



Council of the
European Union

Brussels, 4 May 2018
(OR. en)

8679/18

**Interinstitutional File:
2018/0115 (NLE)**

**SAN 137
PHARM 26
MI 322
SOC 232
RECH 167
EDUC 149
TELECOM 122**

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	26 April 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2018) 244 final
Subject:	Proposal for a COUNCIL RECOMMENDATION on Strengthened Cooperation against Vaccine Preventable Diseases

Delegations will find attached document COM(2018) 244 final.

Encl.: COM(2018) 244 final



Brussels, 26.4.2018
COM(2018) 244 final

2018/0115 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

on Strengthened Cooperation against Vaccine Preventable Diseases

{SWD(2018) 149 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Vaccination is one of the greatest successes of medicine. Vaccination saves lives, protects our societies, reduces illness and contributes to longer life expectancy. Before vaccines existed, many children would die young, or become crippled for life. Vaccination has led to the eradication of smallpox, near elimination of polio and has prevented countless deaths from many other diseases such as measles, diphtheria and meningitis.

Worldwide, every year, vaccination prevents 2.7 million people from contracting measles, 2 million from getting neonatal tetanus, and 1 million from getting pertussis. In Europe, seasonal influenza vaccination prevents around 2 million people from getting influenza each year.

And yet, as mentioned in the President Juncker State of the Union speech of 13 September 2017, today, in the European Union, children are still dying from diseases such as measles that can easily be prevented with vaccines. This is unacceptable.

Vaccination programmes have become increasingly fragile; in the face of low uptake of vaccines, vaccine hesitancy, the increasing cost of new vaccines and shortages in vaccine production and supply in Europe.

This proposal is a call for joint action to increase vaccination coverage and to ensure that everybody in the European Union has access to vaccination bridging inequalities and gaps in immunisation. The genuine questions and doubts surrounding vaccination, expressed by citizens throughout Europe, signal the urgent need for Member States and the health community to recognise and respond accordingly. This proposal is a concerted effort to respond to such concerns.

Several EU Member States and neighbouring countries are currently facing unprecedented outbreaks of vaccine-preventable diseases, due to insufficient vaccination coverage. In 2017 alone, in the EU, over 14,000 people contracted measles - more than three times the number reported in 2016. In the past two years, 50 persons died due to measles and two due to diphtheria. Europe is failing to eliminate measles in line with agreed WHO targets.

The risk of poliovirus reintroduction in the EU persists, putting the Union's polio-free status at risk. Seasonal influenza vaccination coverage rates remain significantly below the 75% coverage target for older age groups set out by the 2009 Council Recommendation on seasonal influenza vaccination. In fact, seasonal influenza vaccination coverage in older age groups has decreased in the past few years in the majority of EU Member States.

While national vaccination programmes are planned, organised, and conducted differently across Member States, all EU countries are grappling with these common challenges: declining coverage, supply shortages and growing vaccine hesitancy.

There are several drivers contributing to low levels of vaccine coverage and preventable immunisation gaps:

Vaccine hesitancy and waning confidence. Misconceptions about vaccination have shifted the public focus away from the benefits of vaccination, towards a distrust in

science and fear of possible side effects. There are a number of factors at play in this increased reticence: a lack of reliable information and, in some cases, distrust in the providers of available information; 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; and media controversies on vaccine safety fuelled by misinformation. As vaccine-preventable diseases have decreased thanks to routine vaccination in the past, citizens are not sufficiently aware of the vital role of vaccination in saving lives and the risks of nonvaccination.

Vaccination policies and programmes vary considerably between countries regarding the selection of vaccines, type of vaccine used, number of doses administered, and timing. This variance between Member States is often due to social, economic, or historical factors, or simply due to how the healthcare system is organised at national level. However, such variances across countries have added to a perception of diverging opinions on the vaccines themselves, which in turn contributes to the growing levels of vaccine hesitancy. The rapid spread of disinformation through online media and vocal vaccine deniers has also fuelled misconceptions. In addition, given such differences in national vaccination schedules, citizens who live in a number of EU Member States throughout their lives face difficulties in understanding which vaccine to take when, which can result in children not taking all the vaccines they need.

A number of countries are also facing vaccine shortages due to both supply and demand issues. There is an industry disinvestment in vaccines in the EU, allegedly due to a fragmented and partially unpredictable demand. In addition, legal difficulties persist in sharing vaccines across borders in case of crisis. At the same time, production capacity is limited by long lead times; procurement processes remain cumbersome and inefficient and the lack of forecast planning coupled with the variance of vaccination schedules render the demand unpredictable. Changes in the demography of the target population due to migration and ageing are further hampering accurate forecast planning.

