



EU collaboration on vaccination – AIM's view

The current outbreak of COVID-19, its crippling effects on European economies and societies and the race to find a vaccine against the disease have put to the fore the fragility of our societies. It has also made the importance of vaccination more evident than ever and thumbed its nose to the most sceptical. Beyond and before COVID-19, outbreaks of illnesses which we thought have been controlled had already made vaccination and vaccine safety a priority at European and global level (where it has always been). A debate was launched on whether and how vaccination could be organised at EU level and an EU-wide campaign started to fight against vaccine hesitancy. The dire consequences of COVID-19 in the European Union have now made these debates even more relevant and call for decisive action. With the present paper, AIM would like to draw the attention of EU institutions to different key aspects in the fight vaccine-preventable diseases.

Our calls:

1. AIM calls for strong access conditions to be attached to public funding for COVID-19 vaccines.
2. AIM calls for the full reimbursement of the vaccines which are part of schedules established on the basis of scientific recommendations.
3. AIM believes that vaccination should be integrated in public health programmes and that compulsion can be envisaged in programs with the purpose of eradicating a disease.
4. Vaccines should be administered outside clinical settings if there is a real added value in terms of coverage and if the administrator is properly trained.
5. AIM supports an EU vaccination schedule.
6. AIM believes joint procurement of vaccines should be made possible on a voluntary basis, as it is currently the case.
7. EU guidelines and tools on communicating about vaccination should be provided.
8. Common liability rules for very rare, but possible complications could best be implemented at EU level.

1. AIM calls for strong access conditions to be attached to public funding for COVID-19 vaccines

The EU has committed funds to support the development of medicinal products to fight COVID-19, including vaccines. Strong access clauses must be included in funding contracts, in order to make sure that everyone can access the much needed products developed through these funding programmes.

Intellectual property (IP) deserves a specific attention as they maintain prices high, which mechanically prevents access. In order to effectively protect against COVID-19, vaccines prices must allow access globally, in order to contain the pandemic and its crippling effects on societies and economies across

the world. There are currently international efforts to pool intellectual property rights in order to allow for competitive and accelerated production of COVID-19 treatments. The European Commission should give full attention and support to such collaboration.

2. AIM calls for the full reimbursement of the vaccines which are part of schedules established on basis of scientific recommendations.

High vaccination coverage rates can only be achieved if vaccines are accessible to all. One of the key aspects of accessibility is financial and thus linked to reimbursement. Vaccines included in vaccination schedules should be fully reimbursed so as to remove any potential financial obstacle. To guarantee patient safety but also safeguard citizens' trust, it is key for those schedules to be established on the basis of scientific recommendations taking different groups of people and risks into consideration.

Additional vaccinations, for example in an occupational health context, should also be reimbursed given that their safety and efficacy have been proven. Other vaccines which are not in the schedule but are recommended to specific vulnerable groups or in the case of severe conditions should also be reimbursed if those vaccines are evidence-based and provide a demonstrated health gain. Vaccination necessary to travel abroad should be paid by the traveller or by their employer if the travel takes place in the frame of the individual's professional activity.

It is important that the reimbursement of those vaccines does not fall solely on health insurance institutions but is also borne by the State as it is a public health responsibility.

3. AIM believes that vaccination should be integrated in public health programmes and that compulsion can be envisaged in programs with the purpose of eradication of a disease.

Compulsion seems to be a solution to increase coverage rates and achieve herd immunity. Yet, compulsion could be understood as an attack to the values of freedom and democracy on which the European Union was built. Compulsory vaccination could be considered, in the frame of some national legislations, as an invasion of privacy and be against constitutionally guaranteed rights. In other countries, compulsion is the rule.

Member States have the competence regarding the decision on compulsion. Compulsion can be envisaged in programs with the purpose of eradication of a disease. If vaccination is not compulsory, it is of utmost importance that patients are properly informed. Citizens thus need to be empowered by tailored and comprehensive information describing the risk-benefits balance. They should be able to make well-informed decisions and to avoid unreasonable fear of side effects. Hence, other incentives to change behaviour can be used such as: social marketing, removal of price barriers, improving other non-price barriers to access, nudging, etc.

In the case of non-compulsion, one solution to ensure to reach a higher coverage could be to envisage a policy option such as opting-out of vaccination. An opt-out would be subject to a formal process while raising the awareness about risks of not being covered. Concretely, if a person does not want to get her/his vaccine (or his/her children to get it), they would be obliged to meet a healthcare professional before opting out.

The issue of vaccination of healthcare professionals themselves is also big problem. The Council Recommendations on *Strengthened Cooperation against Vaccine Preventable Diseases* states that "(...) in cases where vaccination coverage rates of healthcare workers are considered insufficient with

respect to national recommendations should be addressed in order to protect those workers and their patients”. To ensure proper coverage of the healthcare staff, compulsion should be introduced for some vaccines. This is the case not only for healthcare workers but also for teachers or children as a precondition to be admitted in school.

