Horizon 2020.¹⁵

The dental industry has already developed new cost-effective and timesaving alternatives to amalgam which are already used by dentists. ¹⁶

Nowadays dentists can choose between different products which can be processed more easily and quickly than amalgam, yet which are just as cost-effective and long-lasting and significantly more aesthetic.





6. Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices

Since the prohibition to use amalgam for vulnerable populations already exists in all EU countries - the use of the mercury-free alternatives is not just an option anymore, it is a must.

This ban, also implies that dental school curricula need be updated to promote mercury-free dentistry. The expansion of using the mercury-free alternatives to other patient groups, from technical point of view, should not pose a problem.

All dental schools have been teaching dental students how to place mercury-free fillings for years, so dentists are prepared to stop amalgam use and increasingly expect amalgam will be phased out.

Many dentists across Europe already work successfully with mercury free alternatives. They comprise approximately **66% of tooth restorations in the EU**.

7. Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration and encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration

The only consistent measure for a transition to mercury-free dentistry would be to start integrating new cost and clinical-effective filling materials into the national reimbursement schemes. In most countries these alternatives are already well established but only accountable through the private sector.

Even though new alternatives will lead to a significant reduction of additional environmental costs, the transition from amalgam could lead to elevated direct costs for the treatment. Although the processing effort is no longer a significant factor for a basic treatment (it could be even more time-saving with new materials than for a properly made amalgam fillings), the higher material costs should be taken into account. For the majority of cavities are small **the costs will remain manageable**. (In many countries for example the reimbursement for the use of alternative filling materials **in incisors and premolars are already equal to amalgam fillings**.)

The increase of the cost for the material is calculated to be 4-5 times more (**Amalgam: 1 EUR**, **Composite or Glass Ionomer: 5 EUR**)¹⁷. It can be assumed that material costs have fallen further in the meantime and will continue to account for only a small proportion of the total treatment costs in the future. It will be of central importance how these costs can be absorbed and distributed.

For the majority of the population, these extra costs would certainly be affordable, (especially if they could benefit from the reduced environmental costs).

The actual cost for the Member States which should be considered for the transition to mercury-free dentistry mainly depends on the contributions of the public health care system. Different possibilities to adapt the social system and the distribution of the costs between insurances, dentists and the patients should therefore be analysed thoroughly. The examples below should be taken into account.

Social systems in the EU

There is no single health care system in the European Union. Basically, the systems can be divided into two categories: Tax-financed and contribution-financed.

As the name suggests, tax-financed health care systems are mainly financed by tax revenues, while contribution-financed systems receive their funds from social contributions. In the majority of cases, however, there are mixed systems with different focuses.





Supplementary/specialised dental insurances are popular in Europe

It is possible to take out supplementary insurance in various countries. Different models are used. In countries such as Belgium, Germany and the Netherlands, it is possible to generally switch from statutory to private health insurance. In many European member states, patients have the option of taking out voluntary supplementary insurance. These supplementary insurances extend the scope of health insurance benefits to include specific benefits like the coverage of cost for alternative filling materials.

In most European Countries patients are free to choose their dentist.

Dentists are usually divided into two categories:

- I. Dentists contracted to public health insurance companies The services provided by these dentists are billed directly to the respective health insurance fund and treatment costs are reimbursed within the limits of the applicable maximum rates.
- II. Dentists without contracts to the public health system, free to determine their fees In most countries, cost accounting is governed by detailed guidelines. However, the dentist may also enter into a personal agreement with the patient about the fee prior to treatments.

In several countries also dentists with a public health contract are free to offer additional services and bill the patients directly. Only a proportion of the invoiced amounts to the patients is then covered by the health insurance funds.

The private accounting generally offers more possibilities for the dentist to calculate the actual cost of a treatment in regard of the scope of the preparation or special aesthetic or minimal invasive requirements.

The majority of the European patients are willing to pay extra for alternative treatments to amalgam (66%).¹⁵

Financial interest of the private sector

Even though amalgam is actually more expensive than most, possibly all, other fillings when including environmental costs, the transition from amalgam to alternatives as a basic supply could lead to elevated direct costs for the individual treatment with fillings.

