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Proposal for a

COUNCIL RECOMMENDATION

on vaccine-preventable cancers

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Introduction

Europe's Beating Cancer Plan¹ (the Cancer Plan) is a key public health priority of the Commission and a cornerstone of the European Health Union². Together with the Horizon Europe Cancer Mission³, it is the Commission's response to the increasing number of cancer cases and cancer-related deaths across the EU.

As a flagship initiative of the Cancer Plan, the Commission intends to support EU Member States' efforts to strengthen and expand routine vaccination of girls and boys against Human papillomaviruses (HPV) to eliminate cervical cancer and other cancers caused by HPV, such as vulvar, vaginal, penile and anal cancers as well as some head-and-neck cancers. The goal set in the Cancer Plan is to fully vaccinate at least 90 % of the EU target population of girls and to significantly increase the vaccination of boys by 2030. In the Cancer Plan, the Commission also announced that it would help to ensure access to vaccination against Hepatitis B virus (HBV) in order to boost vaccination uptake and thus help prevent disease caused by HBV, including liver cancer.

The Commission is therefore proposing a Council Recommendation on vaccine-preventable cancers to help EU Member States prevent and reduce the cancer risks linked to HPV and HBV infections by boosting HPV and HBV vaccination uptake.

The proposed Council Recommendation was included in the 2023 Commission work programme⁴ under the Commission priority 'Promoting our European Way of Life'.

It aims to help EU Member States to achieve the United Nation's Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages, specifically Target 3.3: 'By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases'⁵.

Both HPV and HBV vaccines can prevent viral infections that may lead to cancer. These vaccines are therefore vital in protecting both individual and public health and in supporting resilient and fair health systems.

They also both fit into the life-course perspective on vaccination that the Commission has been promoting since the adoption, in 2018, of the Council

¹ Communication from the Commission to the European Parliament and the Council on the Europe's Beating Cancer Plan, COM/2021/44 final.

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', COM/2020/724 final.

³ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en

⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Commission work programme 2023: A Union standing firm and united, COM(2022) 548 final.

⁵ <https://sdgs.un.org/goals/goal3>

Recommendation on strengthened cooperation against vaccine-preventable diseases⁶. That Council Recommendation called for a series of actions⁷ to increase the uptake of vaccination throughout life, including the set-up of the European Vaccination Information Portal⁸, where people can easily find evidence-based information on vaccination and vaccines, including for specific age groups. An EU information and awareness-raising campaign on vaccination as a disease prevention measure, #UnitedInProtection⁹, that can be adjusted to address national challenges and needs, was launched in November 2022 and will run at least until November 2024.

HPV and HBV vaccination target different population groups. HPV vaccines are mainly offered to adolescent and preadolescent girls and boys, as well as to young adults as part of targeted catch-up campaigns. HBV vaccines are offered to a large number of heterogeneous population groups, ranging from infants to adults at high risk and sometimes in disadvantaged situations, such as people who inject drugs, prison populations, men having sex with men, trans gender persons, migrants, asylum seekers and refugees from countries where HBV is endemic, as well as health professionals. This requires different approaches to ensure sufficient uptake, including in terms of communication.

The COVID-19 pandemic and the new vaccines made available by the Commission¹⁰ and rolled out by EU Member States highlighted the importance of vaccination as a crisis management tool, but the lockdown measures that were implemented by countries to halt the spread of the virus also disrupted the continuity of national routine vaccination programmes. In addition, the ‘infodemic’ that surrounded the pandemic tested people’s confidence in vaccination because it was hard to differentiate between accurate and false information. This situation was made worse by mis- and disinformation on social media and other media as well as by feelings of ‘vaccination fatigue’. It is therefore important that interdisciplinary expertise to amplify efforts to counter vaccine mis- and disinformation is used by Member States, as highlighted in the Council Conclusions on vaccination¹¹ that were adopted in 2022.

