

ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE INITIATIVE	Strengthened cooperation against vaccine preventable diseases
LEAD DG – RESPONSIBLE UNIT	DG SANTE PA01 / C3
LIKELY TYPE OF INITIATIVE	Council Recommendation
INDICATIVE PLANNING	Adoption expected by Q2 2018
ADDITIONAL INFORMATION	https://ec.europa.eu/health/vaccination/overview_en

This Roadmap aims to inform stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have. The Roadmap is provided for information purposes only and its content may change. This Roadmap does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content.

A. Context, problem definition and subsidiarity check

Context

Recent outbreaks of measles with fatal outcomes, the activity of anti-vaccines groups or claims about lower vaccination status of incoming migrants and refugees all draw increased political attention on vaccination. This was highlighted by President Juncker in his State of the Union Speech and letter of intent. Vaccination programmes face major challenges: declining coverage, supply shortages and growing vaccine hesitancy. These are hard to address, as vaccination programmes are planned, organised, and conducted very differently across Member States. A Council Recommendation, reflecting Commission and Member States' commitment to pursue actions with EU added value, will strengthen cooperation and coordination between EU countries, industry and other relevant stakeholders to help increase vaccination coverage, foster the alignment of vaccination schedules across the EU, promote vaccine acceptance, support vaccine research and strengthen vaccine supply, procurement and stock management, especially in cases of emergency. These activities will decrease the incidence of vaccine preventable diseases.

Problem the initiative aims to tackle

Vaccination is the main tool for primary prevention of disease. Currently, Europe is facing avoidable large measles outbreaks in a number of countries. Even worse, Europe is exporting measles to other parts of the world. In addition, the risk of poliovirus re-introduction or importation to the EU remains a possibility, putting the current EU polio-free status at risk and undermining the global polio eradication initiative. Seasonal influenza vaccination currently prevents up to 37,000 deaths each year in the EU. Yet, seasonal influenza vaccination coverage rates in the majority of EU countries are significantly below the agreed objective of 75 % for elderly.

The following drivers contribute to low levels of vaccine coverage and preventable immunisation gaps:

- Misconceptions about vaccination have shifted the public focus away from the individual and collective benefits of vaccination to increased distrust of science and fear of possible side effects. There are a number of factors at play in this increased reticence: a lower acceptance of any potential risks associated with vaccines administered to healthy persons (in particular children); a lack of understanding on the individual versus community benefits of vaccination; a lack of reliable and trustworthy information; and media controversies on vaccine safety fuelled by anti-vaccination activists. The fact that vaccine preventable diseases have decreased, thanks to routine vaccination in the past, has also increased public complacency about the overall need for vaccination. Vaccination programmes vary considerably between countries regarding vaccines included, type of vaccine used, total number of doses administered, and timing of vaccinations. This variance between Member States is often due to social, economic, or historical factors, but also different needs related to how the healthcare system is organised at national level. All childhood immunisation schedules have been shown to work well both in terms of safety and effectiveness, however such differences across countries have sometimes given rise to a perception of diverging opinions on the vaccines themselves, which in turn could add to growing vaccine hesitancy as well
- A number of countries are facing vaccine shortages due to both supply and demand issues. Industry disinvests in the EU alleging a fragmented and partially unpredictable demand and legal difficulties persist in sharing vaccines across borders in case of crisis; production capacity is limited by long lead times;

procurement processes remain cumbersome and inefficient and the lack of forecast planning coupled with a variety of vaccination schedules contributes to render the demand unpredictable.

- There are also challenges related to research and development for new and existing vaccines. Substantial financial investment and expertise is needed for the development of new innovative vaccines and the improvement or adaptation of existing ones (e.g. improved safety profile, adaptation to different age risks groups or pathogens) much more complex, challenging, costly and risky.

These challenges have left a number of EU Member States facing difficulties in implementing national or regional immunisation programmes over the last few years. Changes in the demography of the target population due to migration flows and ageing are also hampering proper forecast planning. Some Member States are experiencing problems with vaccines availability and/or face high costs of vaccines – which also mean that national stockpiles are often not available or limited in scope.

