



Brussels, 26.4.2018
COM(2018) 245 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

Strengthened Cooperation against Vaccine Preventable Diseases

INTRODUCTION

Vaccination has brought immense health and socio-economic benefits to individuals, populations and society as a whole. It is one of the most cost-effective public health interventions, a mainstay of prevention programmes worldwide, and the elective primary prevention measure against infectious diseases.

Thanks to vaccination, humanity managed to wipe out smallpox, which caused at least three hundred million deaths in the 20th century alone; and the complete eradication of polio, another extraordinary threat to human health, is now well within reach. The World Health Organisation estimates that, today, vaccines save between 1 and 3 million lives every year¹, and in the coming decade vaccines are projected to save 25 million more people². In all EU Member States, diseases such as diphtheria and tetanus are now very rare events, and tremendous progress has also been achieved in the control of diseases such as pertussis and rubella.

Yet in spite of the overall benefits of vaccination, a number of key challenges still remain to ensure sustainable, equitable and effective vaccination programmes in all Member States, and to secure that the added benefits of vaccination are not lost.

The most pressing challenges include overcoming vaccine hesitancy (the delay in acceptance or refusal of vaccines despite availability of vaccination services), halting the spread of vaccine preventable communicable diseases, sustaining high vaccine coverage, and guaranteeing equal access to vaccination across all ages and populations. The financial sustainability of vaccination programmes is also key, to ensure stronger support to monitor the impact and effectiveness of vaccines, to mitigate the risk of shortages, and to tackle vaccine hesitancy and its impact on immunisation programmes. Hesitancy is a growing concern in Europe and worldwide, which risks undermining the public health value of vaccination.

In recent years, significant outbreaks of vaccine-preventable diseases and a number of events with cross-border relevance have brought to the fore the continued gaps the EU is facing in vaccination coverage. Measles is a particular challenge. In the last years, the EU has experienced a dramatic resurgence of the disease. More than 14,000 cases of the disease were notified in 2017 alone³, which is more than three times the number of cases reported in 2016. The root cause remains a sub-optimal vaccine uptake below the minimum required 95%. Europe is failing to eliminate measles in line with agreed WHO targets⁴ and the accumulation over time of susceptible children, estimated at close to 4 million between 2006 and 2016⁵, calls for political and public health action.

Recent fatal cases of diphtheria in the EU have also reminded that individuals who are not immunised against diseases rarely seen remain at risk⁶. In 2016, vaccination coverage for diphtheria, tetanus and pertussis among children in the EU was below the required 95%⁷, and there is still a need to ensure continued protection in adulthood, particularly travellers, older people, as well as those with social connections to endemic countries.

¹ WHO, Immunization Coverage, Fact Sheet 2018, <http://www.who.int/mediacentre/factsheets/fs378/en/>

² Rappuoli R (2014), DG Research New Horizon for Vaccine Conference, https://ec.europa.eu/research/health/pdf/event17/s2-2-rino-rappuoli_en.pdf

³ ECDC. Monthly measles and rubella monitoring report, January 2018, <https://ecdc.europa.eu/sites/portal/files/documents/Monthly%20measles%20and%20rubella%20monitoring%20report%20-%20JAN%202018.pdf>

⁴ <http://www.euro.who.int/en/media-centre/sections/press-releases/2018/europe-observes-a-4-fold-increase-in-measles-cases-in-2017-compared-to-previous-year>

⁵ These estimates refer to children in the vaccination target group below 2 years of age, ECDC, unpublished.

⁶ ECDC. A fatal case of diphtheria in Belgium, 24 March 2016, <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/RRA-Diphtheria-Belgium.pdf>

⁷ 2016 WHO/UNICEF Estimates of National Immunization Coverage http://www.who.int/immunization/monitoring_surveillance/who-immuniz.pdf?ua=1

Seasonal influenza vaccination rates in the EU remain significantly below the 75% coverage target for those above 65 years⁸, and seem to be further declining⁹. Despite evidence of the severity of influenza among older people, only one EU Member State has reached the coverage target¹⁰.

