Results: Survey on Adverse Reactions Reporting with NORCE

Replies so far: 19

Countries: Denmark (DK), Croatia (HR), Hungary (HU), Slovakia (SK), Malta (MT), Spain (ES), Czech Republic (CZ), Germany (DE), Austria (AU), Belgium – VVT (BE), France (FR), Greece (GR), Lithuania (LT), Norway (NO), United Kingdom (UK), Finland (FI), Portugal (PT), Sweden (SE), Netherlands (NL)

Q1) Do you think dentists in your country in general are aware of the mandatory reporting of adverse clinical and environmental reactions to dental materials (medical devices) described in the Regulation (EU) 2017/745 (MDR)[1]? [1] In UK there is the Yellow Card system (https://yellowcard.mhra.gov.uk/)

Reply	DK	HR	HU	SK	MT	ES	CZ	DE	AU	BE	FR	GR	LT	NO	UK	FI	PT	SE	NL
Yes																			
No																			
Do not know																			

Other comments:

Denmark: https://www.retsinformation.dk/eli/retsinfo/2021/9368 There is national legislation that obligates dentists to report adverse reactions, to the Danish Medicines Agency.

Austria: In Austria professionals who use or operate medical devices, as well as technical safety officers of hospitals, must immediately report to the Federal Office for Safety in Health Care (BASG) any serious incidents of which they become aware as a result of their professional activities.

France: In France, dental surgeons are now legally obliged to report serious adverse events to the ANSM, the French national agency for drug safety. Dentists are also obliged to inform their patients of the CMR risks involved in the manufacture of prostheses containing a cobalt alloy. These obligations are the subject of communications (professional press, professional association, etc.) and also of teaching in the faculties.

Lithuania: Legally regulated since 2010, but some professionals may not have sufficient knowledge.

Finland: Both professional users and manufacturers of medical devices are obliged to notify Finnish Medicines Agency (Fimea) of incidents and potential incidents involving medical devices.

Portugal: In Portugal Dentists are obliged to report adverse reaction to dental materials. INFARMED (National Authority in Drugs and Medicine) provides a reporting channel for reporting (https://www.infarmed.pt/web/infarmed/notificar)

Sweden: In order for it to work effectively, it is also essential to ensure that the bureaucracy — in this case, the reporting process — is kept as simple as possible.

Q 2) Does your organization consider that the EU MDR reporting is sufficient in relation to offering enough data and information on such adverse reactions?

Reply	DK	HR	HU	SK	MT	ES	CZ	DE	AU	BE	FR	GR	LT	NO	UK	FI	PT	SE	NL
Yes																			
No																			
Do not know																			

Other comments:

Lithuania: The regulator says that not all market participants are providing high quality and complete information in accordance with the law.

Norway: Weakness in the system as the reporting is dependent on the producers' assessment.

Portugal: We consider the legislation is enough but the information and training the health professionals is still very weak.

Sweden: Even if only a few report, the size of the dental profession within the EU is hopefully sufficient for the system to still yield meaningful and useful results.

Q3) Do you think that a system for voluntary, producer independent, reporting of adverse reactions to dental materials could be a useful complement to the mandatory reporting according to the Regulation (EU) 2017/745 (MDR)?

Reply	DK	HR	HU	SK	MT	ES	CZ	DE	AU	BE	FR	GR	LT	NO	UK	FI	PT	SE	NL
Yes																			
No																			
Do not know																			

Other comments:

France: In France, healthcare professionals are obliged to report any serious event arising from a medicinal product or medical device to the ANSM. The general public and healthcare professionals are becoming increasingly aware of this obligation, particularly among new generations of practitioners. The declaration is made to an independent body via a dedicated internet portal.