Monitoring of vaccination coverage rates is important to inform interventions aimed at increasing vaccination uptake. Whereas some EU Member States have centralised, population-based Immunisation Information Systems to monitor vaccination coverage rates in their country, including at subnational level, monitoring is fragmented in others. In addition, some EU Member States report issues in relation to the collection of vaccination data as part of the monitoring of vaccination programmes in the context of the national approach to the implementation of provisions of the EU’s General Data Protection Regulation¹² which can be further specified by EU Member States. From another administrative perspective, some EU

⁶ Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (OJ C 466, 28.12.2018, p. 1).

⁷ https://health.ec.europa.eu/system/files/2022-12/2019-2022_roadmap_en.pdf

⁸ <https://vaccination-info.eu/en>

⁹ https://vaccination-protection.ec.europa.eu/index_en

¹⁰ Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank on an EU Strategy for COVID-19 vaccines, COM/2020/245 final.

¹¹ <https://data.consilium.europa.eu/doc/document/ST-14771-2022-INIT/en/pdf>

¹² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

Member States point to issues in the national procedures to obtain parental consent to vaccinate minors, having a possible negative impact on the uptake.

During the COVID-19 pandemic, the European Centre for Disease Prevention and Control (ECDC) collected, analysed and displayed data to monitor the vaccination uptake in the EU and the European Economic Area (EU/EEA) countries through the COVID-19 Vaccine Tracker¹³. The data showed where further public health action was needed to increase coverage rates.

Building on the work already done by the World Health Organization (WHO) to monitor vaccination coverage rates for the 53 countries in the WHO European Region, the ECDC was tasked to monitor the level of vaccination coverage in EU Member States. This is part of the extended mandate given to the ECDC as a building block of the European Health Union¹⁴. ECDC can, however, only accomplish its monitoring task if there are reliable data available from countries.

The proposed Council Recommendation focuses on supporting EU Member States in better monitoring of HPV and HBV vaccination coverage rates. Better monitoring of the uptake of HPV and HBV vaccines, however, goes hand in hand with better monitoring of the uptake of all vaccines included in national immunisation programmes and should not be dealt with separately from this.

HPV-related cancer burden and HPV vaccination

The WHO reports HPV to be the most common viral infection of the reproductive tract causing a range of conditions in both women and men, including precancerous lesions that may progress to cancer. While most HPV infections are asymptomatic and usually resolve spontaneously, some result in disease¹⁵.

Only a few of the more than 200 HPV types identified are oncogenic¹⁶, namely HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58 and 59. These high-risk HPV types are, however, responsible for practically all cervical cancer cases. They are also causally linked to other anogenital cancers (vulvar, vaginal, penile and anal cancers) in both women and men as well as to certain head-and-neck cancers, particularly oropharyngeal cancers¹⁷.

Among the high-risk HPV types, HPV16 and HPV18 have the biggest oncogenic potential. HPV16, the most oncogenic type of all, is consistently the most frequent type detected in HPV-related cancers both in Europe and worldwide¹⁸. The low-risk HPV types 6 and 11 are associated with anogenital warts and recurrent respiratory papillomatosis. It is estimated that there are around 28 600 cases of and 13 700 deaths from cervical cancer every year in EU/EEA countries¹⁹. The age-standardised

¹³ <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>

¹⁴ Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 853/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1).

¹⁵ <https://www.who.int/news-room/fact-sheets/detail/cervical-cancer>

¹⁶ Meaning that they may cause cancer.

¹⁷ European Centre for Disease Prevention and Control. Guidance on HPV vaccination in EU countries: focus on boys, people living with HIV and 9-valent HPV vaccine introduction, 2020. Stockholm: ECDC; 2020.

