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**COMMISSION STAFF WORKING DOCUMENT**

**Synopsis Report**

*Accompanying the document*

**Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and The Committee of Regions**

**and**

**Proposal for a Council Recommendation**

**on Strengthened Cooperation against Vaccine Preventable Diseases**

{COM(2018) 245} - {COM(2018) 244}

# SYNOPSIS REPORT

## 1. INTRODUCTION

This report covers input from citizens and from administrations, associations and other organisations ('stakeholders') on a Commission initiative developed by the Directorate-General for Health and Food Safety (DG SANTE) as a Council Recommendation on strengthened cooperation against vaccine-preventable diseases ('the Recommendation').

Citizens and stakeholders had four weeks to provide feedback on the Commission's roadmap on the Recommendation<sup>1</sup> that was published on the Better Regulation Portal<sup>2</sup>.

An online public consultation<sup>3</sup> via EU Survey, available in 23 EU languages<sup>4</sup> ran from 21 December 2017 to 15 March 2018. The analysis of the results was made via DORIS Public Consultation Dashboard and through qualitative analysis.

In addition, two targeted consultations with stakeholders took place. Selected stakeholders<sup>5</sup> were invited to respond to a questionnaire via EU-Survey between 17 January 2018 and 14 February 2018. The questionnaire featured more open questions than the public consultation, and was also analysed through DORIS and qualitative analysis.

Face-to-face stakeholder meetings took place between 18 January and 9 February 2018 with groups representing the healthcare and clinical professionals, medical students, international organisations, non-governmental organisations, civil society and the vaccine industry.

Overall, 355 responses were submitted on the Commission's roadmap, with 90% of replies being vaccine hesitant.

The public consultation received 8894 replies; of which 8 688 from citizens and 206 from stakeholders. On 14 March, one day before closure, the public consultation received almost 6 000 responses from France (60% of total answers). Most of these answered using the '*no opinion*' option to all questions. These responses may be linked to an online message by the *Institut pour la protection de la santé naturelle*<sup>6</sup> suggesting that this option was the only possible answer to a perceived pro-vaccine bias in the questionnaire.

33 stakeholders responded to the online targeted consultation and 20 took part in the face-to-face meetings.

A total of 33 participants (14 citizens and 19 stakeholders) uploaded additional PDF documents to the roadmap, and 3 stakeholders did the same for the public consultation. These additional documents will be taken into account in the analysis.

13 responses to the roadmap and 127 responses to the public consultation were not taken into account, due to duplication, anonymity, non-relevance or inadequate language.

Over 25% of stakeholders were NGOs, followed by health administrations and professional

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<sup>1</sup> [http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5925775\\_en](http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5925775_en)

<sup>2</sup> From 4 December 2017 to 1 January 2018.

<sup>3</sup> [https://ec.europa.eu/info/consultations/open-public-consultation-strengthened-cooperation-against-vaccine-preventable-diseases\\_en#how\\_to\\_submit](https://ec.europa.eu/info/consultations/open-public-consultation-strengthened-cooperation-against-vaccine-preventable-diseases_en#how_to_submit)

<sup>4</sup> The questionnaire was not available in Gaelic.

<sup>5</sup> Members of the Health Policy Platform; applicants to the EU Health NGO Award contest on vaccination; stakeholders representing the appointed national contact points involved in the EU Joint Action on Vaccination; Member State representatives in the Advisory Forum and the Network for Vaccine-preventable Diseases of the European Centre for Disease Prevention and Control (ECDC)'s.

<sup>6</sup> <https://www.ipsn.eu/vaccins-commission-europeenne-demande-avis-15-mars>

associations. As for the citizens, 8 769 came from the EU, the vast majority from France (78.3%), followed by Italy (4.4%) and Belgium (3.9%). There were 200 responses from non-EU countries.

This report summarises all the responses received from the 4 consultations. They are grouped along the initiative's 3 main pillars: (1) tackling vaccine hesitancy; (2) sustainable vaccine policies in the EU; and (3) EU coordination, including the promotion of stakeholders' dialogue and contribution to global health.

## **1. PILLAR I: TACKLING VACCINE HESITANCY**

Over 50% of the respondents to the public consultation considered that the fear of side effects, lack of information on risks, introduction of mandatory vaccination and levels of confidence in the effectiveness of vaccines have the highest impact on vaccine hesitancy.