Lithuania: A separate dental-only system would probably not create any additional value

Norway: Reporting from all dentists treating patients will give a more complete overview over suspected or documented adverse reactions of dental materials and also contribute to securing that information about potential adverse effects will be common knowledge as early as possible. Such knowledge is important from a patient safety perspective and also for the patient to be able to give informed consent. We also agree that voluntary manufacture-independent reporting can be useful since it helps track time trends/changes over time, signals in relation to new types of reactions, and contributes to detecting infrequent reactions. Such a system is already more commonly in place for pharmaceuticals.

Portugal: In Portugal, healthcare professionals are obliged to report any serious event arising from a medicinal product or medical device to the INFARMED.

Sweden: If mandatory reporting does not function adequately, we are doubtful that a voluntary system — even if simpler — would add significant value. Even with a simplified process, a substantial amount of information will still be required for the data to be useful.

Q4) Do you think a system for voluntary, producer independent, reporting of adverse reactions to dental materials could be implemented in your country?

Reply	DK	HR	HU	SK	MT	ES	CZ	DE	AU	BE	FR	GR	LT	NO	UK	FI	PT	SE	NL
Yes																			
No																			
Do not know																			

Other comments:

Denmark: It can be implemented, but it would become an unnecessary additional bureaucratic burden for dentists. The Danish Medicines Agency already collects data, and the results are available to dentists.

Germany: Healthcare facilities in Germany are required by law to report adverse reactions to medical devices to the competent authority. https://www2.bfarm.de/medprod/mpsv/

France: In France, there is already an institutional body that records serious events relating to DM materiovigilance issues: the Agence de securite du medicaments et des produits de sante: ANSM.

Lithuania: As there is already a designated state body in Lithuania for monitoring and data collection, a voluntary system is likely to be difficult to implement

Norway: In Norway we already have such a system of voluntary producer, independent reporting, see answer to next question.

Portugal: I think another system for reporting will overlap the one's already exists

Sweden: It will be perceived as additional bureaucracy and extra workload.

Q5) If a system for voluntary, producer independent, reporting of adverse reactions to dental materials was implemented in your country – what organization do you think should/could be responsible?

DK	Health authorities
HR	Croatian dental Chamber
HU	Health authorities
SK	Health authorities
MT	Health authorities
ES	National dental association
CZ	National dental association
DE	National dental association
AU	Health authority: Bundesamt für Sicherheit im Gesundheitswesen BASG (see 1)
BE	Health authorities
FR	Health authorities
GR	National Evaluation Center of Quality and Technology in Health
LT	Health authorities
NO	Health authorities

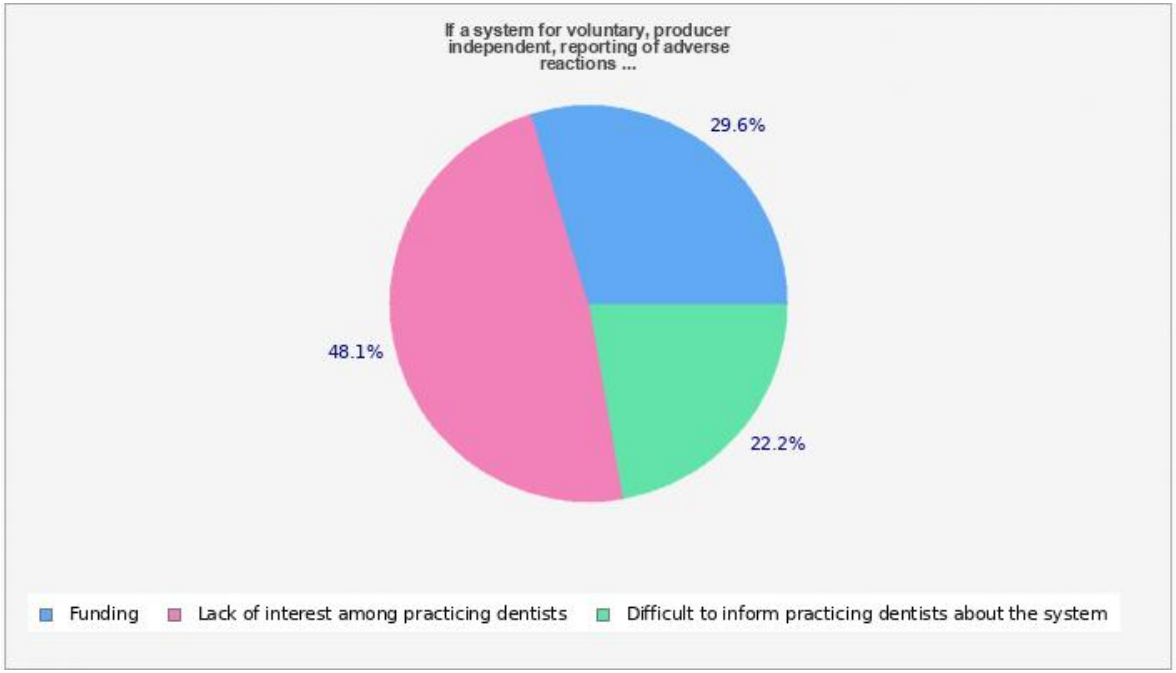
UK	MHRA - Medicines and Healthcare products Regulatory Agency
FI	Health authorities
PT	Health authorities
SE	Swedish Medical Products Agency, perhaps?
NL	Health Authorities