¹⁸ *Ibid.*

¹⁹ [ECIS - European Cancer Information System](#), accessed on 27/10/2023. EU/EEA figures computed as the sum of values for [EU-27](#), [Norway](#), and [Iceland](#).

incidence rates (European std. population 2013) are 11.8 cases and the mortality rates are 5.3 deaths per 100 000 women²⁰. In addition, among the most relevant HPV-related head-and-neck cancers, it is estimated that there were around 19 700 cases of oropharyngeal cancers in EU/EEA countries in 2022, mostly (around 15 000) in men²¹. Whereas this figure does not cover only HPV-related cancers, increasing trends in the incidence of HPV-positive head and neck cancers have been consistently observed in the last decade in concomitance with the decline in tobacco use²². HPV infections are thought to play an important role in connection with oropharyngeal cancer globally²³, especially in Europe and North America²⁴. In line with this, the United States' Centres for Disease Control and Prevention report that HPV is thought to cause 70 % of oropharyngeal cancers in the United States²⁵.

All EU Member States recommend vaccinating adolescent and preadolescent girls against HPV, and many also recommend it for boys of those age groups. In some EU Member States, the recommendations are currently being extended, via targeted catch-up campaigns, to also cover young adults who did not get vaccinated during adolescence or preadolescence or who are only partially vaccinated, including due to the lockdown measures implemented during the COVID-19 pandemic.

There are currently three HPV vaccines licensed in the EU: a bivalent vaccine that contains virus-like-particles of HPV types 16 and 18, a quadrivalent HPV vaccine that includes virus-like-particles of HPV types 6, 11, 16 and 18 and a nonavalent vaccine that contains virus-like-particles of HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. All vaccines contain virus-like-particles of HPV types 16 and 18, the high-risk HPV types with the biggest oncogenic potential. Vaccine products in use in individual EU Member States depend on national public procurement policies.

Coverage rates vary significantly across the EU. For example, data for vaccination uptake show that whereas a few EU Member States have vaccinated 90 % or more of adolescent and preadolescent girls with one dose out of the two doses required for those age groups, this figure remains low, below 50 %, in other EU Member States²⁶.

²⁰ *Ibid.*

²¹ *Ibid.*

²² European Centre for Disease Prevention and Control. Guidance on HPV vaccination in EU countries: focus on boys, people living with HIV and 9-valent HPV vaccine introduction, 2020. Stockholm: ECDC; 2020.

²³ Castellsagué X, Alemany L, Quer M, Halc G, Quirós B, Tous S, Clavero O, Alòs L, Biegner T, Szafarowski T, Alejo M, Holzinger D, Cadena E, Claros E, Hall G, Laco J, Poljak M, Benevolo M, Kasamatsu E, Mehanna H, Ndiaye C, Guimerà N, Lloveras B, León X, Ruiz-Cabezas JC, Alvarado-Cabrero I, Kang CS, Oh JK, Garcia-Rojo M, Iljazovic E, Ajayi OF, Duarte F, Nessa A, Tinoco L, Duran-Padilla MA, Pirog EC, Viarheichyk H, Morales H, Costes V, Félix A, Germar MJ, Mena M, Ruacan A, Jain A, Mehrotra R, Goodman MT, Lombardi LE, Ferrera A, Malami S, Albanesi EI, Dabed P, Molina C, López-Revilla R, Mandys V, González ME, Velasco J, Bravo IG, Quint W, Pawlita M, Muñoz N, de Sanjosé S, Xavier Bosch F; ICO International HPV in Head and Neck Cancer Study Group. HPV Involvement in Head and Neck Cancers: Comprehensive Assessment of Biomarkers in 3680 Patients. *J Natl Cancer Inst.* 2016 Jan 28;108(6):djv403. doi: 10.1093/jnci/djv403. PMID: 26823521.

²⁴ de Martel C, Plummer M, Vignat J, Franceschi S. Worldwide burden of cancer attributable to HPV by site, country and HPV type. *Int J Cancer.* 2017 Aug 15;141(4):664-670. doi: 10.1002/ijc.30716. Epub 2017 Jun 8. PMID: 28369882; PMCID: PMC5520228.

²⁵ https://www.cdc.gov/cancer/hpv/basic_info/hpv_oropharyngeal.htm

²⁶ https://immunizationdata.who.int/pages/coverage/hpv.html?CODE=EUR&ANTIGEN=PRHPV1_F&Y_EAR=&ADVANCED_GROUPINGS=EURO

Only limited data are currently available for vaccination uptake in boys as well as for young adults.