A number of disease outbreaks in the last years have been linked to transmission by healthcare workers. This is alarming and raises fundamental patient safety issues. Directive 2000/54/EC¹¹ on the protection of workers from risks related to biological agents and Directive 2010/32/EU implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU¹² lay down minimum requirements to ensure healthcare workers' protection, including the need to offer vaccines to those not previously immunised.

These challenges require intervention on several fronts, including better understanding the underlying causes of the declining coverage. Investment not only in monetary terms but also in training of healthcare workers on vaccination is essential. Such investment should be seen as 'smart' spending with a view to preventing illness at the related avertable costs to the healthcare system, and as a contribution to overall goals of efficiency and sustainability¹³.

While these challenges affect Member States in different ways, EU-wide action is needed to achieve meaningful progress and turn political visions into effective operational vaccination plans at national and EU level, to protect citizens' health in accordance with Article 168 of the Treaty on the Functioning of the European Union. Vaccine preventable diseases are not confined within national borders. One Member State's immunisation weakness puts at risk the health and security of citizens across the EU.

This Communication presents a framework for actions to be undertaken by the Commission, with the collaboration of Member States, under three key pillars 1) tackling vaccine hesitancy and improving vaccination coverage; 2) sustainable vaccination policies in the EU; 3) EU coordination and contribution to global health. The magnitude of the challenges ahead requires close cooperation between all stakeholders. This is why the Commission will also present a Council Recommendation on strengthened cooperation against vaccine preventable diseases so that Member States and the Commission work hand in hand. The Communication and the proposed Council Recommendation also contribute to implementing the European Pillar of Social Rights and to meeting the Agenda 2030 Sustainable Development Goals.

⁸ Council Recommendation on seasonal influenza vaccination, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>

⁹ Commission SWD 2014 on State of play on implementation of the Council Recommendation on seasonal influenza vaccination, https://ec.europa.eu/health/sites/health/files/vaccination/docs/seasonflu_staffwd2014_en.pdf

¹⁰ ECDC Overview of vaccination recommendations and coverage rates in the EU Member States for the 2013–14 and 2014–15 influenza seasons. <http://ecdc.europa.eu/en/publications/Publications/Seasonal-influenza-vaccination-antiviral-use-europe.pdf>

¹¹ Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0054&from=EN>

¹² Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU, <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32010L0032&from=EN>

¹³ Commission SWD on Investing in Health https://ec.europa.eu/health/sites/health/files/policies/docs/swd_investing_in_health.pdf

PILLAR I – Tackling vaccine hesitancy and improving vaccination coverage

Key challenges

Vaccine hesitancy and its impact on immunisation programmes are a growing concern in Europe and worldwide. In Europe, safety-related concerns are a key determinant of hesitancy¹⁴ for both members of the public and healthcare professionals¹⁵. This is despite the fact that vaccines in the EU undergo rigorous testing both pre- and post- licensure, in line with Directive 2001/83/EC¹⁶ and Regulation (EU) No.726/2004¹⁷. The decrease in certain diseases incidence together with action undertaken by anti-vaccination activists, have led to a shift of focus from the dangers, and even risk of death, posed by unseen diseases towards fear of unproven side events. In addition, the rapid spread of disinformation, understood as verifiably false or misleading information, through online media make sifting science facts from unfounded claims a real challenge for those seeking trustworthy information on vaccines.

Vaccine hesitancy is highly specific to the context, country, and type of vaccine, and the public perception of a given vaccine can change rapidly. This means that there is no one-size-fit-all solution, and a sustainable investment in improving dialogue with citizens, understanding their concerns, and developing tailored intervention strategies is required.

Healthcare workers are especially important, as they remain, rightly, the most trusted source of information for patients. They are best placed to understand hesitant patients, respond to worries, and explain the benefits of vaccination. However, healthcare workers themselves can be vaccine-hesitant, whether considering vaccination for themselves or their patients. Continuous training of all healthcare workers during their studies and once in professional practice is a priority in order to build a confident healthcare workforce that can advise the public on vaccination needs and deliver immunisation effectively.

