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From: General Secretariat of the Council
To: Working Party on Public Health

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Subject: Proposal for a Council Recommendation on Strengthened Cooperation
against Vaccine Preventable Diseases

Introduction

1. On 26 April 2018, the Commission adopted its proposal¹ for a Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases together with a Communication² on the same subject.
2. The proposal was presented to the Working Party on 7 June 2018.
3. On 4 and 13 July 2018, the Working Party examined the text of the proposal in its entirety and on 18 July some final changes were tentatively agreed.

State of play

4. Following the meeting of the Working Party on 18 July 2018, the tentatively agreed text has been subject to linguistic revision. The resulting text is set out in the Annex to this Note.

¹ See 8679/18 + ADD 1.

² See 8676/18 + ADD 1.

5. Changes to the text of the Commission proposal are indicated as follows:
- deletions of text from the Commission proposal presented in the previous document (10851/1/18 REV 1) are set out in ~~striketrough~~,
 - deletions that are new in the present document are set out in ~~striketrough and~~ underlined,
- and
- new text already presented in the previous document (10851/1/18 REV 1) is set out in ***bold italics***,
 - new text presented for the first time in this document is set out in ***bold italics and*** ***underlined***.

In addition to the convention explained above, changes suggested during the linguistic revision are **highlighted in grey** and, when deemed appropriate and necessary, explained in footnotes.

Future procedure

6. Delegations are invited to inform the Presidency and the Council Secretariat before 17 August 2018 if they request any changes to the text as set out in the Annex.
7. The text will be examined by the Permanent Representatives Committee at one of its meetings in September, with the aim of confirming agreement on a text that can be adopted by the Council (EPSCO) at its session on 7 December 2018.

2018/0115 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

on ~~Strengthened Cooperation against Vaccine Preventable Diseases~~ **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~~ **must**³ be ensured in the definition and implementation of all Union policies and activities. Union action, which ~~shall~~ **is to**⁴ complement national policies, ~~shall~~ **must** 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~~ **set out in** that Article to improve public health, **in particular** in relation to ~~in particular~~ **fight against** **combating**⁵ 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.

³ The word 'shall' is generally avoided in recitals. The word 'must' has been chosen to avoid 'should', which in legislative texts directly reflects an obligation ('shall') in the enacting terms.

⁴ The word 'shall' is generally avoided in recitals. The word 'must' is not appropriate here.

⁵ This recital refers to Article 168(5) TFEU, which uses the word 'combat'.

- (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 **ing** or limiting **ing** the spread of epidemics and diseases with a cross-border dimension.
- (5) The rapid spread of **disinformation misinformation**⁶ through social media and **by** vocal anti-vaccination activists **have 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 **side adverse** events⁷. Action is needed to strengthen **the** dialogue with citizens, **and** to understand their genuine concerns **or and** doubts about vaccination and to adequately address **these these issues, on the basis of individual according to their** needs.
- (5a) *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 **continuous continuing**⁸ education and training on vaccination in accordance with national recommendations.*
- (6) The insufficient **Where Cases where** vaccination coverage rates of healthcare workers⁹ **are considered insufficient in-line with respect to national recommendations** and their adequate training on vaccination must **should** be addressed **in order** to **protect those workers and their patients ensure their own and their patients' protection, in line with national** recommendations.

⁶ The word 'disinformation' means false information propagated *deliberately*. The word 'misinformation', includes also unintentionally false information.

⁷ The concept 'side events' means an event accompanying a 'main event' at for example a festival. The Presidency therefore proposes to use 'adverse event', which is a defined concept used in pharmacovigilance that covers adverse reactions to vaccines.

⁸ "continuing" means 'ongoing (after completion of an initial education phase)', "continious" normally means 'without pause'.

⁹ The Presidency proposes to delete the following reference as the recital refers also to other cases than influenza.

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>

- (7) The variation of in vaccination schedules between Member States with regards to recommendations, type of vaccines used, number of doses administered, and timing¹⁰ increases the risk that citizens, in particular children, miss taking a vaccination 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 in society, in particular through community-based providers ~~such as pharmacies and school medical programmes~~. 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 the healthcare workers and to 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 lifelong protection and contributes to healthy living and healthy ageing as well as the sustainability of healthcare systems.