As a result, some Member States are experiencing problems with vaccines availability or face high costs of vaccines – which in turn means that national stockpiles are often not available or limited in scope. In this context, if a Member State is not able to control an outbreak on its own, in the absence of European co-operation in this area, such outbreak is likely to spread across borders to other Member states, putting citizens' health and security at risk throughout the Union.

There are also challenges related to research and development of 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 ages, risk groups or pathogens), which makes research and development much more complex, costly and risky.

Finally, on the resource side, there are constraints linked to public financing. Vaccination currently represents a minor fraction of prevention budgets in EU countries, accounting for up to 0.5% of the healthcare budgets and there is evidence that spending is further decreasing. Spending on vaccination should be regarded as an essential and smart investment in health, given its broader economic impact and societal value.

This Council Recommendation, is aimed at strengthening cooperation and coordination between EU countries, industry and other relevant stakeholders to help increase vaccination coverage, foster the possibility of alignment of vaccination schedules across the EU, promote vaccine acceptance, support vaccine research and development and strengthen vaccine supply, procurement and stock management, including in cases of emergency. These activities should ultimately decrease the incidence of vaccine preventable diseases and increase the health prospects of European citizens, and improve health security in the European Union as a whole.

The proposal sets out recommendations to the Member States, joint actions by the Member States and the Commission, and welcomes the Commission's intention to carry out a number of initiatives, taking into account ongoing UN and other global health initiatives.

The Recommendation envisages a possibility of establishing a European Vaccine Information Sharing System with a view to **developing guidelines on a EU common vaccination schedule, an EU vaccination card** and a **web-portal** with reliable updated information on the benefits and safety of vaccinations.

Providing possible options towards developing a **common EU vaccination card** would ensure the continuity of immunisation when citizens, in particular children, move from one Member State to another. Currently, the wide variety in vaccination schedules and recording poses practical issues for effectively tracking, monitoring and documenting immunisation history, as well as for communication between different vaccine providers within and across countries. Key issues include: vaccination documentation in national language only; issues around recalling whether vaccinations were given and which doses; lack of recognition and ability to continue an immunisation series already initiated in the country of origin, especially if the child is in the middle of a vaccination course that is part of the schedule of the country of origin but not of the country of destination. A common EU card with an agreed core set of information for each vaccination could facilitate interpretation of vaccination records, facilitate movement of citizens and lower barriers to vaccination while providing both citizens and health providers with the relevant information they need to ensure that citizens are immunised against vaccine preventable diseases. In the 2009 Commission stakeholder consultation on childhood vaccination, 87% of the respondents were positive towards having a common EU vaccination card.

The Recommendation further advocates **creating a virtual data warehouse of vaccine needs and stocks** which could enable Member States and the Commission to identify available stocks of vaccines in cases of outbreaks or severe shortages and to mutually exchange the surpluses. In addition, it envisages identifying the options for a **physical stockpile of vaccines** to be available in cases of serious outbreaks or global shortages. Furthermore, it foresees a **Coalition for Vaccination** bringing together representatives of healthcare workers associations and relevant student associations to commit to increasing vaccination coverage in Europe.

The proposed identification of options for a possible vaccine **stockpile** stems from the fact that many EU Member States are experiencing shortages of routine vaccines. Each Member State needs to have preparedness plans in place and hence the Recommendation calls for improving forecasting processes. To assist Member States in covering short term shortages as a result of, for example, disease outbreaks, underestimating stocks or manufacturing disruptions or extraordinary events, such as an influx of migrants, a concerted EU assistance would be very beneficial. A 2015

risk assessment report on vaccine shortages by the European Centre for Disease Prevention and Control concludes that vaccine shortages in the EU/EEA appeared to be more significant than in the past and concluded it is advisable for countries to plan for stockpiles for routine programmes to avoid disruptions of immunisation in case of future shortages. Member States have already requested vaccines from the Commission to overcome shortages via the EU Health Security Committee. However, the current EU health funding instruments do not enable the procurement of vaccines. For this reason, the Commission now plans to work with Member State experts and in dialogue with industry to identify options for a stockpile at EU level, also taking into account the call by the European Parliament on the Commission and the Member States to develop solutions to increase vaccine supply and availability, including arrangements for stockpiling vaccines.