For dentists, it needs to be considered that they could be concerned of being forced to offer more elaborate fillings for a lower reimbursement. This could happen when the basic publichealth-care-fees for alternatives are going to remain the same as for dental amalgam (In fact, the higher workload for large fillings and the elevated material costs would have to be taken into account). Dentists are also concerned to lose the freedom of an individual and appropriate chargeable treatment for which they were free to bill before. This could happen for example when standard composites (2mm) are becoming the new basic filling material covered by the public health care system (the public reimbursements generally offer very limited billing options).

In general, dentists could be concerned of restrictions in private accounting for alternative filling materials, which gives them the liberty to compensate for additional costs (including costs for demographic differences).

Nowadays private dentists and supplementary insurances benefit from the poor and unpopular basic material amalgam. It highly motivates the patients to choose better alternatives and makes them willing to pay for them.

Economically, it should be noted that the dental care has an enormous financial potential, which clearly exceeds the technical expenditure. Patients are willing to pay comparatively high sums





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for their teeth. The gap widens even further due to the development of new cost-effective materials.

New alternative materials open up new possibilities

New materials offer the possibility to guarantee a basic dental care without particularly attacking the private sector of higher quality fillings (with aesthetic disadvantages).

For the basic treatment of **small cavities** (the majority of cavities) can be filled with glass ionomer, compomer or composite fillings without problems.

Bigger cavities can be filled in a time-saving manner with the new generation of **bulk-fill composites** which are available **only in a limited choice of colours.**

So dentists can continue to satisfy patients with a sufficient second class filling and offer them high quality and aesthetic fillings by charging them according to the conditions of private insurance systems.

The public health care system should merelyadjust the reimbursement fees to the slightly higher material-costs of the alternative filing materials for the basic treatment, always keeping in mind that the additional high environmental costs for the use of dental amalgam will be significantly reduced.¹⁷

Examples of reimbursement schemes for a social distribution of costs for filling materials in Europe

Depending on the social orientation and the economic conditions, there are different reimbursement systems to regulate the distribution of costs for dental fillings in Europe. Many countries have a variation of the following systems:

1. General full reimbursement scheme for basic filling materials

A common problem of the full public reimbursement scheme is the limit of the applicable rates for basic treatments. Alternative private accounting systems for "*upper class*" alternatives are often much **more defined and well established.** As already mentioned above, private charging dentists benefit from a poor and unpopular basic material like amalgam since it highly motivates the patients to choose better alternatives and makes them willing to pay for them.

When alternatives are introduced in healthcare systems as basic treatment, reimbursements will have to be adapted to meet individual cases and a better accountability for dentists would be recommended. **Otherwise, to continue with the system, another generation of** "2nd class" filling materials should be introduced to substitute amalgam as basic treatment. This material could be bulk-fill composite, which has aesthetic deficits, too.

Most of the countries, which fully reimburse amalgam, **already subsidize alternative treatments with the same amount than for amalgam**. As this already corresponds to a proportional reimbursement system, a phase out of amalgam could therefore lead to **a reconsideration of the system**. Possibly a general implementation of **a partial reimbursement scheme** could become a better solution.

Countries: Austria¹⁸, Latvia¹⁹, Poland²⁰, Germany²⁰ and Czech Republic²¹,

2. Proportionate reimbursement schemes for basic filling materials

For countries which have already a proportionate reimbursement scheme, the transition to mercury free dentistry shouldn't be a big deal since patients are used to contribute to the payment of the dentures. The cost for new alternative fillings is reasonable. Some countries already do proportionate reimbursements regardless of the material used.

Countries: France²²



3. Fix subsidies for any filling treatment

Fix subsidies help patients to cover the costs for the dental treatment regardless of the materials used. Statutory systems should control the availability of affordable dentures.

Countries: Bulgaria²⁰, Finland²⁰

4. No public reimbursement for filling materials

In countries where the public health insurances do not reimburse the cost of fillings or give only a minimal contribution, oral health is more depending on the financial situation of the patients than in other countries. For patients who could possibly not afford the treatment, pulling out the teeth is still a realistic consequence. In some countries patients actually treat themselves with do-it-yourself-kits.