Other comments:

Norway: Independent unit with financing from the health authorities. In Norway we already have the Dental Biomaterials Adverse Reaction Unit which is organized as a unit in NORCE. The adverse reaction group was established in 1992 by the Norwegian Directorate of Health as a project group under the Faculty of Dentistry, University of Bergen. From 1999, the group became permanent with funding over the national budget. The main tasks of the Adverse Reaction Unit are (1) Investigation of referred patients (2) Registration and monitoring of adverse reaction reports submitted to the National Adverse Reaction Registry for Dental Biomaterials (3) Information and research on adverse reactions related to dental biomaterials The Adverse Reaction Unit is affiliated with a council with representatives from the fields of medicine and dentistry.

Sweden: It is difficult to identify an appropriate body to take responsibility. Logically, the Medical Products Agency would be a candidate, but they already operate the mandatory reporting system. There is also a risk that professionals may hesitate to report to a voluntary system if it is possible to compare who reported where. The national dental association does not have the resources or capacity to take on such a task without external funding. In countries where dentists are required to be members of a national dental chamber, it might be feasible for such organizations to manage a voluntary reporting system. However, given Sweden's healthcare structure – with a mix of private providers and regional authorities – this would be more challenging.

Q6) If a system for voluntary, producer independent, reporting of adverse reactions to dental materials was implemented in your country – what do you think could be the main challenges? (multiple answers possible)



Other comments:

France: The most complex part is communicating and raising awareness of the importance of this approach. New generations of practitioners are better trained and more aware of this obligation during their studies, whereas the 45-65 generation of practitioners did not encounter this teaching during their initial training. There is still a lot of work to be done in terms of communication and motivation about this obligation.

Norway: Funding from the health authorities is often a challenge, so it is important that also the National Dental Associations are aware of the weaknesses in the MDR-reporting system and contribute to general awareness of this by including it in their lobbying activities. National report systems can be organized at many levels and need not be so costly. In Norway, the NDA has close collaboration with Dental Biomaterials Adverse Reaction Group and try to include the Adverse Reaction Groups in its Dental Exhibitions (connected to the annual congress) to keep awareness up. The NDA Dental journal also publishes the Adverse Reaction Reporting Form in most of its publications. However, it can be a challenge to keep motivation up amongst the members to continuously report adverse reactions to dental materials. It is therefore helpful that the Norwegian Authorities have a compensation system in place that give a standard reimbursement sum for time spent to dentists who send in the Adverse Reaction Reporting Form.

Sweden: All three issues will pose major challenges, and each one alone could be enough to undermine the entire system.