The proposed Council Recommendation calls for measures to increase the uptake of HPV vaccination among adolescent and preadolescent girls and boys. It also calls for better monitoring of HPV vaccination uptake, to close data gaps and inform public health action.

HBV-related cancer burden and HBV vaccination

HBV is a global health challenge, and chronic infection with the virus is a major cause of chronic liver disease, cirrhosis and liver cancer. Globally, HBV and Hepatitis C virus (HCV) infections are estimated to cause 1.1 million deaths per year²⁷. For 2021, 30 EU/EEA countries reported 16 187 newly diagnosed HBV infections, a large share of those (43 %) being classified as chronic²⁸. Based on data from 2015, it is estimated that across the EU/EEA and the United Kingdom, HBV and HCV infections are responsible for approximately 55 % of all liver cancer deaths and 45 % of all deaths due to cirrhosis and other chronic liver disease and result in approximately 64 000 deaths annually²⁹.

Transmission of HBV, which is a bloodborne virus, may happen perinatally at birth from infected mothers to children (vertical transmission) or through sexual intercourse, unsafe injecting of drugs, contaminated blood or blood products, or suboptimal infection prevention and control practices in healthcare settings.

Despite a steady decline in the overall incidence of HBV over time due to effective vaccination programmes and other prevention strategies, it is estimated that approximately 3.6 million people in EU/EEA countries are living with a chronic HBV infection³⁰. Modelling studies³¹ suggest that associated morbidity and mortality could rise if responses are not further scaled up.

The burden of infection with HBV in EU/EEA countries is higher in some population groups at high risk and sometimes in disadvantaged situations, including people who inject drugs, prison populations, men having sex with men, trans gender persons and migrants, asylum seekers and refugees from countries where HBV is endemic, than in the general population. However, heterosexual intercourse remains a common route of HBV in Europe. And even if vertical transmission is now uncommon in this part of the world, prevention strategies are needed as most infants who are infected perinatally will become chronically infected³².

Most EU Member States recommend vaccination of all children against HBV. In addition, countries have various strategies in place to prevent vertical transmission, including screening of pregnant women for hepatitis B surface antigen (HBsAg), vaccination with the first HBV vaccine dose within 24 hours from birth (also known as ‘birth dose’) and post-exposure prophylaxis for infants born to HBV-infected mothers.

²⁷ Prevention of hepatitis B and C in the EU/EEA. Stockholm: ECDC; 2022.

²⁸ Hepatitis B. In: ECDC. Annual epidemiological report for 2021. Stockholm: ECDC; 2022.

²⁹ Prevention of hepatitis B and C in the EU/EEA. Stockholm: ECDC; 2022.

³⁰ *Ibid.*

³¹ Such as Razavi-Shearer, D. et al. The disease burden of hepatitis B and hepatitis C from 2015 to 2030: the long and winding road [Abstract OS050]. J. Hepatol. 77, S43 (2022).

³² Prevention of hepatitis B and C in the EU/EEA. Stockholm: ECDC; 2022.

There are 12 HBV vaccines authorised in the EU, all of which use HBsAg adsorbed onto aluminium adjuvants. Whereas one vaccine is authorised for use in all ages, the others are authorised for specific age groups. Four vaccines are authorised for use in children, of which three also include antigens for diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type b. In addition to the 12 vaccines authorised in the EU, two others are authorised nationally only. Vaccine products in use in individual EU Member States depend on national public procurement policies.

In 2017, the WHO, in the Action plan for the health sector response to viral hepatitis in the WHO European Region, put forward the goal of eliminating hepatitis as a public health threat in its European Region by 2030³³. However, data from 2021 show, despite gaps, that coverage rates in many EU Member States still need to be improved to reach even the 2020 interim targets set by the WHO of 1) 95 % coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination, and 2) 90 % coverage with interventions to prevent vertical transmission (HBV birth-dose vaccination or other approaches)³⁴, not to mention the 2030 targets of 1) 95 % vaccination coverage (3rd dose) of childhood HBV vaccination, 2) 95 % of pregnant women screened for HBsAg, and 3) 95 % of newborns who received timely (within 24 hours of birth) HBV birth-dose vaccination³⁵.

