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#### **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject: Proposal for a Council Recommendation on strengthened cooperation  
against vaccine-preventable diseases  
*- Preparation for adoption*

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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 is to be ensured in the definition and implementation of all Union policies and activities. Union action, which is to complement national policies, is to 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 set out in that Article to improve public health, in particular in relation to combating major health scourges, and 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 the common challenges faced by national immunisation programmes would benefit from more coordinated EU action and approaches to preventing or limiting the spread of epidemics and diseases with a cross-border dimension.

- (5) The rapid spread of misinformation through social media and by vocal anti-vaccination activists has fuelled misconceptions that are shifting the public focus away from the individual and collective benefits of vaccination and the risks posed by communicable diseases and towards increased distrust and fears of unproven adverse events. Action is needed to strengthen dialogue with citizens, to understand their genuine concerns and doubts about vaccination and to adequately address these issues, on the basis of individual needs.
- (6) Healthcare workers play a key role in working towards the goal of improved vaccination coverage rates. To support their efforts, they should be offered opportunities for continuing education and training on vaccination in accordance with national recommendations.
- (7) Cases where vaccination coverage rates of healthcare workers are considered insufficient with respect to national recommendations should be addressed in order to protect those workers and their patients.
- (8) The variation in vaccination schedules between Member States with regard to recommendations, type of vaccines used, number of doses administered, and timing increases the risk that citizens, particularly children, miss a vaccination while moving from one Member State to another.

- (9) The need to bring immunisation services closer to citizens requires dedicated efforts to reach out to the most vulnerable in society, in particular through community-based providers. The European Structural Funds, in particular the European Social Fund ('ESF') and the European Regional Development Fund ('ERDF'), offer significant opportunities for Member States to strengthen vaccine-related training of healthcare workers and to reinforce health infrastructure capacities in the area of vaccination.
- (10) 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 adequate lifelong protection and contributes to healthy living and healthy ageing as well as the sustainability of healthcare systems.
- (11) Vaccine shortages have direct consequences for the delivery and implementation of national vaccination programmes; Member States face various vaccine supply disruptions, production capacities in the EU remain limited 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 the event of outbreaks of communicable diseases.

- (12) 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 links between disciplines and sectors, as well as investment in social and behavioural science research to improve understanding of context-specific determinants underpinning vaccine-hesitant attitudes.
- (13) The Council conclusions on vaccination as an effective tool in public health<sup>1</sup> 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.
- (14) The Council conclusions on childhood immunisation<sup>2</sup> 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.

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<sup>1</sup> Council conclusions on vaccination as an effective tool in public health (2014/C 438/04) (OJ C 438, 6.12.2014, p. 3)

<sup>2</sup> Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward (2011/C 202/02) (OJ C 202, 8.7.2011, p. 4)

- (15) The Commission Communication on the implementation of the Digital Single Market Strategy<sup>3</sup> and the Communication on the eHealth Action Plan 2012-2020<sup>4</sup> recall the importance of the digital health agenda and the need to prioritise the development of eHealth and big data solutions. These initiatives are reinforced by the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market<sup>5</sup>, to ensure modern and sustainable healthcare models as well as empowered citizens and healthcare workers.

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<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

- (16) Directive 2000/54/EC<sup>6</sup> 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 Council Directive 2010/32/EU<sup>7</sup> implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU provides 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.
- (17) Decision 1082/2013/EU<sup>8</sup> 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.

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<sup>6</sup> 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 (OJ L 262, 17.10.2000, p. 21).

<sup>7</sup> Council 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 (OJ L 134, 1.6.2010, p. 66).

<sup>8</sup> 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 (OJ L 293, 5.11.2013, p. 1).



- (18) The Council conclusions on common values and principles in European Union health systems<sup>9</sup> 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 geographical location, in accordance with national and regional immunisation programmes.
- (19) Regulation (EC) No 851/2004<sup>10</sup> mandates the European Centre for Disease Prevention and Control ('ECDC') to support the prevention and control of communicable diseases and foster the exchange of best practices and experience with regard to vaccination programmes. In addition, the ECDC coordinates data collection, validation, analysis and dissemination at EU level, including on vaccination strategies.

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<sup>9</sup> Council conclusions on common values and principles in European Union health systems (2006/C 146/01) (OJ C 146, 22.6.2006, p.1).

<sup>10</sup> 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 (OJ L 142, 30.4.2004, p. 1).