- **Consistency with existing policy provisions in the policy area**

The Council Recommendation on vaccination is consistent with, and builds further upon, the existing policies in the area of vaccination. 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 also takes into account 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); Joint Procurement Agreement to procure medical countermeasures and the objectives of the Joint Action on Vaccination (start 2018), co-funded by the Health Programme.

The Recommendation is consistent with EU actions and policy in the area of occupational safety and health and with the principles of the European Pillar of Social Rights, especially Principle 10 on health and safety at work and Principle 16 on universal access to preventative and curative health care.

- **Consistency with other Union policies**

The Recommendation will exploit synergies with related EU actions and policies e.g., the Agenda on Security, the 2030 Agenda for Sustainable Development, the European One Health Action Plan against Antimicrobial Resistance, the Communication on digital transformation of health and care, the Communication on online disinformation, current and future EU framework programmes for Research and Innovation, and the European Structural and Investment Funds.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities as referred to in Article 168(1) TFEU. Union action, which shall complement national policies, shall be directed

towards improving public health, preventing physical and mental illness and disease, and obviating sources of danger to physical and mental health.

In accordance with Article 168(6) TFEU the Council, on a proposal from the Commission may adopt recommendations for the purposes of that Article to improve public health, in relation to in particular fight against major health scourges, monitoring, early warning of, and combating serious cross-border threats to health. Vaccine-preventable diseases are considered major health scourges. The Union action in the field must respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

- **Subsidiarity (for non-exclusive competence)**

Vaccination programmes are the responsibility of Member States. However, 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, and all Member States are facing the vaccination challenges highlighted above. Due to the cross-border nature of vaccine-preventable communicable diseases, Member States have requested intensified EU level support, and stressed the need for common EU action and more coordinated approaches to limit the spread of vaccine-preventable diseases across borders.

There is clear added value in strengthening cooperation among all relevant sectors at EU level, including health authorities, the vaccine industry, research and innovation, and healthcare actors. A Council Recommendation requires engagement, commitment and endorsement by the Member States. Moreover, Member States are broadly united on the benefits of vaccination and a Council Recommendation will enable the presentation of a joint EU position reflecting science-based risk assessments and risk management, reducing the impact of vaccine hesitancy, building public confidence and cooperation and improving the effectiveness of EU vaccine research and development. At the same time, it respects Member States competence for the definition of their health policy and for the organisation and delivery of health services and medical care.

- **Proportionality**

The proportionality principle is fully respected as the recommendations put forward are limited to actions within the respective scope and mandates of the European institutions and the Member States.

- **Choice of the instrument**

The instrument appropriate for the initiative is a Council Recommendation, providing guidance to Member States on how to strengthen cooperation, improve vaccination coverage, and as a result, reduce the impact and severity of vaccine-preventable diseases.

The Recommendation allows the EU level and the Member States to work further together to address the different dimensions of the problem at the appropriate level.

The key added value of a Recommendation is to call for action and galvanise political support to reboost policies and actions on vaccination and immunisation in Europe. This focused approach will provide the necessary political visibility, raise awareness and build momentum. Concerted efforts are needed from all Member

States and stakeholders to boost vaccine coverage, reduce immunisation gaps and increase confidence and trust in vaccination.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Stakeholder consultations

Several stakeholder consultations have been conducted to inform this initiative over the course of 2017 and in early 2018. This included an open public consultation and targeted meetings with representatives of Member States through the Health Policy Platform.

Specifically, a public consultation took place between 21 December 2017 and 15 March 2018, during which 8,984 responses were received¹.

A stakeholder consultation took place in January and February 2018, with 33 responses to a questionnaire and six targeted meetings with healthcare professionals associations, international organisations, non-governmental organisations working on public health, the scientific community and the vaccine industry.

There was a clear call for more transparent and easily accessible information on vaccination in general and in particular on the safety and potential side effects of different vaccines. The pivotal role of healthcare workers in explaining vaccination to their patients was highlighted whilst at the same time the need for more emphasis on vaccination in medical curricula and continued professional training was mentioned. There was also broad agreement that vaccination should be offered in different settings and that there is a need to simplify the process.

The consultations carried out showed that there is a high degree of Member States interest in more EU-level action on this issue, while also showing the extent of the concerns expressed by those who refuse or who are reluctant to accept vaccination as well as who oppose mandatory vaccination in some societal groups.

• Collection and use of expertise

The Recommendation relies on a thorough scientific basis and expertise, a review of established scientific consensus, an analysis of current vaccination trends derived from comparative data, and the results of a public and stakeholder consultation.