¹⁰ European Centre for Disease Prevention and Control. Vaccine schedules in all countries Schedules in All Countries of the European Union (online platform): Online Platform, <https://vaccine-schedule.ecdc.europa.eu/>

- (10) Vaccine shortages have direct consequences for the delivery and implementation of national vaccination programmes¹¹; Member States face various vaccine supply disruptions¹²; production capacities in the EU remain limited¹³; 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 the event** 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 **inter**links between disciplines and sectors, as well as investment in social and behavioural science research to **improve understanding of** ~~better understand~~ context-specific determinants underpinning vaccine-hesitant attitudes.
- (12) The Council ~~Conclusions on Vaccination as an Effective Tool in Public Health~~ **conclusions on vaccination as an effective tool in public health**¹⁴ 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.

¹¹ 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>

¹² 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** *SAGE, April 2016 meeting*; http://www.who.int/immunization/sage/meetings/2016/april/2_Benes_shortages_SAGE_Apr2016.pdf

¹³ Vaccines Europe, The EU Vaccine Industry in Figures 2014; <https://www.vaccineseurope.eu/about-vaccines/vaccines-europe-in-figures/>

¹⁴ 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 Immunisation~~ ***conclusions on childhood immunisation***¹⁵ 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 Strategy¹⁶ and the Communication on the eHealth Action Plan 2012-2020¹⁷ recall the importance of the digital health agenda and the need to prioritise the development of eHealth and ~~Big Data based~~ ***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; ~~empowering citizens and building a healthier society~~¹⁸, to ensure modern and sustainable ~~health care~~ ***healthcare*** models as well as empowered citizens and healthcare workers.

¹⁵ 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)

¹⁶ 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>

¹⁷ 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

¹⁸ 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; <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0233&from=EN>

- (15) Directive 2000/54/EC¹⁹ 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/EU²⁰** implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU **foresees 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.
- (16) Decision 1082/2013/EU²¹ on **serious cross-border threats to health** **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 systems** **Conclusions on Common values and principles in European Union Health Systems²²** 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.

¹⁹ 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>

²⁰ **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; <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32010L0032&from=EN>
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0032&rid=11>

²¹ 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

²² Council **Conclusions on Common values and principles in European Union Health Systems** **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>

- (18) Regulation (EC) No 851/2004²³ 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 **Centre *ECDC*** coordinates data collection, validation, analysis and dissemination at EU level, including on vaccination strategies.
- (19) Directive 2001/83/EC²⁴ and Regulation (EU) No 726/2004²⁵ 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 Plan²⁶ 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 *for* research *on* and development of new vaccines for pathogens associated with antimicrobial resistance *to be boosted*.**

²³ 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>

²⁴ 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>

²⁵ 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

²⁶ Commission Communication on a One Health **action plan *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) The European Parliament ~~Motion for a~~²⁷ **resolution** ~~Resolution~~ of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe²⁸ 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 Disinformation** ~~online~~ **disinformation**²⁹ aims to contribute to the development of an EU-level strategy on ~~how to~~ **tackle** **tackling** the spreading of disinformation, and the Commission Communication on tackling disinformation³⁰ addresses online platform challenges as regards the spreading of disinformation.
- (23) The Commission **has supported** ~~supports~~ improving access to modern and essential vaccines in the 77 poorest countries through **Gavi**³¹ ~~The GAVI~~ the Vaccine Alliance (**'Gavi'**) since its inception in 2000. EUR 83 million ~~had~~ **have** been contributed ~~until~~ **by** 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, **and another EUR 200 million have been pledged for the period 2016-2020**³², with plans to immunise another 300 million children ~~in~~ **between** 2016 ~~and~~ -2020.

²⁷ ~~The EP Plenary~~ voted the resolution on 19 April 2018, so 'Motion for a' is no more needed.

²⁸ European Parliament, ~~Committee on the Environment, Public Health and Food Safety. Draft Motion for a Resolution~~ resolution on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951RSB) 19 04 2018:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2018-0188+0+DOC+XML+V0//EN>

²⁹ 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>

³⁰ ~~Commission Communication~~ **Communication** on Tackling Online **Disinformation** ~~Disinformation~~: a European Approach, COM(2018)236 <https://ec.europa.eu/digital-single-market/en/news/communication-tackling-online-disinformation-european-approach>

³¹ GAVI is now called '**Gavi, The Vaccine Alliance**'.

³² This part of the sentence is moved to clarify that EUR 83 million were contributed until 2015, which resulted in immunisation of 277 million children and that another 200 million will be used until 2020.