Vaccine hesitancy in Europe can also be driven by issues related to the affordability, geographical accessibility, or availability of information on immunisation. Access to vaccination must be widened and made easier to the recipient, particularly for vulnerable and underserved communities. This involves removing legal, financial or structural barriers to improve equity in access, but also considering the expansion of points to deliver vaccination, such as through community-based services, which include nurses, pharmacies or school-based programmes. Vaccination should be systematically integrated as part of routine preventative services at different stages of life. Any encounter with the healthcare system should be used as an opportunity for catch-up vaccinations to close immunity gaps.

Improving access to high-quality objective and transparent information on vaccines and vaccination, including on effectiveness and safety aspects, is crucial.

¹⁴ Larson H, De Figueiredo A, Xiaohong Z, et al. The State of Vaccine Confidence 2016: Global Insights Through 67-Country Survey. *EBioMedicine* 2016;12:295–30.

¹⁵ ECDC Vaccine hesitancy among healthcare workers and their patients in Europe, 2015.

<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/vaccine-hesitancy-among-healthcare-workers.pdf>

¹⁶ Directive 2001/83/EC on the Community code relating to medicinal products for human use, [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF)

¹⁷ Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf

It is also essential to be able to establish a sustainable and reliable monitoring system of vaccination coverage rates across all ages, geographies, and also population subgroups, e.g. healthcare workers. As hesitancy differs across countries, populations and vaccines, having reliable stratified coverage data can help detecting sub-groups with lower uptake, assess the root-cause, and thus tailor the necessary intervention. EU action should allow the standardisation of tools and methodologies to assess and report on coverage data across all ages, beyond the traditional paediatric age group, leveraging, in particular, the potential of electronic immunisation information systems.

Priority activities

Priority activities should aim to:

- Strengthen the monitoring of vaccine uptake across all age groups, including healthcare workers, according to common guidance and methodologies, and share such data at EU level;
- Strengthen the effective application of Union rules on protection of healthcare workers, in particular by ensuring adequate training of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary;
- Convene a Coalition for Vaccination to bring together European associations of healthcare workers to commit to delivering accurate information to the public, combating myths and exchanging best practice;
- Optimise awareness-raising activities, including through partnerships with the education sector, social partners and action directed towards the media;
- Combat the spread of disinformation in the digital era and counter disinformation spread across borders;
- Produce, in the context of the State of Health in the EU process, a *State of Confidence in Vaccines in the EU* report to generate data for action at national and EU level;
- Improve access to objective and transparent information on vaccines and their safety, following the assessment of information needs on the part of both public and healthcare workers;
- Identify the barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups;
- Foster behavioural research to better understand context-specific determinants of hesitancy from the end-user perspective, and design tailored intervention strategies;
- Develop evidence-based tools and guidance at EU level in order to support countries to anticipate, pre-empt or respond to crises situations.

PILLAR II – Sustainable vaccination policies in the EU

Key challenges

Budgetary pressures, demographic shifts, and changes in the vaccine ecosystem pose challenges to the sustainability of vaccination policies in EU Member States.

Immunisation programmes are a national competence, and thus decisions on the introduction, funding, and implementation of vaccination policies remain at the national level. As a result, vaccination schedules vary between Member States on aspects such as timing, doses administered, type of healthcare workers involved in the delivery and vaccine purchasing practices. The differences are often due to social, economic and historical factors, or, simply, how the healthcare system is organised. Regardless of the differences, all immunisation schedules have been shown to achieve their objective of disease prevention provided there is a high and timely uptake. At EU level this diversity may however lead to difficulties for citizens and healthcare workers in resuming vaccination when moving across borders. They may not understand the rationale for different policies across countries, raising doubts on the scientific base for the decision-making of vaccination policies.

Varying systems are also in place to document individual immunisation history, ranging from paper-based records to advanced electronic information systems. Differences exist as to the formats and languages used, but also with regards to the type of information recorded. Such differences may be at the expense of the quality of vaccination records, and may at times pose practical issues in the effective documentation of immunisation history, but also in the communication between different providers within and across countries.