The collaboration with international expert groups, such as the World Health Organisation's Strategic Advisory Group of Experts on Immunization (SAGE) and the European Technical Advisory Group of Experts on Immunization (ETAGE), and the Global Health Security Initiative and Agenda processes has added to the EU expertise.

• Impact assessment

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.

¹ https://ec.europa.eu/info/consultations/open-public-consultation-strengthened-cooperation-against-vaccine-preventable-diseases_en; Commission Staff Working Document. Synopsis Report Accompanying the Council recommendation on Strengthened Cooperation against Vaccine Preventable Diseases

- **Regulatory fitness and simplification**

Some key expected impacts stemming from this Recommendation would be improved coordination within and among Member States and simplified monitoring and reporting criteria for vaccination and vaccine-preventable diseases.

- **Fundamental rights**

The initiative strengthens the entitlement of the European citizens to preventive and curative health care of good quality, as enshrined in the European Pillar of Social Rights.

4. **BUDGETARY IMPLICATIONS**

This Recommendation has no direct financial implications to the EU budget. All work related to Recommendations aimed at the Commission will be carried out within existing resources.

5. **OTHER ELEMENTS**

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission would monitor implementation in the Member States and review the Recommendation in cooperation with the Member States and after consulting the concerned stakeholders, ensuring a sufficiently long period to evaluate the effects of the initiative after it has been fully implemented. The effectiveness of the Recommendation could be measured on the basis of existing and new data and of information gathered through Member States' reporting.

At the same time, one of the current impediments to a comparative evaluation of European protection against these diseases is the absence of standardized tracking criteria. More standardized criteria is needed to encourage Member States to collect and publish reliable – and comparable – statistics on vaccination.

- **Detailed explanation of the specific provisions of the proposal**

Points # 1 to 9 of the Recommendation are for the consideration of the Member States, aim to accelerate the development and implementation of national vaccine action plans to meet the goals and targets of the World Health Organization's European vaccine action plan. There is also specific emphasis on measles vaccination given the current outbreak in Europe. The proposal recognises the need to simplify and broaden the opportunities for vaccination and for targeted outreach towards vulnerable groups in order to close immunity gaps. The proposal calls for educational authorities to strengthen vaccination training in medical curricula and continuous medical training for all health workers. It further highlights the need for increased communication and awareness raising activities on the benefits of vaccination. Exploiting the synergies with eHealth and digital technologies to establish electronic vaccination records for all citizens is also an important element of the proposal that would be included into the information exchange between healthcare providers across borders in the context of the work of the eHealth Network.

Points # 10 to 16 concern actions that the Commission intends to undertake in close cooperation with Member States and include aiming at establishing a European Vaccination Information Sharing system which could bring together related

vaccination information and expertise together with the national public health authorities. Under this system, various stakeholders could come together to **develop guidelines for a possible core EU vaccination schedule**, share common methodologies for monitoring coverage, and launch a web portal with transparent evidence on vaccines benefit and risks including tracking vaccine myths and misinformation. The proposal also highlights the need to strengthen the effectiveness of the existing Directive² on health and safety at work which guarantees that health workers are vaccinated against specific diseases.

Finally, to address shortages and increase supply, the proposal puts forward the idea of **creating a virtual data warehouse for Europe on vaccine needs and stocks and a mechanism for mutual exchange of vaccines among Member States; identification of options for a physical vaccine stockpile in case of outbreaks** or global shortages of vaccines and envisages working with industry and other stakeholders to improve EU manufacturing capacity of vaccines.

Points # 17 to 25 welcome the Commission's intention to carry out a number of activities including presenting options **for a common EU vaccination card** with standardised information on vaccination history; presenting a report on *the State of Vaccine Confidence* in the EU is requested in addition to actions to better understand the barriers and increase access to vaccination for disadvantaged and socially excluded groups; convening a **Coalition for Vaccination** with associations of European healthcare workers and relevant student associations aimed at promoting vaccination and strengthening partnerships and collaboration on vaccination with international partners is another important element of this proposal.