Countries: Cyprus²⁰, Italy²⁰, Portugal²⁰, Spain²³, Malta²⁰

5. Full reimbursement for selected patient groups

In several countries the reimbursement for dentures is **depending on the socio-economic situation or the age of the patient**.

For example, in Sweden the patients under the age of 20 years are getting full reimbursements and adults from 20-29 years and older than 75 years are specially supported.

Or as in Scotland where patients are supported according to detailed conditions for example if they receive benefits and are already included in an award like an income support or a support which includes an element for a child and/or limited capability for work or limited capability for work related activity or a pension support.

The advantage of this reimbursement scheme is that **the basic supply of the population remains guaranteed**. Dentists can freely agree the services with the majority of patients and adapt them to the market. The oral health and the quality of the fillings depend on how much the patients are able and willing to pay.

With the new alternative materials, a transition to mercury free dentistry will not be a special burden for the society.

Countries: Sweden²⁴, Belgium²⁰, Scotland²⁵, Northern Ireland²⁶, Estonia²⁰, Slovakia²⁷, Netherlands²⁸

6. Limited reimbursement per year

Some countries have developed a scheme which limits the reimbursement to certain periods of time.

In Sweden for example patients receive 300 Krona for dental examinations or treatments per year which can be saved for a maximum of 2 years.

The advantage of this system is **that patients are motivated to go to the dentist at regular intervals**. Otherwise the subsidies expire.

Countries: Sweden²⁴, Czech Republic²¹, Netherlands²⁹ **7. Guarantee on fillings**

In some countries dentists are responsible for the durability of fillings.

If the filling lasts less than 2 years without the patient causing the damage, then the dentist has to pay for the replacement. (Germany, Austria)

Dentists are free to give further guarantees on the longevity of their fillings if they like.





Countries: Germany²⁹, Austria¹⁸

8. Reimbursements based on preventive examinations

In Slovakia with regard to extra-cost-free dental interventions (tooth decay) the conditions are based on a preventive examination in the year previous to the intervention.

In Belgium patients pay a personal share or the part of the invoice that is not reimbursed by the health insurance of 11.50 euro for a tooth filling. As soon as patients don't go to the dentist for a year, they will pay 21.50 euros, 10 euros more.

Countries: Slovakia³⁰, Belgium³¹

Recommended steps to adopt the public health care system

For most of the population, reasonable extra costs for new alternative filling materials would certainly be affordable. In the private sector these materials are already established, and the rates will continue to stabilize through the free market.

For the public health care system an introduction of standard composite fillings (2mm) could lead to significant additional costs, but more convenient bulk-fill composites (4mm), glass ionomer and compomer fillings could be introduced for the basic supply. Furthermore, the share of public reimbursements could be reconsidered in accordance with the examples presented in this document (some systems even lead to a better oral health prevention).

Therefore, we recommend the following steps:

1. To better assist the transition to mercury-free dentistry, the reimbursement positions for alternative filling materials in the public health care system need to be introduced.

The accessibility of alternatives without extra payments for the general population would lead to **a free choice of the basic filling material for all patients**.

These new fees should be introduced as soon as possible and preferably by January 2020.

In Latvia for example since January 2019 new reimbursement fees for the use of alternative materials in molars have already been introduced for the general population.¹⁹ In the table below you can see how the material costs and effort of the elaboration have been considered in comparison to dental amalgam.

2. After a period of transition and extra training of the dentists the use of alternative fillings could be further pushed by limiting the subsidies for amalgam to exceptional cases.

Latvia		2019		1
Introduced for the general population				
Surfaces in molars	Amalgam	Glas lonomer	Compomer	Composite
1	10,65 €	15,10 €	15,66 €	17,90 €
2	13,03 €			23,05 €
3	15,30 €			27,05 €
4+	20,84 €			33,14 €
+Crown				37,24 €
* *For now it is specified that pregnant women, breastfeeding women and children under 14				

years of age (including) do not use amalgam, but use composite or / and glass ionomer or / and a composer. In general, the reimbursement for this manipulation is done if indicated by the specialists in dental care services.