- (24) At The Ministers of Health, 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 by 2020. In 2014 the European Regional Committee of the World Health Organisation ('WHO') adopted the European Vaccine Action Plan 2015-2020.
- (25) The Goal 3 of the 2030 Agenda for Sustainable Development³³ 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. Furthermore And³⁴, through the European Consensus on Development 'Our World, Our Dignity, Our Future'³⁵, 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 Union's action in the field of health³⁶, 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 consistent with the principles of subsidiarity and proportionality.

³³ Resolution 70/1 adopted by the General Assembly of United Nations on 25 September 2015: 'Transforming our world: the 2030 Agenda for Sustainable Development'.

³⁴ It is strange to start a sentence with "and".

³⁵ 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'.

³⁶ Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March March 2014 on the establishment of a third Programme for the Union's Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.

HEREBY RECOMMENDS THAT THE MEMBER STATES:

1. Develop and implement *vaccination plans, at national and/or regional level, as appropriate, vaccination plans*, aimed at increasing vaccination coverage ~~towards~~ *with a view to* reaching the goals and targets of the ~~WHO's World Health Organization's~~ European *Vaccine Action Plan vaccine action plan* by 2020. These plans ~~should~~ *could include, for example, 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~~ *Aim to achieve by 2020,* for measles in particular, ~~by 2020, the~~ *a* 95% vaccination coverage rate, with two doses of the vaccine for the targeted child~~hood~~ population, and ~~else~~ *work towards closing* the immunity gaps across all other age groups, ~~in~~ *with a view to* 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 *health* care system and through additional measures³⁷ *taken, for example such as at when beginning* (pre-) school ~~entry,~~ in the workplace or in care facilities, *according to national capacities possibilities*.
4. Facilitate access to national and/or regional vaccination services, by:
 - a. *simplifying* ~~Simplifying~~ and broadening opportunities to offer vaccination, leveraging community-based providers ~~such as pharmacies, nurses, and school and workplace~~ medical services; *and*
 - b. ~~Targeted~~ *ensuring*³⁸ *targeted* outreach to the most vulnerable groups, including the socially excluded *groups and minorities*, so as to bridge inequalities and gaps in vaccination coverage.

³⁷ 'school entry', 'workplace' and 'care facilities' are not in themselves 'measures'. Therefore, the word 'taken' is added.

³⁸ The word 'ensuring' is added simply to start b with a verb in the same form as that used in a.

5. ~~Ensure, in cooperation~~ **Encourage and co-operate** with higher education institutions and **relevant** stakeholders, that national medical curricula and any continuous medical education programmes, ~~to consider including~~ **include** or ~~and strengthening~~ **strengthen** training on vaccine-preventable diseases, vaccinology, and immunisation **in national medical curricula and any continuous continuing**³⁹ **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 European Social Fund (ESF) and the European Regional Development Fund (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 infrastructures capacities, including electronic immunisation information exchange systems⁴⁰, in the area of vaccination.

6. ~~Increase, wherever~~ **Wherever** necessary, ~~increase~~ communication activities and awareness-raising on the benefits of vaccination by:
- ~~Presenting~~ **presenting** scientific evidence **in a form understandable to laypersons, thereby**⁴¹ **using different context-based strategies**, to counter the spread of ~~disinformation~~ **misinformation**⁴², including, **for example**, through digital tools and partnerships with civil society and other relevant stakeholders;
 - ~~Engaging~~ **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.

³⁹ Compare recital (5a).

⁴⁰ The Presidency proposes to replace 'information exchange systems' with 'electronic immunisation information systems' in order to make the link to vaccination activities clear. (The expression comes from recital (26).)

⁴¹ The word "thereby" is not needed here since the phrase (abbreviated) reads 'Member States should increase communication activities by presenting scientific evidence using different strategies, to ...'.

⁴² Compare recital (5).

7. *Explore the possibility of developing* Develop the capacity of **health and** healthcare institutions to have up-to-date electronic information on the vaccination status of citizens, *for example* based on information systems providing reminder functionalities, capturing *up-to-date* 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, where~~ **Where appropriate, increase** support ~~to~~ **for** vaccine research and innovation so that sufficient resources are available for a rapid advancement of new or improved vaccines, and facilitate ~~the~~ prompt 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 **to establish** ~~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** ~~Together~~ with the national public health authorities,
 - i. examine the ~~options~~ **feasibility** of establishing, by 2020, guidelines for a core EU vaccination schedule **taking into account WHO recommendations for routine immunisation**, aiming to ~~facilitate~~ **improve**⁴³ 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 **the feasibility of creating** a common vaccination card;

⁴³ It was pointed out that 'compatibility' can't be facilitated, as it is a state. The Presidency therefore proposes to replace 'facilitate' by 'improve'.