Basis for EU intervention (legal basis and subsidiarity check)

Vaccine-preventable diseases are major health scourges as referred in Article 168 TFEU, which gives the EU the overall competence to support, coordinate or supplement the actions of the Member States for the protection and improvement of human health. Vaccination programmes are the responsibility of Member States. However, due to the cross-border nature of vaccine-preventable diseases and challenges to national vaccination programmes, some Member States have requested support, suggesting the need for common EU action and more coordinated approaches to limit the spread of epidemics and cross border diseases. There is clear added-value to strengthen cooperation among all critical sectors at EU level, including health authorities, vaccine industry, research and innovation, healthcare and others. This will result in better data and vaccine supply/stock management, increasing consistency and transparency of the assessment of new vaccines. This will also allow better fight vaccine sceptical activist groups. Member States are broadly united on the benefits of vaccination and a Council Recommendation will allow to present a joint position on science-based risk assessments and risk management, intensifying the fight against vaccine hesitancy and improving the effectiveness of EU vaccine Research and Development..

B. What does the initiative aim to achieve and how

The Council Recommendation aims at strengthening coordination between Member States, and cooperation with industry and other relevant stakeholders at EU level to reinforce and consolidate vaccination programmes all over Europe, increase vaccination coverage and enhance EU level preparedness in health. It aims to:

- ensure equal access to vaccines to the EU population reaching out to the most vulnerable;
- establish a sustainable mechanism of cooperation at EU level for vaccine policy development and implementation in Member States;
- align and coordinate vaccination calendars/schedules within a medium-term horizon (e.g. 5-10 years) by facilitating dialogue and cooperation between Member States;
- effectively tackling vaccine hesitancy by addressing vaccine concerns, improving citizens trust in vaccines and support for vaccination by health professionals and health authorities for example through analysis, information exchange and training;
- explore possible ways of improving vaccine supply and availability, also by looking at the feasibility of EU level arrangements for procurement and stock management, including through vaccine stockpiles;
- contribute to improving crisis management and preparedness in health across Europe through activation of existing mechanisms and tools, where vaccines can be mobilised to control outbreaks in third countries
- ensure that research and innovation agendas and plans support the development of safe, innovative, better targeted and more effective vaccines;
- support Member States in achieving the Sustainable Development Goals (SDG), especially SDG 3.3 on eliminating and combating communicable diseases.

The Recommendation will be structured along three areas with clear and concrete deliverables: tackling vaccine hesitancy; sustainable vaccine policies in the EU; and EU coordination, including the promotion of stakeholders' dialogue and contribution to global health. It will address recommendations to Member States, the European Commission and joint recommendations to both, taking into account ongoing UN and other global health initiatives (WHO and UNICEF) and national developments. This will include a common approach towards an EU vaccination schedule and an EU vaccination card and registries, establishing EU vaccine stockpiles for emergency situations, and an EU research and innovation agenda for vaccination. A Council Recommendation requires the active approval of Member States, guaranteeing their engagement and commitment.

The Council Recommendation on vaccination will exploit synergies with related EU actions and policies e.g. the Communication on protecting citizens against health threats, the Agenda on Security, the Action Plan against Antimicrobial Resistance, the Communication on digital transformation of health and care, and the work on crisis management and preparedness in health of the Commission.

C. Better regulation

Consultation of citizens and stakeholders

A public consultation will be launched in December 2017 for 12 weeks open to citizens, patient organisations, the

vaccine industry, health professionals associations, civil society, international organisations the scientific community. The questionnaire will be made available in all EU official languages. Replies can be made in any of the official EU languages.

A consultation through the Health Policy Platform will also be performed and targeted consultations through specific meetings with: vaccine industry and health professionals associations (doctors, nurses, pharmacists, public health professionals).

The results of all consultation activities will be summarised in a synopsis report.

Evidence base and data collection

No impact assessment is needed for this initiative as it will not introduce new regulatory requirements beyond what already provided or planned through relevant existing policy instruments. The Recommendation will aim to set out policy orientations for, and better coordination of, the implementation at Member State level of existing policy instruments (including the Council recommendation on seasonal influenza vaccination (2009), the Council conclusion on childhood immunisation (2011) and the Council conclusions on vaccination as an effective tool in public health (2014)).

The Recommendation will be based on the objectives of the Council conclusions on vaccination as an effective tool in public health (2014); the report on the implementation of Decision 1082/2013 on serious cross-border threats to health (2015); the report of the high-level hearing on the implementation of the Council recommendation on seasonal influenza vaccination (2015); the European Court of Auditors Special report 28/2016 Dealing with serious cross-border threats to health in the EU (2016); the final report of the SANTE high level workshop "Seeking new partnerships for EU action on vaccination" (May 2017); the midterm review of the Digital single Market (potential of big data high performance computing for infectious diseases outbreaks, 2017); and the objectives of the joint action on vaccination (start 2018), co-funded by the Health Programme.

The Recommendation will be accompanied by a Staff Working Document presenting the potential impacts of the different recommendations