²

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 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>

Proposal for a

COUNCIL RECOMMENDATION

on Strengthened Cooperation against Vaccine Preventable Diseases

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(6) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Pursuant to Article 168 of the Treaty of Functioning of the European Union (TFEU), a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and disease, and obviating sources of danger to physical and mental health.
- (2) In accordance with Article 168(6) TFEU the Council, on a proposal from the Commission may adopt recommendations for the purposes of that Article to improve public health, in relation to in particular fight against major health scourges, monitoring, early warning of, and combating serious cross-border threats to health. Vaccine-preventable diseases are considered major health scourges.
- (3) Vaccination is one of the most powerful and cost-effective public health measures developed in the 20th century and remains the main tool for primary prevention of communicable diseases.
- (4) While vaccination programmes are the responsibility of the Member States, the cross-border nature of vaccine-preventable diseases and common challenges faced by national immunisation programmes would benefit from more coordinated EU action and approaches to prevent or limit the spread of epidemics and diseases with a cross-border dimension.
- (5) The rapid spread of disinformation through social media and vocal antivaccination activists have fuelled misconceptions that are shifting the public focus away from the individual and collective benefits of vaccination and the risks posed by communicable diseases, towards increased distrust and fears of unproven side events. Action is needed to strengthen the dialogue with citizens and to understand their genuine concerns or doubts about vaccination and to adequately address those according to their needs.

- (6) The insufficient vaccination coverage rates of healthcare workers³ and their adequate training on vaccination must be addressed to ensure their own - and their patients' - protection, in line with national recommendations.
- (7) The variation of vaccination schedules between Member States with regards to recommendations, type of vaccines used, number of doses administered, and timing⁴ increases the risk that citizens, in particular children, miss taking a vaccine while moving from one Member State to another.
- (8) The need to bring immunisation services closer to citizens requires dedicated efforts to reach out to the most vulnerable of society, in particular through community-based providers such as pharmacies and school medical programmes. The European Structural Funds, in particular the European Social Fund and the European Regional Development Fund, offer significant opportunities for Member States to strengthen vaccine-related training of the healthcare workers and reinforce the health infrastructures capacities in the area of vaccination.
- (9) Demographic changes, mobility of people, climate change and waning immunity are contributing to epidemiological shifts in the burden of vaccine preventable diseases, which require vaccination programmes with a life-course approach beyond childhood years. This approach aims to ensure a lifelong adequate protection and contributes to healthy living and healthy ageing as well as the sustainability of healthcare systems.
- (10) Vaccine shortages have direct consequences for the delivery and implementation of national vaccination programmes⁵; Member States face various vaccine supply disruptions⁶; production capacities in the EU remain limited⁷; and difficulties persist in sharing vaccines across borders, while the lack of coordinated forecast planning contributes to demand uncertainty. In this context, the European Union and its citizens remain vulnerable in case of outbreaks of communicable diseases.
- (11) The need to rapidly advance research and development of new vaccines and improve or adapt existing ones requires innovative partnerships and platforms, high-level expertise and stronger interlinks between disciplines and sectors, as well as investment in social and behavioural science research to better understand context-specific determinants underpinning vaccine-hesitant attitudes.
- (12) The Council Conclusions on Vaccination as an Effective Tool in Public Health⁸ already identify some of these key challenges and ways forward, and call on Member States and the Commission to develop joint actions to share best practices on vaccination policies.

³ European Centre for Disease Prevention and Control. Seasonal influenza vaccination in Europe. Vaccination recommendations and coverage rates in the EU Member States for eight influenza seasons: 2007–2008 to 2014–2015. Stockholm: ECDC; 2017, <https://ecdc.europa.eu/sites/portal/files/documents/influenza-vaccination-2007%E2%80%932008-to-2014%E2%80%932015.pdf>

⁴ European Centre for Disease Prevention and Control. Vaccine Schedules in All Countries of the European Union Online Platform, <https://vaccine-schedule.ecdc.europa.eu/>

⁵ European Centre for Disease Prevention and Control. Shortage of acellular pertussis-containing vaccines and impact on immunisation programmes in the EU/EEA – 2 February 2016. Stockholm: ECDC; 2016. <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/RRA-shortage-of-aP-containing-vaccines.pdf>

⁶ WHO Regional Office for Europe, Dealing with vaccine shortages: current situation and ongoing activities. Impact of shortages and solutions set up by countries, SAGE April 2016 Meeting http://www.who.int/immunization/sage/meetings/2016/april/2_Benes_shortages_SAGE_Apr2016.pdf

⁷ Vaccines Europe, The EU Vaccine Industry in Figures 2014, <https://www.vaccineurope.eu/about-vaccines/vaccines-europe-in-figures/>

⁸ Council conclusions on vaccination as an effective tool in public health (2014/C 438/04), [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XG1206\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XG1206(01)&from=EN)