In addition to efficient record keeping, a comprehensive electronic immunisation information system in Member States can provide large data banks to strengthen the sustainability and performance of vaccination programmes. Effort is needed at EU and Member State level to develop operational guidelines and remove infrastructural, legal and standardisation barriers to facilitate interoperability and electronic data sharing in the area of vaccination, and harness the deployment of immunisation information systems to inform operational and strategic decisions.

In addition, with an increasing number of vaccines licensed for different age groups, decision-making on their introduction and monitoring is becoming increasingly complex. There is value in better EU-coordinated efforts and pooling of joint EU technical expertise to assess the evidence in the pre- and post-licensing phase of a vaccine. In the pre-licensing phase, EU collaborative approaches can improve the qualitative and quantitative efficiency of the decision-making process while maintaining a strong and coordinated network of national vaccine experts. Post-authorisation passive and active monitoring and specifically designed studies are also needed to provide further real-life robust evidence on the safety, effectiveness, and impact of vaccines after use, and overcome current fragmented efforts at EU level.

Furthermore, ageing, mobility of people, and the shift in the burden of traditional vaccine-preventable diseases from childhood to later years of life call for a careful assessment of the cost-effectiveness of a life-course approach to vaccination. Adult vaccination, questions around immune-senescence (loss of immunity over time), and new vaccines licensed for adults and older people are becoming central topics of interest, with the potential for public health and economic gains. While all Member states have well established vaccination programmes for children, vaccination recommendations and programmes for adults, where they exist, differ greatly.

At the same time, recent events of shortages and discontinued supply of traditional vaccines have hampered the effective delivery of routine childhood immunisation programmes. Challenges linked to vaccine shortages cut across both demand and supply side issues, and include production issues, limited supplier base and production capacities, global increase in demand, as well as insufficient forecasting services, inflexible procurement design and limited stockpiling options.

The current EU health instruments do not enable the procurement of routine vaccines at EU level. For this reason, methods for working with Member States for mutual exchange of surpluses and the possibility of developing a concept for a possible stockpile at EU level should be explored.

As regards vaccine research and development, innovative approaches and novel vaccines are needed to better address the unmet public health needs and specific target group needs. This includes the need for vaccines as complementary tools to antibiotics in the global fight against antimicrobial resistance. There are also technical bottlenecks which span the entire product development pipeline, and novel adjuvants are needed for vaccines for which conventional formulations have failed.

Priority activities

Priority activities should aim to:

- Develop EU guidance for establishing comprehensive electronic immunisation information systems for effective monitoring of immunisation programmes;
- Develop guidance to overcome legal/technical barriers to interoperability and linkages with the broader healthcare system infrastructure;
- Develop a common EU citizens vaccination card retrievable through electronic information systems and recognised for use across borders, in view of standardising the reporting on immunisation history;
- Strengthen the efficiency and consistency of decision making on vaccines/vaccination policies by facilitating technical cooperation between public health authorities in support of the work conducted by National Immunisation Technical Advisory Groups and affiliated bodies;
- Create a sustainable and multi-stakeholder platform for EU post-authorisation studies monitoring the safety, effectiveness, and impact of vaccination;
- Develop common methodologies to assess the relative effectiveness of vaccines, including as part of the EU cooperation on Health Technology Assessment;
- Establish guidelines for a core EU vaccination schedule to facilitate compatibility of national schedules and promote equity in citizens' health protection, that can be used as reference to optimise national schedules, as well as meet the needs of citizens moving across borders;
- Mitigate risks of shortages by developing a virtual EU data warehouse on vaccine needs to facilitate voluntary exchange of information on available supplies and shortages of essential vaccines;
- Identify options for physical stockpiling at EU level by engaging in dialogue with vaccine producers;
- Establish partnerships and research infrastructures, including for clinical trials, facilitating early dialogue with developers, public health organisations and regulators to support the authorisation of innovative vaccines, including for emerging health threats;
- Bolster the effectiveness and efficiency of EU and national vaccine research and development funding and develop a roadmap on priority areas of needs.

PILLAR III. EU coordination and contribution to global health

Key challenges

Policy coordination on vaccination at EU level remains limited and follows a reactive, case-by-case basis. Equally, there are no operational structures to enhance EU cooperation in order to address vaccine challenges, including the current fragmented vaccine research and development landscape.