- 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~~ **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 ~~World health Organisation (WHO)~~; ~~Collect~~ **and collect** such data and share them at EU level;
- b. ~~By 2019,~~ establish, **by 2019,** a European vaccination information portal, with the support of the European Medicines Agency, to provide ~~online~~ objective, transparent and updated evidence **online** on **vaccination and** vaccines, their benefits and safety, and the pharmacovigilance process.
 - c. ~~counter~~ Monitor ~~Counter~~ online vaccine misinformation and develop evidence-based information tools and guidance to support Member States in ~~countering~~ **responding to** vaccine hesitancy, in line with the Commission Communication on tackling online disinformation.
11. With the support of the European Medicines Agency **and in cooperation with the ECDC European Centre for Disease Prevention and Control**, continuously monitor the benefits and risks of vaccines **and vaccinations**, at EU level, **including through post-marketing surveillance studies**.
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 **Council** Directive 2010/32/EU, **taking into account national competences**, in particular by ~~ensuring adequate training~~ **supporting continuous continuing**⁴⁴ **education** 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~~ **and** postgraduate education.
15. ~~Strengthen~~ **Work towards strengthening** vaccine supply and ~~mitigate~~ **mitigating** risks of shortages by ~~aiming at~~:
 - a. **considering** ~~Developing~~ **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~~ **Considering developing** a concept for a mechanism for exchanging vaccine supplies from one Member State to another in ~~case~~ **the event** of an outbreak, improving ~~the~~ links between supply ~~of~~ and demand ~~of~~ **for** vaccines;
 - c. **exploring** ~~Exploring~~ **the feasibility of** ~~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~~ **and exploring, together with the European Medicines Agency, the options for licensing vaccines manufactured by vaccine manufacturers outside the EU in order to increase availability of vaccines in the EU;**

⁴⁴ Compare recital (5a).

- d. ~~considering~~ Jointly ~~Considering~~, jointly with stakeholders, *in particular with and the vaccine-manufacturing industry, which has a key role in meeting these aims, possibilities for* improving EU manufacturing capacity, ~~and~~ ensuring continuity of supply *and ensuring diversity of suppliers*;
- e. ~~exploring~~ Exploiting ~~Exploring~~ the possibilities of joint procurement of vaccines or antitoxins to be used in ~~cases of~~ pandemics, unexpected outbreaks and in cases of small vaccine demand (small number of cases or very specific populations to be covered);
- f. ~~supporting~~ Supporting the EU Official Medicines Control Laboratories network and its work to ensure ~~that the high quality of~~ vaccines ~~put~~ *placed* on the EU market ~~are of high quality~~.
- g. ~~monitoring~~ Monitoring ~~compliance with the fulfilment of~~ the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC) ~~and envisaging means, at national and EU level, to enforce exploring ways to enhance compliance with this that obligation~~.
- h. ~~Considering 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*.
16. Increase the effectiveness and efficiency of EU and national vaccine research and development funding by efforts to:
- a. ~~Reinforcing~~ *reinforce existing and establishing new* partnerships and research infrastructures ~~and establish new ones~~⁴⁵, 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~~;

⁴⁵ It's not possible to skip the first noun phrase in this double-verb construction.

- b. ~~seek~~ **Seeking for** ~~consensus on~~ 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 ~~Disease diseases~~ Preparedness ('GloPID-R');
- c. ~~consider~~ Investing **Considering 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~~ **for addressing** them, including ~~developing by~~ **examining the feasibility of developing** a common ~~EU citizens'~~ vaccination card/passport **for EU citizens (that accounts for 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.**
- 18. 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~~ **report on the state of vaccine confidence** in the EU, to monitor attitudes ~~towards~~ **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.
- 19. Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant ~~students'~~ **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, **in line with national recommendations.**

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~~ **research and innovation** for the development of safe and effective new **vaccines** and the optimisation of existing vaccines
24. Strengthen **existing** partnerships and collaboration with international actors and initiatives, such as the ~~WHO 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** ~~GAVI the Vaccine Alliance~~, ~~the Coalition for epidemic preparedness innovations (CEPI)~~, **GloPID-R and JPIAMR (the Joint Programming Initiative on Antimicrobial Resistance)** ~~and the Global Research Collaboration for Infectious disease Preparedness (GloPID-R)~~.
25. Report on a regular basis on progress in implementing this Recommendation **based** on ~~the~~ basis of data made available by the **indicators agreed with** Member States and **on information from** other relevant sources.

Done at Brussels,

For the Council

The President