Many EU Member States also recommend vaccination for groups at high risk and sometimes in disadvantaged situations, such as the ones referred to above, as well as for health professionals. There are, however, gaps in data on vaccination uptake.

The proposed Council Recommendation calls for measures to increase access to HBV vaccination for all population groups for whom vaccination is recommended in order to increase vaccination uptake. It also calls for better monitoring of HBV vaccination uptake, to close data gaps and facilitate efficient, data-driven public health action.

Looking into the future

Other vaccines against cancers caused and not caused by infections are in development, including through the mRNA platform that was also used for some COVID-19 vaccines. Research on prophylactic vaccines against cancers caused by infections is being supported by the Commission's Horizon Europe (2021-2027) Framework Programme for Research and Innovation. For example through the Vax2Muc³⁶ project, targeting the bacterium *Helicobacter pylori* that can cause stomach cancer. In addition, the Innovation Task Force of the European Medicine's Agency (EMA) and its PRIME scheme provide support to the development of innovative medicines targeting unmet medical needs. In the future, prophylactic vaccines against cancers caused by infections may therefore have an even more important role to play than today. Such perspectives, however, go beyond the scope of the proposed Council Recommendation and are not addressed therein.

³³ World Health Organization. Regional Office for Europe. (2017). Action plan for the health sector response to viral hepatitis in the WHO European Region. World Health Organization. Regional Office for Europe.

³⁴ Prevention of hepatitis B and C in the EU/EEA. Stockholm: ECDC; 2022.

³⁵ Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022-2030 (2023). World Health Organization. Regional Office for Europe.

³⁶ <https://cordis.europa.eu/project/id/101080486>

Commission supportive actions

The proposed Council Recommendation contains recommendations to EU Member States to boost HPV and HBV vaccination uptake. The Commission is planning to carry out a series of actions to support countries in implementing the recommendations. These actions will, in particular, aim to support EU Member States in communicating about the importance of HPV and HBV vaccination in a cancer prevention perspective and better monitoring vaccination uptake to inform public health interventions, but will also go beyond those areas.

On communication, the Commission intends to develop a model for evidence-based awareness-raising campaigns on the importance of HPV and HBV vaccination as cancer prevention tools, adaptable to national challenges and needs and taking into account national specificities, and with the involvement of stakeholder associations at European level, including health professionals' associations, and national counterparts, and with an in-built strategy to continue monitoring and addressing mis- and disinformation specifically related to HPV infection and HPV vaccination, including on social media. It also intends to request the European Medicines Agency and the ECDC to communicate regularly on the outcomes of updated reviews and studies on the safety and effectiveness of the HPV and HBV vaccines in order to provide up-to-date information and address safety-driven acceptance issues faced in the EU, including through the European Vaccination Information Portal.

On monitoring, the Commission intends to support EU Member States in developing or upgrading electronic vaccination registries in compliance with the General Data Protection Regulation, including by mapping national approaches across the EU and discussing successful ones with Member States. This would happen without prejudice to the tasks of the national data protection authorities and in respect of any relevant guidance of the European Data Protection Board. The Commission also envisages to support EU Member States in streamlining their procedures for obtaining parental consent to vaccinate minors in respect of national legislation in the field, including by sharing and discussing national approaches. Moreover, it is the Commission's intention to continue, in collaboration with the ECDC, to develop state-of-the-art guidance to EU Member States in terms of building or upgrading electronic vaccination registries that enable the availability of data at national and subnational level and to which data recorded by different vaccine providers can be seamlessly transferred, in order to improve and strengthen the monitoring of vaccination coverage rates, including for HPV and HBV vaccination. By the end of 2024, the Commission intends to request that the ECDC displays available national data on HPV and HBV coverage rates in EU Member States in a dedicated dashboard together with national monitoring methodologies and goals and targets to be met.