Vaccination is a global issue and thus international coordination aspects remain crucial. There is a strong need for better global preparedness against communicable diseases, and the impact of strong immunisation programmes in the EU and worldwide is key to the success of the International Health Regulations. In recent years, the G7 and G20 have addressed global health including health security. Vaccination is an area which could receive further political impetus if addressed by these groups.

The World Health Organisation Global Vaccine Action Plan (GVAP) is a framework to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities. In May 2017, Ministers of Health from 194 countries endorsed a new resolution on strengthening immunisation to achieve the goals of the GVAP. The resolution calls on countries to expand immunisation services beyond infancy, mobilize domestic financing, and strengthen international cooperation.

Immunisation will also play an important role in achieving the 2030 Sustainable Development Goals (SDGs). SDG 3 on ensuring healthy lives and promoting well-being for all at all ages, underlines the importance of vaccines in protecting people against disease. With the European Consensus on Development “Our World, Our Dignity, Our Future”, the EU and the Member States expressed strong commitment to the implementation of the 2030 Agenda. In this context, the EU and its Member States have reaffirmed their commitment to protecting the right of everyone to enjoy the highest attainable standard of physical and mental health, including helping secure access to affordable essential medicines and vaccines for all. The EU development policy line concerning the health sector in developing partner countries is one of strengthening health systems to achieve universal health coverage. This approach is also followed in the EU support provided to several Global Health Initiatives including GAVI the Vaccine Alliance.

The Commission has supported GAVI since its inception in 2000 providing EUR 83 million until 2015 and a further pledge of EUR 200 million for the period 2016-2020. The Commission and a number of Member States are also working to coordinate vaccine research and development with other research funders from around the world. The primary forum for this coordination is the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)¹⁸, a network that includes nearly 30 research funders as well as the WHO and the Coalition for Epidemic Preparedness Innovations (CEPI) as observers. Through GloPID-R, research funders are developing a strategic research agenda for infectious diseases with pandemic potential, and the network responds to major disease outbreaks by launching clinical studies, including for vaccine development.

Priority activities

The main activities should aim to:

¹⁸ Global Research Collaboration for Infectious Disease Preparedness <https://www.glopid-r.org/>

- Develop operational opportunities at EU level, such as the European Vaccination Information Sharing system, to increase coordination on relevant vaccination activities
- Exploit the opportunities offered by the European Social Fund (ESF) and European Regional Development Fund (ERDF) in order to reinforce national and regional health infrastructures capacities in the area of vaccination.
- Strengthen partnerships and collaboration with international actors and initiatives, such as the World Health Organisation and its Strategic Advisory Group on Immunization (SAGE), the European Technical Advisory Group of Experts on Immunization (ETAGE), the Global Health Security Initiative, Global Health Security Agenda, UNICEF and financing and research initiatives like GAVI The Vaccine Alliance and the Coalition for epidemic preparedness innovations (CEPI) and the Global Research Collaboration for Infectious Diseases Preparedness (GloPID-R)

Conclusions

Cooperation at EU level in the area of vaccination will complement and support national vaccination policies. Concerted actions will enhance the sustainability of national vaccination programmes and strengthen national capacities to tackle growing vaccine hesitancy, global vaccine shortages, disinvestment of vaccine manufacturers, and lack of coordination in vaccine research and development.

More effective and efficient operational tools, structures and mechanisms will improve cooperation among all stakeholders involved at EU level. This cooperation will increase synergies between vaccination and related policies, including those on crisis preparedness, e-health, Health Technology Assessment, R&D and pharmaceutical industry. It will thus contribute to the effectiveness and efficiency of national health systems and improve health security within Europe and beyond, while respecting country specificities and the competences of EU national and regional authorities.

Synergies with international initiatives such as GAVI and CEPI should also be sought. Mechanisms for better preparedness, detection and response against vaccine preventable health threats, linking to EU preparedness planning and the implementation of the International Health Regulations should include provisions to ensure support to poorer countries, particularly in cases of emergency.