### **1.1. BETTER COMMUNICATION ON SAFETY AND EFFECTIVENESS OF VACCINES**

Respondents highlighted the need for face-to-face interaction at the local level, including:

- providing a patient-centred approach in the dialogue with healthcare professionals;
- developing local awareness-raising programmes and events;
- communicating directly with parents, including during pre-natal courses;
- introducing trusted mediators in vulnerable groups (e.g. Roma communities, refugees);
- improving the comprehension of vaccine safety studies (e.g. info-graphics, videos, leaflets);
- opening the debate for supporters and opponents to give a balance of benefits and risks; and
- checking facts on fake news and conflicts of interest on a proactive basis.

The feedback on the roadmap also supported better access to information. Training at the workplace and at university was almost unanimously accepted<sup>7</sup> as the most effective methods of communication to healthcare workers.

On the EU's communication on vaccine safety and effectiveness, over 60% of citizens<sup>8</sup> and stakeholders believe that it is inadequate. Healthcare professionals noted that<sup>9</sup>:

- online data from the European Medicines Agency (EMA) and the European Centre for Disease Control (ECDC) are fragmented, insufficiently circulated and accessible;
- updated information on a single platform should be set up by the ECDC (as the US Centers for Disease Control and Prevention);
- EU should encourage national websites on vaccine hesitancy EU should promote an interactive campaign on vaccination.

Feedback on the roadmap suggested that the Commission should improve its engagement with vaccine hesitant groups.

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<sup>7</sup> By the respondents to the public consultation and the targeted consultation.

<sup>8</sup> Not including those who provided no opinion on the matter.

<sup>9</sup> Answering the targeted consultation only.

## 1.2. BETTER COOPERATION BETWEEN ACTORS IN TACKLING VACCINE HESITANCY

Respondents<sup>10</sup> suggested to promote recommended vaccinations and to provide the scientific evidence backing those recommendations.

Other suggestions focused on educating the public:

- distinguish essential vaccines (e.g. polio) from voluntary ones (e.g. influenza);
- involve women as the main carers of children and the elderly and celebrities in advocacy;
- display images of vaccine-preventable diseases, on the model of cigarette packs; and
- raise awareness of herd immunity and individual responsibility.

Stakeholders<sup>11</sup> also highlighted the role of the vaccine industry in:

- providing transparent information on vaccines, prices and ingredients;
- prioritising public health over commercial gains; and
- improving the quality and supply of vaccines through more R&D.

## 1.3. BETTER SUPPORT TO HEALTHCARE PROFESSIONALS

81.33% of citizens believed that healthcare professionals should be better supported in advocating vaccination and be provided with material to inform the public.

Stakeholders<sup>12</sup> consider that the EU should support healthcare professionals through training on communication (82%), online information (79%), scientific material (70%) and developing EU campaigns on vaccination (66%). They also suggested:

- developing hard mandates (e.g. mandatory vaccination for high-risk groups);
- ensuring all healthcare professionals receive relevant vaccination themselves;
- improving working hours conditions to enable more patient communication;
- increasing education standards; and
- creating common EU recommendations, with fees for rule breaches.

Stakeholders that responded to the targeted consultation believe in need to promote continuous education on vaccination to pharmacists. Feedback on the roadmap supported improving education programmes and health promotion through digital tools.

## PILLAR II: SUSTAINABLE VACCINE POLICIES IN THE EU

To overcome national differences in the sustainability of vaccination programmes, stakeholders<sup>13</sup> (81%) suggested harmonising vaccination schedules in the EU.

## 1.4. INVESTMENT IN E-HEALTH AND DIGITALIZATION

Developing an electronic vaccination record was the most endorsed e-health investment with almost unanimous consensus<sup>14</sup>. Potential benefits include sending notifications on recalls and tracking coverage rates.

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<sup>10</sup> Answering the OPC and the targeted consultation.

<sup>11</sup> Answering the targeted consultation only.

<sup>12</sup> Answering the targeted consultation only.

<sup>13</sup> Answering the targeted consultation only.

<sup>14</sup> The OPC respondents were not involved on this topic.

## 1.5. BETTER COMMUNICATION WITH THE VACCINE INDUSTRY

Citizens supported obliging industries to supply the required vaccines (24.55%). In contrast, stakeholders<sup>15</sup> supported mapping vaccine demand (70.87%) and establishing national systematic forecasts of vaccines (65.53%). Stakeholders<sup>16</sup> also suggested:

- creating an EU alert and planning mechanisms;
- simplifying EU legislation on marketing authorisation to increase capacity;
- promoting cooperation between vaccine industry and WHO; and
- creating national and EU vaccine producers' federations.

