

ROADMAP FOR THE IMPLEMENTATION OF ACTIONS BY THE EUROPEAN COMMISSION BASED ON THE COMMISSION COMMUNICATION AND THE COUNCIL RECOMMENDATION ON STRENGTHENING COOPERATION AGAINST VACCINE PREVENTABLE DISEASES

| ACTIONS | TIMELINES AND DELIVERABLES | | | | |
|---|--|------|------|------|---|
| | 2018 | 2019 | 2020 | 2021 | 2022 |
| <p>Examine 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.</p> | <p>Feasibility study for the development of a common EU vaccination card</p> | | | | <p>Commission proposal for a common vaccination card/passport for EU citizens</p> |
| <p>CR 16 and CC*</p> | | | | | |
| <p>Produce on a regular basis 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.</p> | <p>State of Vaccine Confidence in the EU 2020 Follow up of the study published in October 2018 https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_vaccine_confidence_en.pdf</p> <p>Guidance on countering vaccine hesitancy tailored to specific needs identified by the Member States and/or vaccine specific issues</p> | | | | |
| <p>CR 17 and CC</p> | <p>Special Eurobarometer - Europeans' attitudes towards vaccination https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/survey/getsurveydetail/instruments/special/surveyky/2223</p> | | | | |

* Basis for action:

CR for Council Recommendation and the number of the Recommendation in the legal text. CC for Commission Communication

ACTIONS

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|--|------|--|---|------|------|
| <p>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.</p> <p>CR 18 and CC</p> | | <p>Convened in March 2019, follow-up meeting in September 2019</p> | <p>Annual meeting from 2020, to take note of compliance with commitments made by members of the Coalition for Vaccination</p> | | |
| <p>Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities.</p> <p>CR 19</p> | | <p>EU public awareness initiative on vaccination during the European Immunisation Week</p> | | | |
| <p>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.</p> <p>CR 20 and CC</p> | | <p>Guidance on increasing access to vaccination for disadvantaged and socially excluded groups</p> | <p>Country reports on research-based determinants behind high and low vaccination coverage</p> <p>E-learning platform to share country reports, provide a database on structured country reports</p> <p>Series of webinars about specific cases, projects and initiatives dealing with vaccine hesitancy and uptake-related issues, involving broad range of stakeholders</p> | | |

ACTIONS

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2018

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Guidance on electronic immunization information systems: handbook to help countries upgrading current EIS systems in place or set up new ones where these are not in place yet.
https://ecdc.europa.eu/sites/portal/files/documents/designing-implementing-immunisation-information-system_0.pdf

Develop **EU guidance for establishing comprehensive electronic immunization information systems** for effective monitoring of immunization programmes.

Outline of core functionalities for information sharing and vaccine coverage assessment pilot platform, based on input from stakeholders

Protocol for harmonized estimations of vaccination coverage of first and second dose with mumps-measles-rubella vaccine (MMR1 and MMR2)

Open-source computer algorithm that can be shared and run by regions, countries with electronic immunisation information systems or other similar data source, completed by data on doses of measles containing vaccines

Common pilot online platform where vaccine coverage estimations for cross-border vaccine coverage assessments can be shared publicly

Report on data collection procedures, datasets used and interoperability assessment of electronic immunisation information systems in the EU area

Report that describes existent reminder systems and provides recommendations for future systems

Report that describes the feasibility of conducting coordinated cross-border measles vaccination campaigns

CC

| ACTIONS | TIMELINES AND DELIVERABLES | | | | |
|---|---|---|------|---|------|
| | 2018 | 2019 | 2020 | 2021 | 2022 |
| <p>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.</p> <p style="text-align: right;">CR 21 and CC</p> | | | | <p>Guidance on overcoming legal (and technical) barriers to the interoperability of national immunisation information systems</p> | |
| <p>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.</p> <p style="text-align: right;">CR 22</p> | <p>Projects funded under Horizon 2020 and Horizon Europe (HE)</p> | | | | |
| <p>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).</p> <p style="text-align: right;">CR 23 and CC</p> | | <p>Global Vaccination Summit, taking place on 12 September 2019 organized by the European Commission in cooperation with the World Health Organization. https://ec.europa.eu/health/vaccination/ev_20190912_en</p> | | | |

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Report on previous experience about vaccine shortages and responses of EU countries

Guidelines on procedures to estimate vaccine needs and procurement in the EU

Report on the financial mechanism for joint procurement based on an evaluation of the financing mechanisms in different countries

Establish a vaccine network with Member States to leverage the sustainability of activities of the joint action beyond the project. <https://eu-jav.com/>

Develop an "integration of outcomes of the joint action into national policies & sustainability" plan to strive towards a converging vaccine agenda for the most commonly used vaccines at EU level. <https://eu-jav.com/>

Overview of EU-level and national legal and technical frameworks and operational criteria for decision-making on vaccination policies and available (EU and national) platforms

Survey on the range of attributable costs used for the most recent MS-National Immunisation Technical Advisory Groups (NITAGs) evaluations available

Pilot of a technical collaboration to establish an active cooperation structure across NITAGs

Pilots to provide an overview about the evidence-base of national immunisation programmes

CC

Develop evidence-based tools and guidance at EU level in order to support countries to **anticipate, pre-empt or respond to crisis situations**.