- (20) Directive 2001/83/EC<sup>11</sup> and Regulation (EU) No 726/2004<sup>12</sup> 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.
- (21) The Commission One Health Action Plan<sup>13</sup> 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 for research on and development of new vaccines for pathogens associated with antimicrobial resistance to be boosted.

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<sup>11</sup> 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 (OJ L 311, 28.11.2001, p. 67).

<sup>12</sup> 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 (OJ L 136, 30.4.2004, p. 1).

<sup>13</sup> Commission Communication on a One Health Action Plan to support Member States in the fight against antimicrobial resistance COM(2017)339.

- (22) The European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe<sup>14</sup> 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.
- (23) The Commission Action Plan on Fake News and Online Disinformation aims to contribute to the development of an EU-level strategy on tackling the spreading of disinformation, and the Commission Communication on tackling disinformation<sup>15</sup> addresses online platform challenges as regards the spreading of disinformation.

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<sup>14</sup> European Parliament resolution on vaccine hesitancy and the drop in vaccination rates in Europe (Not yet published in the OJ).

<sup>15</sup> Commission Communication on Tackling Online Disinformation: a European Approach, COM(2018)236.

- (24) The Commission has supported improving access to modern and essential vaccines in the 77 poorest countries through Gavi, The Vaccine Alliance ('Gavi') since its inception in 2000. EUR 83 million had been contributed by 2015, which contributed to fully immunising 277 million children in the period 2011-2015, and another EUR 200 million have been pledged for the period 2016-2020, with plans to immunise another 300 million children between 2016 and 2020.
- (25) At the 2012 World Health Assembly, ministers for health endorsed the Global Vaccine Action Plan, to ensure that by 2020 no one misses out on vital immunisation. In 2014 the European Regional Committee of the World Health Organisation ('WHO') adopted the European Vaccine Action Plan 2015-2020.
- (26) Goal 3 of the 2030 Agenda for Sustainable Development<sup>16</sup> - 'Ensure healthy lives and promote well-being for all at all ages' - underlines the importance of vaccines in protecting people against diseases. Furthermore, through the European Consensus on Development 'Our World, Our Dignity, Our Future'<sup>17</sup>, 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.

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<sup>16</sup> Resolution 70/1 adopted by the General Assembly of United Nations on 25 September 2015: 'Transforming our world: the 2030 Agenda for Sustainable Development'.

<sup>17</sup> 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' (OJ C 210, 30.6.2017, p. 1).

- (27) A Joint Action on Vaccination, co-funded by the third Programme for the Union's action in the field of health<sup>18</sup>, starting in 2018, is to focus on sharing 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.
- (28) 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 immunisation policies, institutional set-up, regional differences, and healthcare capacities.
- (29) This Recommendation is consistent with the principles of subsidiarity and proportionality.

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<sup>18</sup> Regulation (EU) No 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 (OJ L 86, 21.3.2014, p. 1).

## **HEREBY RECOMMENDS THAT THE MEMBER STATES:**

1. Develop and implement vaccination plans, at national and/or regional level, as appropriate, aimed at increasing vaccination coverage with a view to reaching the goals and targets of the WHO's European Vaccine Action Plan by 2020. These plans could include, for example, 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. Aim to achieve by 2020, for measles in particular, a 95% vaccination coverage rate, with two doses of the vaccine for the targeted child population, and work towards closing the immunity gaps across all other age groups, with a view to eliminating measles in the EU.
3. Introduce routine checks of vaccination status and regular opportunities to vaccinate across different stages of life, through routine visits to the primary healthcare system and through additional measures taken, for example when beginning (pre-) school, in the workplace or in care facilities, according to national capacities.

4. Facilitate access to national and/or regional vaccination services, by:
  - (a) simplifying and broadening opportunities to offer vaccination, leveraging community-based providers; and
  - (b) ensuring targeted outreach to the most vulnerable groups, including socially excluded groups, so as to bridge inequalities and gaps in vaccination coverage.
5. Encourage and co-operate with higher education institutions and relevant stakeholders to consider including and strengthening training on vaccine-preventable diseases, vaccinology, and immunisation in national medical curricula and any continuing medical education programmes for healthcare workers across all sectors whenever advisable, to strengthen their key role in aiming for higher vaccination coverage rates.

Make use of the opportunities offered by the ESF and the ERDF in order to support the training and skills development of healthcare workers on vaccine-preventable diseases, vaccinology and immunisation and to reinforce national and regional health infrastructure capacities, including electronic immunisation information systems, in the area of vaccination.