4. Vaccines should be administered outside clinical settings if there is a real added value in terms of coverage and if the administrator is properly trained.

“The need to bring immunisation services closer to citizens” by “(...) reach[ing] the most vulnerable in society, in particular through community-based providers (...)” was rightly highlighted in the Council Recommendations on *Strengthened Cooperation against Vaccine Preventable Diseases*.

Vaccination programmes outside “clinical” settings may be beneficial if they lead to improved access to vaccination. Pharmacists, nurses or public health workers (e.g. carers) may be, depending on national legislation, entitled to vaccinate as well. Before allowing such practices, their added value must first of all be investigated. Moreover, caution must be observed as vaccination requires, in addition to technical skills, a corresponding hygienic environment (cold chain) and coping with adverse effects. Furthermore, if vaccines are to be made available outside clinical settings, the administrator must be properly trained to communicate with the patient in order to provide him with comprehensive information without inducing fear, and to respect safety measures. Other issues such as control liability and proper registration of administered vaccines also have to be clarified.

5. AIM supports an EU vaccination schedule.

The variation in vaccination schedules between and within Member States increases the risks that citizens, children more particularly, miss vaccination while moving from one Member State to another, or even from one region to another within the same country. It could help fight health inequities by reducing variation in coverage.

An EU-wide schedule would allow to reduce confusion around diverging schedules and lack of consistency between and within Member States. European recommendations on certain types of vaccines such as measles could help foster vaccination rates. An EU schedule would also be an added value in the case of cross-border care, cross-border movement/migration, joint procurement of vaccines and to generate much needed statistics at EU level. Higher added value could be achieved by including additional recommendations for the regional level and special circumstances.

As long as it provides minimum standards and as long as national levels of protection can be maintained an EU-wide schedule is to be welcome. National authorities should remain able to decide on further vaccination recommendations and reimbursement. It is indeed a government responsibility to set its priorities and goals in consultation with all stakeholders.

Healthcare institutions should have the capacity to have electronic information on the vaccination status of citizens

The development of a common vaccination Passport for EU Citizens compatible with electronic immunization information systems and recognised for use across borders would support the implementation of the above-mentioned schedule. It would also help in cases of cross-border movement of citizens. For such a Passport to work, healthcare institutions and all healthcare professionals involved in vaccination must have the capacity to electronically register the vaccination

status and information of citizens. This EU vaccination passport should not entail duplicating work at national level. It is therefore key to work on the interoperability of the existing national databases.

6. AIM believes joint procurement of vaccines should be made possible on a voluntary basis, as it is currently the case.

In the current COVID-19 emergency, EU joint procurements could help reach a vaccine price which would be both affordable and accessible to many. A combined purchase by many Member States is expected to lead to economies of scale on the side of suppliers (one order covering many markets) and on the side of public authorities (one administrative procedure for many markets).

Relevant forecast planning taking into account vaccination schedules should help better predict demand and make such a joint procurement easier to organise. Furthermore, joint procurement of vaccines could help solve the problem of shortages that some countries faced already before the COVID-19 outbreak and of the industry's disinvestment in vaccines in the EU due to a fragmented and partially unpredictable demand.

Anyhow, before addressing questions such as joint procurement, free access to vaccinations listed on an agreed EU schedule should be reached. In the meantime, voluntary joint agreements between smaller groups of Member States (as they already take place) should be encouraged under the frame of the Joint Procurement Agreement.¹ The EU could also explore the possibilities to establish a cross-border pooling option (joint stock) for vaccines/ immunoglobulins/ antitoxins.

7. EU guidelines and tools on communicating about vaccination should be provided.

Each country has its own challenges and culture. National and regional targeting are proven to have a better impact on citizens. AIM is of the opinion that general guidance and data/statistics could be provided at EU level. Furthermore, EU guidelines could be especially beneficial to Member States with limited resources.

There is need for those communication tools to be addressed to different networks: decision makers, procurement specialists, healthcare professionals, healthcare payers, teachers, vulnerable groups, etc. Communication tools to share knowledge between countries should also be developed. With that objective, the European Centre for Disease Prevention and Control (ECDC) has established a network for the managers of National Immunization Technical Advisory Groups (NITAG). AIM is in favour of strengthening such a collaboration at European level.