Countering online vaccine misinformation, taking into account the Commission Communication on tackling online disinformation

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.

CR 9c and CC

Online and offline promotion of the new information tools (through social media, search engine optimisation, specialised media) in particular towards the sectors of health care, education, social services, media

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|--|------|--|---|------|------|--|
| Establish a European Vaccination Information Sharing system. | | <p>Launch of the key projects to establish a European Vaccination Information Sharing System</p> | | | | |
| | | <p>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</p> | | | | |
| | | <p>Strengthen consistency, transparency, and methodologies in the assessment of national and regional vaccination plans, by sharing scientific evidence and tools with the support of NITAGs</p> | | | | |
| | | <p>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</p> | | | | |
| | | | <p>Collect vaccination coverage data and share them at EU level</p> | | | |
| | | <p>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</p> | | | | |
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| | 2018 | 2019 | 2020 | 2021 | 2022 |
| <p>Continuously monitor the benefits and risks of vaccines and vaccinations, at EU level, including through post-marketing surveillance studies.</p> <p style="text-align: right;">CR 10 and CC</p> | | <p>Create a sustainable and multi-stakeholder platform for EU post-marketing surveillance studies monitoring the safety, effectiveness, and impact of vaccination</p> | | | |
| <p>Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes.</p> | | | | <p>Guidance on methodologies to assess relative effectiveness of vaccines and vaccination programmes</p> | |
| <p>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.</p> <p style="text-align: right;">CR 12 and CC</p> | | <p>Evaluation of implementation of Directive 2000/54/EC in the various Member States</p> | | | |
| <p>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</p> <p style="text-align: right;">CR 13 and CC</p> | | <p>Development of e-learning training modules targeting GPs and primary healthcare providers focused on improving skills to address hesitant populations and promote behavioural change</p> | | | |

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Develop common principles for vaccine demand forecasting

Development of a concept for a regional or European data warehouse for (virtual stockpiling and vaccine management) needs and stocks
Work ongoing with the HSC and in the GHSI on exchange of medical countermeasures to consider

Consider 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.

CR 14a and CC

Develop 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

Explore feasibility of **physical stockpiling** and engage 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.

CR 14 b and c and CC

Study exploring the feasibility of and identifying options for physical stockpiling of vaccines

Consider 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 for vaccines.

Concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak

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| | 2018 | 2019 | 2020 | 2021 | 2022 |
| <p>Consider, 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.</p> <p style="text-align: right;">CR 14d</p> | | | <p>Conference on improving EU manufacturing capacity and ensuring continuity of supply</p> | | |
| <p>Exploit 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).</p> <p style="text-align: right;">CR 14e</p> | | <p>Joint procurement of pandemic influenza vaccine Framework contracts signed in March 2019 https://europa.eu/rapid/midday-express-28-03-2019.htm#8</p> | | | |
| <p>Support the EU Official Medicines Control Laboratories network and its work to ensure that vaccines placed on the EU market are of high quality.</p> <p style="text-align: right;">CR 14f</p> | | <p>Meeting with the EU Official Medicines Control Laboratories network</p> | | | |
| <p>Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC) and explore ways to enhance compliance with that obligation.</p> <p style="text-align: right;">CR 14g</p> | | <p>Examination whether this article has been implemented in full in national legislation</p> | | | |
| <p>Consider facilitating –together with EMA- early dialogue with developers, national policy-makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats.</p> <p style="text-align: right;">CR 14h</p> | | <p>Actions to facilitate early dialogue with developers, national policy-makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats</p> | | | |

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| | 2018 | 2019 | 2020 | 2021 | 2022 |
| <p>Reinforce existing partnerships and research infrastructures, and establish new ones, including for clinical trials.</p> <p style="text-align: right;">CR 15a and CC</p> | | | <p>Establishment of research networks for clinical trials and fostering collaborative research infrastructures and/or programmes e.g. clinical trial network to be established, ECRIN, support to CEPI, EDCTP-2, etc.</p> | | |
| <p>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 diseases Preparedness (GloPID-R).</p> <p style="text-align: right;">CR 15b and CC</p> | <p>Roadmap of unmet population needs and agreed priorities for vaccines</p> | | <p>Agree on a subset of vaccines as regards research priorities</p> | | |
| | <p>Define a concept framework for decision-making on research priorities for an agreed subset of vaccines</p> | | | | |
| | | | | <p>Define a proposal for an annual list of EU vaccine research priorities</p> | |
| | <p>Report on a proposal for shared funding mechanisms based on an analysis of funding gaps and hurdles for cooperation among funders</p> | | | | |
| <p>Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers.</p> <p style="text-align: right;">CR 15c and CC</p> | | <p>Set of actions funded by Horizon 2020 and actions undertaken by ECDC to address low-vaccine uptake, and behavioural study on vaccination to identify determinants of vaccine hesitancy across different subgroups of the population and health workers</p> | | | |
| <p>Report on a regular basis, on progress in implementing the Recommendation based on indicators agreed with Member States and on information from other relevant sources.</p> <p style="text-align: right;">CR 24</p> | | | <p>Biannual progress report on the implementation of the Council Recommendation</p> | | |