Examples of reimbursement fees for alternative filling materials for pregnant women, breastfeeding women and children

The following examples show how alternative materials have already been introduced into national reimbursement schemes to replace dental amalgam as basic filling material for children and pregnant and breast-feeding women. It should be considered that the fees were most likely not yet adopted to new bulk-fill materials. The percentage of the public population insured is indicated for a better calculation of the additional costs for a transition to mercury-free dentistry.

Austria	* 100% pu	2018	
Surfaces	Amalgam	Glass ionomer (GI)	
molars			
1	19,3 €	37,7 €	
2	30,2 €	48,7 €	
3	44,8 €	64 €	
4+	68,3 €	101,8 €	
*Dentists give a guarantee of 2 Years on GIZ			

If patients chose Composites instead of GIZ they get 80% of the new fee reimbursed The fees for GIZ were adopted from the reimbursement fees for composites for incisors

Sootland

Germany* 90% Population pr	2018 ublic health	insured
Surfaces	Amalgam	(Bulk-Fill)
molars		Composite
1	28,2 €	45,9 €
2	34,4 €	56,4 €
3	43,2 €	74,1 €
4+	51,2 €	88,2 €

*It's still discussed if dentists are allowed to charge extra costs for multiple layer composites. The fee adopted for the vulnerable population was already introduced for patients allergic to amalgam or with kidney diseases, time before Bulk-fill materials were established.

The fee for amalgam is the same than for composites placed in incisors.

Scollanu		010	
	×		
Amalgam	Compos	ite, GI or	
molars	Resin	Fillings	
Small 7,56 £	Small	18,40 £	
big 19,44 £	big	28,60 £	
* Patients who are not entitled to free National Health Service(NHS) Dental Treatment pay 80% of the cost of the NHS dental treatment up to a maximum of £384 per course of treatment			

2010

Northern	Ireland 2018
Amalgam	Composite, GI or
molars	Resin Fillings
9,14 £	20,00 £
13,58 £	26,90 £
17,91 £	34,54 £
23,51 £	44,31 £

Czech Republic	2019
Amalgam or self-polymerizing	Glass ionomer (GI)
Composite Materials*	
495 CZK	495 CZK
* New fee is in place since January had been 275 CZK	2019. So far the fee





Annex

Aspects from which the use of amalgam must be additionally justified from 2020 onwards

April 2020: Corrosion rate of amalgam fillings

The approval regulations for dental amalgams will include a corrosion rate like it already exists for other metallic materials in dentistry. Only then it will be possible to control the release from amalgam fillings on the market. Since the corrosion of the fillings also depends on a proper processing, the introduction of a corrosion rate could also lead to regulations for the use of amalgam and thus to liability on the part of the dentist. Since October 2018, the international working committee ISO/TC 106/SC has been working on a draft which has been released. A standard is expected to enter into force in April 2020 but no later than April 2021. 32

May 2020: Medical Device Directive

According to the Medical Devices Directive, the authorisation of medical devices containing a concentration of more than 0,1 % by mass of carcinogenic, mutagenic or toxic to reproduction ("CMR substances") require a special justification from 26 May 2020. This justification should take into account the availability of alternatives and the risk-benefit balance. (Mercury has been officially classified as toxic to reproduction (Repr. 1B - H360D: May cause harm to the unborn child) by the European Chemicals Agency (ECHA) since 2012. Accordingly, amalgam fillings should no longer be permitted when the new Medical Devices Directive enters into force, as effective and inexpensive alternatives are already available.

June 2020: European Commission report

REGULATION (EU) 2017/852, Article 19

By 30 June 2020, the Commission shall report to the European Parliament and to the Council on the outcome of its assessment regarding the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care.³⁴

It is intended that a European ban on amalgam will be adopted in the European Union. The national action plan in July 2019 will give each Member State the opportunity to take the relevant preparatory or to shape their individual transition to mercury-free dentistry.

December 2020: Annex A of the Minamata-Convention

All major mercury containing products such as batteries and accumulators, switches and relays and non-electronic measuring instruments such as barometers, hygrometers, manometers, thermometers or sphygmomanometers will be banned from 31 December 2020 (except of dental amalgam).³⁵



down ²



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the EU is already taking one of the measures listed in the Minamata Convention.

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