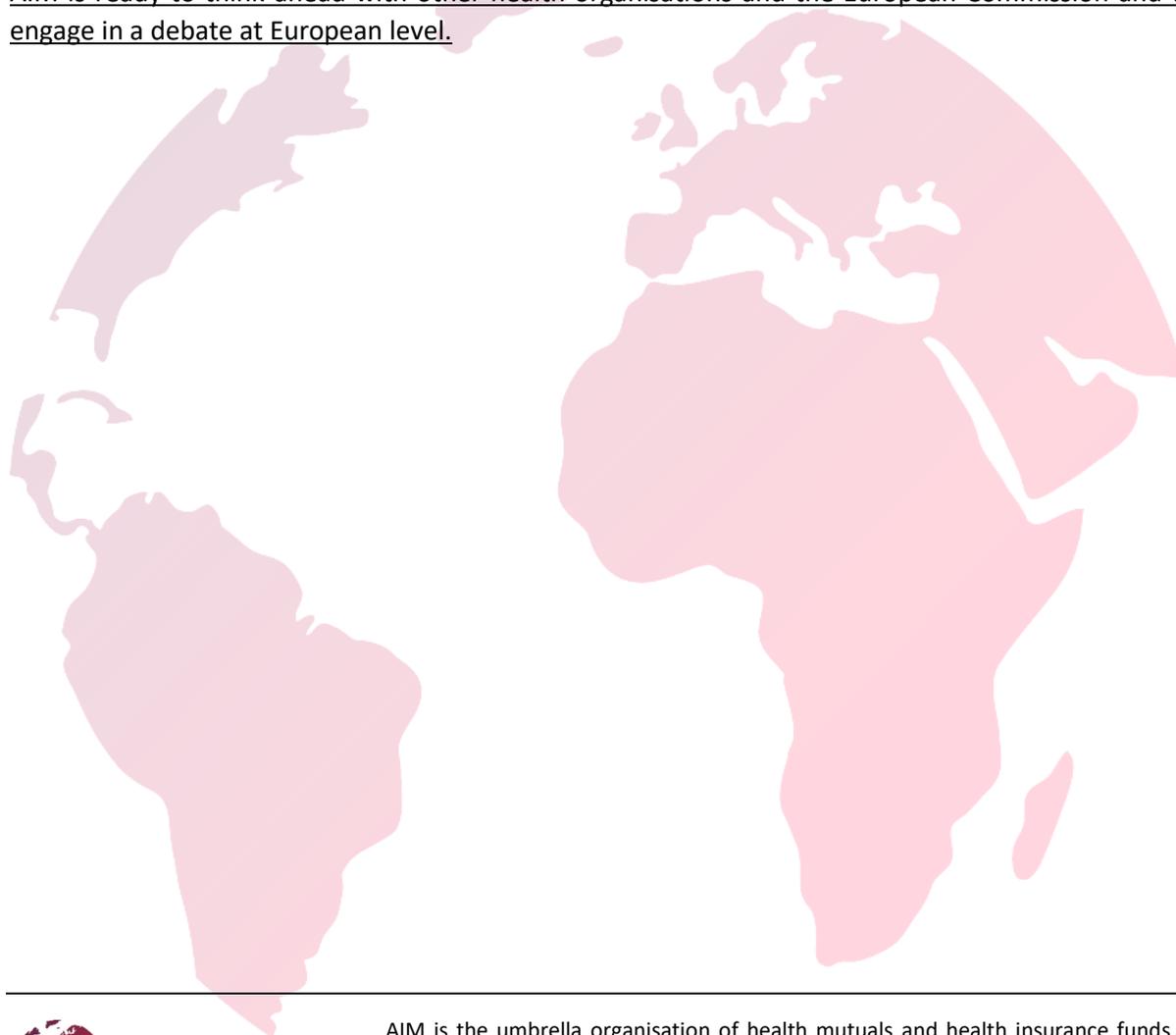
Furthermore, there is a need to make the most of existing instruments, including the EU Pharmacovigilance system. If this collaboration between European Commission, Member States and the European Medicines Agency is of utmost importance, the proper dissemination of its outcomes to the general public is even more crucial. AIM would call for making the information on vaccination resulting from the EU Pharmacovigilance system more visible and accessible to the general public.

¹ The Joint Procurement Agreement provides MS with a framework to jointly procure vaccines. The JPA allows to pool purchasing power of MS, ensuring that pandemic vaccines and others are available in sufficient quantities. It also helps guarantee access.

8. Common liability rules for very rare, but possible complications could best be implemented at EU level.

Vaccines are administered to people who are usually healthy and in most cases to children. Therefore, a higher degree of safety is often expected for vaccines than for other pharmaceuticals or other healthcare interventions. To ensure the safety of vaccines but also citizens' trust in them, it is important to improve spontaneous reporting of adverse event(s) following immunization (AEIF) and pooling of AEIF data globally in order to reduce time to identify rare vaccine reactions. A need for standard methodologies for active surveillance and a standard reporting format for AEIF should be developed. This would help ensure a proper monitoring of vaccines after their use.

AIM is ready to think ahead with other health organisations and the European Commission and to engage in a debate at European level.



AIM Healthcare and social benefits for all

AIM is the umbrella organisation of health mutuals and health insurance funds in Europe and in the world. Through its 59 members from 30 countries, AIM provides health coverage to 240 million people in the world and about 200 million in Europe through compulsory and/or complementary health insurance and managing health and social facilities. AIM strives to defend the access to healthcare for all through solidarity-based and non-for profit health insurance. Its mission is to provide a platform for members to exchange on common issues and to represent their interests and values in the European and international Institutions.

More information: www.aim-mutual.org

Contact: Jessica Carreño Louro • jessica.carreno@aim-mutual.org