- (13) The Council Conclusions on Childhood Immunisation⁹ specifically call for the refinement of immunisation registers and information systems to improve the monitoring of vaccination programmes and facilitate the exchange of information between vaccine service providers.
- (14) The Commission Communication on the implementation of the Digital Single Market Strategy¹⁰ and the Communication on the eHealth Action Plan 2012-2020¹¹ recall the importance of the digital health agenda and the need to prioritise the development of eHealth and Big Data based solutions. These initiatives are reinforced by the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market¹²; empowering citizens and building a healthier society, to ensure modern and sustainable health care models as well as empowered citizens and healthcare workers.
- (15) Directive 2000/54/EC¹³ on the protection of workers from risks related to exposure to biological agents at work lays down minimum requirements to ensure workers' protection, including the need to offer vaccines for those not previously immunised and Directive 2010/32/EU¹⁴ implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU foresees that if the risk assessment reveals that there is a risk to the safety and health of workers due to their exposure to biological agents for which effective vaccines exist, workers should be offered vaccination.
- (16) Decision 1082/2013/EU¹⁵ on Serious Cross-border Threats to Health provides the basis for the establishment of a voluntary mechanism for the advance purchase of medical countermeasures for serious cross-border threats to health,.
- (17) The Council Conclusions on Common values and principles in European Union Health Systems¹⁶ endorse the principles and overarching values of universality, access to good quality care, equity and solidarity, which are of paramount importance to ensure equity of access to vaccination services regardless of age, social status, or geographic location, in accordance with national and regional immunisation programmes.
- (18) Regulation (EC) No 851/2004¹⁷ mandates the European Centre for Disease Prevention and Control to support the prevention and control of communicable diseases and foster

⁹ Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward (2011/C 202/02), [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XG0708\(02\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XG0708(02)&from=EN)

¹⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Mid-Term Review on the implementation of the Digital Single Market Strategy A Connected Digital Single Market for All, COM/2017/0228, <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017DC0228&from=EN>

¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the eHealth Action Plan 2012-2020, COM/2012/736, https://ec.europa.eu/health/sites/health/files/ehealth/docs/com_2012_736_en.pdf

¹² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018)233

¹³ Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 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>

¹⁴ 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>

¹⁵ Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

¹⁶ Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF>

¹⁷ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0851&from=EN>

the exchange of best practices and experience with regard to vaccination programmes. In addition, the Centre coordinates data collection, validation, analysis and dissemination at EU level, including on vaccination strategies.

- (19) Directive 2001/83/EC¹⁸ and Regulation (EU) No.726/2004¹⁹ on the community code relating to medicinal products for human use and establishing a European Medicines Agency, provide regulatory authorities with the mandate to promote and protect public health by authorising the use of safe and effective vaccines, and by continuously assessing their benefit and risk profile following the granting of marketing authorisation.
- (20) The Commission One Health Action Plan²⁰ supports the EU Member States in their fight against antimicrobial resistance (AMR) and calls for streamlined pathways for the authorisation of new antibacterial agents, and to boost the research and development of new vaccines for pathogens associated with antimicrobial resistance.
- (21) The European Parliament Motion for a Resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe²¹ calls on Member States to ensure sufficient vaccination of healthcare workers, take effective steps against misinformation, and implement measures for improving access to medicines. It also calls on the Commission to facilitate a more harmonised schedule for vaccination across the EU.
- (22) The Commission Action Plan on Fake News and online disinformation²² aims to contribute to the development of an EU-level strategy on how to tackle the spreading of disinformation, and the Commission Communication on tackling disinformation²³ addresses online platform challenges as regards the spreading of disinformation.
- (23) The Commission supports improving access to modern and essential vaccines in the 77 poorest countries through GAVI the Vaccine Alliance since its inception in 2000. EUR 83 million have been contributed until 2015 and another EUR 200 million pledged for the period 2016-2020, which contributed to fully immunising 277 million children in the period 2011-2015, with plans to immunise another 300 million children in 2016-2020.
- (24) The Ministers of Health, at the 2012 World Health Assembly, endorsed the Global Vaccine Action Plan, to ensure that no one misses out on vital immunisation by 2020. In 2014 the European Regional Committee of the World Health Organisation adopted the European Vaccine Action Plan 2015-2020.
- (25) The 2030 Agenda for Sustainable Development²⁴ Goal three - to 'Ensure healthy lives and promote well-being for all at all ages' - underlines the importance of vaccines in protecting people against diseases. And, through the European Consensus on

¹⁸ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>

¹⁹ Regulation 726/2004 of the European Parliament and of the Council of 31 March 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

²⁰ Commission Communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (2017), https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

²¹ European Parliament. Committee on the Environment, Public Health and Food Safety. Draft Motion for a Resolution on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951RSB) 19 04 2018

²² Commission High-Level group on Fake News and online disinformation, <https://ec.europa.eu/digital-single-market/en/news/high-level-group-fake-news-and-online-disinformation>

²³ Commission Communication on Tackling Online Disinformation: a European Approach, COM(2018)236

²⁴ Resolution 70/1 adopted by the General Assembly of United Nations on 25 September 2015: Transforming our world: the 2030 Agenda for Sustainable Development

Development "Our World, Our Dignity, Our Future"²⁵, the EU and its Member States reaffirm their commitment to protecting the right of everyone to enjoy the highest attainable standard of physical and mental health, including by helping to secure access to affordable essential medicines and vaccines for all.