6. Wherever necessary, increase communication activities and awareness-raising on the benefits of vaccination by:
  - (a) presenting scientific evidence in a form understandable to laypersons, using different context-based strategies, to counter the spread of misinformation, including, for example, through digital tools and partnerships with civil society and other relevant stakeholders;
  - (b) engaging with and offering training for relevant actors, such as healthcare workers, education stakeholders, social partners and the media as multipliers, to fight complacency and increase trust in immunisation.
7. Explore the possibility of developing the capacity of health and healthcare institutions to have electronic information on the vaccination status of citizens, for example based on information systems providing reminder functionalities, capturing up-to-date vaccination coverage data across all age groups, and allowing data linkages and exchanges across the healthcare systems.
8. Where appropriate, increase support for vaccine research and innovation so that sufficient resources are available for rapid advancement of new or improved vaccines, and facilitate uptake of 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:**

9. Aim to establish a *European Vaccination Information Sharing* (EVIS) system, coordinated by the ECDC, in order to:
- (a) together with the national public health authorities,
    - (i) examine the feasibility of establishing, by 2020, guidelines for a core EU vaccination schedule taking into account WHO recommendations for routine immunisation, aiming to improve the compatibility of national schedules and promote equity in Union citizens' health protection, as well as the feasibility of creating a common vaccination card;
    - (ii) strengthen consistency, transparency, and methodologies in the assessment of national and regional vaccination plans, by sharing scientific evidence and tools with the support of National Immunisation 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 WHO and collect such data and share them at EU level;
  - (b) establish, by 2019, a European vaccination information portal, with the support of the European Medicines Agency, to provide objective, transparent and updated evidence online on vaccination and vaccines, their benefits and safety, and the pharmacovigilance process.
  - (c) counter online vaccine misinformation and develop evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy, in line with the Commission Communication on tackling online disinformation.

10. With the support of the European Medicines Agency and in cooperation with the ECDC, continuously monitor the benefits and risks of vaccines and vaccinations, at EU level, including through post-marketing surveillance studies.
11. Work towards developing methodologies and strengthen capacities to assess the relative effectiveness of vaccines and vaccination programmes.
12. 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 Council Directive 2010/32/EU, taking into account national competences, in particular by supporting continuing education of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary, to ensure adequate levels of patient and healthcare-workers safety.
13. 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 and postgraduate education.

14. Work towards strengthening vaccine supply and mitigating risks of shortages by:
- (a) considering developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks, to facilitate the voluntary exchange of information on available supplies, possible surpluses and global shortages of essential vaccines;
  - (b) considering developing a concept for a mechanism for exchanging vaccine supplies from one Member State to another in the event of an outbreak, improving links between supply of and demand for vaccines;
  - (c) exploring the feasibility of 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) considering, jointly with stakeholders, in particular with the vaccine-manufacturing industry, which has a key role in meeting these aims, possibilities for improving EU manufacturing capacity, ensuring continuity of supply and ensuring diversity of suppliers;

- (e) exploring the possibilities of joint procurement of vaccines or antitoxins to be used in pandemics, unexpected outbreaks and in cases 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 that vaccines placed on the EU market are of high quality.
- (g) monitoring compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC) and exploring ways to enhance compliance with that obligation.
- (h) considering 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.

15. Increase the effectiveness and efficiency of EU and national vaccine research and development funding by efforts to:

- (a) reinforce existing partnerships and research infrastructures and establish new ones, including for clinical trials;
- (b) seek consensus on 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 Disease Preparedness ('GloPID-R');
- (c) consider 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:**

16. Examine issues of insufficient vaccine coverage caused by cross-border movement of people within the EU and look into options for addressing them, including by examining the feasibility of developing a common vaccination card/passport for EU citizens (that takes into account potentially different national vaccination schedules and) that is compatible with electronic immunisation information systems and recognised for use across borders, without duplicating work at national level.
17. Aim at producing on a regular basis, for example 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 to vaccination. Based on that report and taking into account related work by WHO, present guidance that can support Member States in countering vaccine hesitancy.
18. 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.
19. Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities.
20. Identify 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, in line with national recommendations.

21. 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.
22. Continue to support research and innovation through the EU framework programmes for research and innovation for the development of safe and effective new vaccines and the optimisation of existing vaccines
23. Strengthen existing partnerships and collaboration with international actors and initiatives, such as the WHO 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, CEPI, GloPID-R and JPIAMR (the Joint Programming Initiative on Antimicrobial Resistance).
24. Report on a regular basis on progress in implementing this Recommendation based on indicators agreed with Member States and on information from other relevant sources.

Done at Brussels,

*For the Council*  
*The President*

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