## 1.6. BETTER ENGAGEMENT IN FUNCTIONING AND SUSTAINABLE VACCINATION PROGRAMMES

Stakeholders<sup>17</sup> suggested new EU actions to address the sustainability of vaccination programmes:

- exchanging information with authorities outside the EU on vaccine quality;
- improving EU legislation with new binding commitments for vaccine manufacturers;
- establishing an EU platform with guidance on national implementation programmes; and
- performing pharma-economic evaluations.

Grassroots level organisations could support sustainable vaccination policies by:

- forming a stakeholders' alliance to align work and hear patients' voices;
- researching barriers to vaccination access; and
- establishing an EU "Vaccination Ambassador" programme.

Other targeted consultation proposals include shifting tasks from doctors to nurses, seeking cooperation from employers to ensure suitable leave for vaccinations, and reviewing co-payments, out-of-pocket contributions and vaccine injury compensation rights.

One response suggested implementing an EU Technical Advisory Group based on the model of the US Advisory Committee on Immunization Practices.

To ensure effective information flow and monitoring of the impacts at EU level, respondents suggest:

- circulating ECDC data more effectively;
- setting up a fund (with mandatory contributions from the vaccine industry) for vaccine impact studies; and
- setting up an information and monitoring system at EU level to consolidate vaccine data.

## 1.7. BETTER PROMOTION OF VACCINATION TO INCREASE COVERAGE RATES

To promote vaccination, stakeholders propose:

- developing information campaigns;
- formulating robust legal regulation of vaccination, with clear accountability for all actors involved; and

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<sup>15</sup> Answering the open consultation only.

<sup>16</sup> Answering the targeted consultation only.

<sup>17</sup> Answering the targeted consultation only.

- improving vaccination coverage of healthcare professionals, through voluntary encouragement/incentives or mandatory requirement.

82% of other stakeholders<sup>18</sup> believe that the EU should develop a common approach to vaccination schedules. They also propose:

- aligning vaccination schedules and policies;
- providing surveillance methods for specific groups;
- developing an EU interoperable immunisation information system;
- ensuring citizens have adequate and free access to vaccination programmes;
- allowing pharmacists and nurses to prescribe and administer vaccines; and
- improving coordination between Health Ministries and ECDC/WHO.

Stakeholders that responded to the targeted consultation called for greater focus on adolescent and adult vaccinations.

Stakeholders rejected almost unanimously a ‘one-size-fits-all’ strategy. Feedback on the roadmap called for more focus on vaccine injuries, including setting up independent European vaccine adverse effect reporting (VAER) systems.

## **1.8. REDUCTION OF VACCINE SHORTAGES AND IMPROVEMENT OF PRODUCTION CAPACITIES**

Stakeholders that responded to the public consultation and the targeted consultation believe the key policy interventions to mitigate vaccine shortages are forecasting and joint procurements. 36.8% of citizens considered the availability of individual vaccines to be most important.

Stakeholders<sup>19</sup> suggest that EU coordination on vaccine shortages could be improved by:

- creating an industry flag to highlight that a manufacturing problem is anticipated;
- standardising packaging; and
- providing transparent price and volume.

To increase vaccine production and reduce lead times, stakeholders<sup>20</sup> suggest:

- increasing surveillance and investment in production/research;
- amending EU legislation (e.g. simplification of marketing authorisations);
- using new technologies and financial incentives for industry;
- enhancing the joint procurement system and improving coordination of EU vaccination schedules; and
- harmonising vaccine information, including packaging and language.

To enable a sufficient production capacity in the EU, stakeholders propose:

- regulating and prioritising vaccine production;
- coordinating planning, forecasting, joint procurement and funding mechanisms;

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<sup>18</sup> Answering the targeted consultation only.

<sup>19</sup> Answering the targeted consultation only.

<sup>20</sup> Answering the targeted consultation only.

- establishing multiannual budgets for national immunisation schedules and vaccine-dose planning based on epidemiological studies at least 3 years before manufacturing orders; and
- R&D funding mechanisms (based on the US Biomedical Advance Research and Development Authority model - BARDA) for vaccines that are health security priorities.

Feedback also proposed developing European guidelines on vaccines planning.