- (26) A Joint Action on Vaccination, co-funded by the third Programme for the Union's action in the field of health²⁶, starting in 2018, is to focus on sharing of best practices on national vaccination policies and identifying technical requirements regarding electronic immunisation information systems, vaccine forecasting, prioritisation of vaccine research and development, and research to address vaccine hesitancy.
- (27) The actions put forward in this Recommendation aim to increase public health security, reduce inequalities between Member States, and increase the security of vaccine supply within the Internal Market. They complement and reinforce national policies and actions in all Member States while taking into account their different starting points as regards their immunisation policies, institutional set-up, regional differences, and healthcare capacities.
- (28) This Recommendation is in line with the principles of subsidiarity and proportionality.

HEREBY RECOMMENDS THAT THE MEMBER STATES:

1. Develop and implement national and/or regional vaccination plans, aimed at increasing vaccination coverage towards reaching the goals and targets of the World Health Organization's European vaccine action plan by 2020. These plans should include provisions for sustainable funding and vaccine supply, a life-course approach to vaccination, capacity to respond to emergency situations, and communication and advocacy activities.
2. Ensure for measles in particular, by 2020, the 95% vaccination coverage rate, with two doses of the vaccine for the targeted childhood population, and close the immunity gaps across all other age groups in view of eliminating measles in the EU.
3. Introduce routine checks of vaccination status and regular opportunities to vaccinate across different stages of life, through the routine visits to the primary care system and through additional measures such as at (pre) school entry, in the workplace or in care facilities.
4. Facilitate access to national and/or regional vaccination services, by:
 - a. Simplifying and broadening opportunities to offer vaccination, leveraging community-based providers such as pharmacies, nurses, and school and workplace medical services;
 - b. Targeted outreach to the most vulnerable groups including the socially excluded and minorities, so as to bridge inequalities and gaps in vaccination coverage.
5. Ensure, in cooperation with higher education institutions and stakeholders, that national medical curricula and any continuous medical education programmes include or strengthen training on vaccine-preventable diseases, vaccinology, and immunisation for healthcare workers across all sectors.

²⁵ Joint Statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission (2017/C 210/01) the new European Consensus on Development "Our World, Our Dignity, Our Future"

²⁶ Regulation 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC

6. Increase communication activities and awareness-raising on the benefits of vaccination by:
 - a. Presenting scientific evidence to counter the spread of disinformation, including through digital tools and partnerships with civil society and other relevant stakeholders;
 - b. Engaging with healthcare workers, education stakeholders, social partners and the media as multipliers, to fight complacency and increase trust in immunisation.
7. Develop the capacity of healthcare institutions to have up-to-date electronic information on the vaccination status of citizens, based on information systems providing reminder functionalities, capturing vaccination coverage data in real-time across all age groups, and allowing data linkages and exchanges across the healthcare systems.
8. Exploit the opportunities offered by the European Social Fund (ESF) and European Regional Development Fund (ERDF) in order to support the training and skills development of the healthcare workers on vaccinology, immunisation and vaccine-preventable diseases, and to reinforce national and regional health infrastructures capacities in the area of vaccination.
9. Increase support to vaccine research and innovation so that sufficient resources are available for a rapid advancement of new or improved vaccines, and facilitate the promptly uptake of the vaccine research for better informed national or regional vaccination programmes and policies.