## **1.9. BOLSTER RESEARCH AND DEVELOPMENT**

Stakeholders<sup>21</sup> also suggest speeding up R&D by:

- aligning with the GLOPID and the CEPI for developing new vaccines;
- ensuring industry's support for public health-led, independent vaccine studies; and
- establishing joint scientific advice groups and regulators at EU level.

Proposals for the EU to better support the scientific evaluation of new vaccines include:

- closer collaboration with WHO and UN;
- complementing central authorisation procedures with independent vaccine testing;
- creating a network of National Immunisation Technical Advisory Groups, EU regulators, Health Technology Agencies to share strategies and evidence; and
- supporting the development of post-marketing studies based on an EU immunisation information system.

## **2. PILLAR III: EU COORDINATION, INCLUDING PROMOTION OF STAKEHOLDERS' DIALOGUE AND CONTRIBUTION TO GLOBAL HEALTH**

Stakeholders<sup>22</sup> identified new EU cooperation areas for vaccination:

- common regulatory framework and digital record system;
- communication and media;
- cross-border public health campaigns;
- EU funding platform for vaccine studies and research; and
- EU immunisation platform for exchanging information and best practice.

The most important funding instruments for R&D were the EU Horizon 2020 grants (42%) and the EU-funded public-public partnerships (33%).

### **2.1. PROMOTION OF CROSS-BORDER EXCHANGES IN THE EU**

In the targeted consultation, stakeholders<sup>23</sup> (97%) call on the Commission to coordinate the exchange of best practice and vaccine products among Member States.

Citizens<sup>24</sup> (55%) call for an exchange of best practice on vaccine injury compensation.

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<sup>21</sup> Answering the targeted consultation only.

<sup>22</sup> Answering the targeted consultation only.

<sup>23</sup> Answering the targeted consultation only.

<sup>24</sup> Those citizens not providing any opinion were not considered on this matter.

## STRENGTHENING EU COOPERATION IN PUBLIC HEALTH PREPAREDNESS

Respondents to the public consultation and the targeted consultation consider that Member States should collaborate with industry on a crisis management plan to forecast and reduce risks during vaccine manufacturing.

### 2.2. MAKING RESEARCH MORE GLOBAL AND EFFECTIVE

Respondents to the public consultation and the targeted consultation almost unanimously agree that EU action on vaccine research take place within and outside the EU.

To enable collaboration between public health authorities, civil society and the vaccine industry on implementing research, stakeholders suggest:

- setting up expert networks or platforms;
- establishing a regulatory framework, focusing on anticipating shortages;
- establishing a dedicated EU agency to design actions and define funding; and
- developing joint actions and public-private partnerships to build trust and generate/collect new data.

### 3. CONCLUSION

Overall, the results of the consultation called for a more coordinated effort in vaccination at national and EU level. Equal access to vaccination programmes and vaccine hesitancy was identified as the main challenges. Citizens expressed more concern over the safety and effectiveness of immunisation programmes, emphasising the need for more transparent research and information.

The main concerns for vaccine hesitant respondents were (i) side effects and vaccine ingredients, (ii) perceived lack of safety and effectiveness of vaccines, (iii) imposition of mandatory vaccination, (iv) lack of vaccine injury compensation schemes, (v) financial interests of the pharmaceutical industry, (vi) lack of transparent and industry-independent scientific research, (vii) perceived unilateral information on benefits, but not on risks, and (viii) mistrust in public authorities.

Although these groups represent the vast majority of respondents (over 70%), the other respondents endorsed the initiative.

Key suggestions arising from the targeted consultation were to (i) involve pharmacists in vaccine administration, (ii) include immunisation in a wider preventive healthcare concept, (iii) focus more on adult vaccination, and (iv) upgrade access to information and data by the ECDC and EMA.

Feedback from the roadmap focused on the need for dialogue, cooperation and the exchange of best practice, while respecting national specificities and competences.

Respondents to the public consultation and the targeted consultation also called for healthcare professionals to be more involved in promoting vaccination by providing training and information material. Educating and informing the public on vaccination using a local, face-to-face approach was emphasised. The introduction of an electronic vaccination record was strongly supported.

Overall, the role of the Commission as a facilitator in the exchange of information and best practice on vaccines and immunisation among countries was supported.

Due to the high geographical imbalance of contributions, the questionnaire is not statistically



representative as a consultation instrument. However, the high number of responses received compared to other consultations is an indication of the importance of the issue.