HEREBY WELCOMES THE COMMISSION'S INTENTION TO TAKE THE FOLLOWING ACTIONS, IN CLOSE COOPERATION WITH THE MEMBER STATES:

10. Aim at establishing a *European Vaccination Information Sharing* (EVIS) system, coordinated by the European Centre for Diseases Prevention and Control (ECDC), in order to:
 - a. Together with the national public health authorities,
 - i. examine the options of establishing, by 2020, guidelines for a core EU vaccination schedule, aiming to facilitate the compatibility of national schedules and promote equity in Union citizens' health protection, and subsequently ensuring broad uptake of the core schedule as well as a common vaccination card;
 - ii. strengthen the consistency, transparency, and methodologies in the assessment of national and regional vaccination plans, by sharing scientific evidence and tools with the support of National Immunization Technical Advisory Groups (NITAGs);
 - iii. design EU methodologies and guidance on data requirements for better monitoring of vaccination coverage rates across all age groups, including healthcare workers, in cooperation with the World Health Organisation (WHO). Collect such data and share them at EU level;
 - b. By 2019, establish a *European vaccination information portal*, with the support of the European Medicines Agency, to provide online objective, transparent

- and updated evidence on vaccines, their benefit and safety, and the pharmacovigilance process.
- c. Monitor online vaccine misinformation and develop evidence-based information tools and guidance to support Member States in countering vaccine hesitancy, in line with the Commission Communication on tackling online disinformation.
11. With the support of the European Medicine Agency, continuously monitor the benefits and risks of vaccines, at EU level.
 12. Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes, including as part of the European cooperation on health technology assessment.
 13. Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work, as laid down in Directive 2000/54/EC and Directive 2010/32/EU, in particular by ensuring adequate training of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary, to ensure adequate levels of patient and healthcare workers' safety.
 14. Provide evidence and data, including through the *European Schoolnet*, to support Member States' efforts to strengthen the aspects related to vaccinology and immunisation in their national medical curricula as well as postgraduate education.
 15. Strengthen vaccine supply and mitigate risks of shortages by aiming at:
 - a. Developing a virtual European data warehouse on vaccine needs and stocks, to facilitate the voluntary exchange of information on available supplies, possible surpluses and global shortages of essential vaccines;
 - b. Developing a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak, improving the links between supply and demand of vaccines;
 - c. Identifying the options for physical stockpiling and engaging in a dialogue with vaccine producing companies on a mechanism to facilitate the stockpiling and availability of vaccines in case of outbreaks taking into account global shortages of essential vaccines;
 - d. Jointly with stakeholders and industry, improving EU manufacturing capacity and ensuring continuity of supply;
 - e. Exploiting the possibilities of joint procurement of vaccines or antitoxins to be used in cases of pandemics, unexpected outbreaks and in case of small vaccine demand (small number of cases or very specific populations to be covered);
 - f. Supporting the EU Official Medicines Control Laboratories network and its work to ensure the high quality of vaccines put on the EU market.
 - g. Monitoring the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC)
 16. Increase the effectiveness and efficiency of EU and national vaccine research and development funding by efforts to:
 - a. Reinforcing and establishing new partnerships and research infrastructures, including for clinical trials, facilitating – together with the European Medicines

Agency - early dialogue with developers, national policy makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats;

- b. Developing a roadmap of unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level, including leveraging the advantages of the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Research Collaboration for Infectious diseases Preparedness (GloPID-R);
- c. Investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers.

HEREBY WELCOMES THE COMMISSION'S INTENTION TO:

- 17. Examine issues of insufficient vaccine coverage caused by cross-border movement of people within the EU and look into options to address them, including developing a common EU citizens' vaccination card/passport, compatible with electronic immunisation information systems and recognised for use across borders.
- 18. Aim at producing on a regular basis, in the context of State of Health in the EU process, a *Report on the State of Vaccine Confidence in the EU*, to monitor attitudes towards vaccination. Based on that report, present guidance that can support Member States in countering vaccine hesitancy.
- 19. Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations in the field, to commit to delivering accurate information to the public, combating myths and exchanging best practice.
- 20. Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities.
- 21. Identify the barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups including by promoting health mediators and grassroots community networks.
- 22. Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems, having due regard to rules on personal data protection, as set out in the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society.
- 23. Continue to support research and innovation through the EU framework programmes for Research and Innovation for the development of safe and effective new, and the optimisation of existing, vaccines
- 24. Strengthen partnerships and collaboration with international actors and initiatives, such as the World Health Organisation and its Strategic Advisory Group of Experts on Immunization (SAGE), the European Technical Advisory Group of Experts on Immunization (ETAGE), the Global Health Security Initiative and Agenda processes (Global Health Security Initiative, Global Health Security Agenda), UNICEF and financing and research initiatives like GAVI the Vaccine Alliance, the Coalition for epidemic preparedness innovations (CEPI) and the Global Research Collaboration for Infectious disease Preparedness (GloPID-R).

25. Report on a regular basis on progress in implementing this Recommendation on the basis of data made available by the Member States and other relevant sources.

Done at Brussels,

For the Council
The President