Going beyond communication and monitoring, the Commission intends to support the development of modelling tools and analysis to estimate the cost-effectiveness of preventing cancers caused by HPV and HBV infection by vaccination, to support EU Member States in their decision-making on the integration of these types of vaccination in their national immunisation programmes and cancer prevention programmes. The Commission also intends to further promote research, development and innovation in relation to HPV and HBV vaccines, including through the Horizon Europe programme and its successor programmes. And it envisages to further support action to promote HPV and HBV vaccination at global level, including in terms of identifying behavioural determinants for vaccine uptake and addressing

obstacles to vaccination, working with international partners, such as the WHO, the Organisation for Economic Cooperation and Development (OECD) and the United Nations Children's Fund (UNICEF). Finally, the Commission, in line with its comprehensive approach to mental health³⁷, and taking the EU Strategy on the Rights of the Child³⁸ and the European Child Guarantee³⁹ into account, intends to develop a prevention toolkit addressing the links between mental and physical health, including physical health linked to vaccination, of children and thus making an impact in the most vulnerable and formative years of their lives.

The Commission intends to implement all supportive actions in close cooperation with EU Member States.

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

The proposed Council Recommendation complements other actions in the context of the Cancer Plan. These are most notably the European Code against Cancer, also calling for increased uptake of HPV vaccination, the EU Cancer Screening Scheme that foresees the updating of recommendations on screening and new guidelines together with quality assurance schemes and includes the recent Council Recommendation on strengthening prevention through early detection: a new EU approach on cancer screening⁴⁰ and the European Cancer Inequalities Registry⁴¹. The initiative also complements –and in relation to HPV builds directly on– the joint action PartnERship to Contrast HPV (PERCH)⁴². As announced in the Cancer Plan, the EU4Health programme and other EU instruments are key tools to provide support to EU Member States in their efforts to combat cancer.

- **Consistency with other Union policies**

Besides complementing other actions in the context of the Cancer Plan, the proposed Council Recommendation builds on and amplifies the impact of the actions implemented based on the above-mentioned 2018 Council Recommendation on strengthened cooperation against vaccine-preventable diseases, including those implemented by the European Joint Action on Vaccination⁴³, which ran from 2018 to 2022. The initiative also draws on vaccination-related actions under the EU4Health programme, including the 'Overcoming Obstacles to Vaccination'⁴⁴ project on how to reduce obstacles to vaccination of physical, practical or administrative nature by

³⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health, COM(2023) 298 final, 7.6.2023.

³⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an EU strategy on the rights of the child, COM(2021) 142 final, 24.3.2021.

³⁹ Council Recommendation (EU) 2021/1004 of 14 June 2021 establishing a European Child Guarantee (OJ L 223, 22.6.2021, p. 14).

⁴⁰ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: a new EU approach on cancer screening replacing Council Recommendation 2003/878/EC (OJ C 473, 13.12.2022, p. 1).

⁴¹ <https://cancer-inequalities.jrc.ec.europa.eu/>

⁴² <https://www.projectperch.eu/>

⁴³ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/31061266/801495/3HP>

⁴⁴ <https://overcomingobstaclestovaccination.eu/en>

identifying exemplary practices in EU Member States through the Commission's Best Practice Portal⁴⁵ and piloting those practices in interested countries.

The proposed Council Recommendation also complements the EU Strategy on the Rights of the Child⁴⁶ and the European Child Guarantee⁴⁷, in which access to vaccination is a key element in terms of ensuring the right to healthcare for all children. Furthermore, the initiative supports the protection of the health of children and young people in the most vulnerable and formative years of their lives, as mentioned in the Commission Communication on a comprehensive approach to mental health⁴⁸ that calls for a holistic approach to health in general and mental health in particular, including access to preventive healthcare, such as vaccination.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

This proposal for a Council Recommendation is based on Article 168(6) of the Treaty on the Functioning of the European Union (TFEU), according to which the Council, on a proposal from the Commission, may adopt recommendations for the purposes set out in that Article to improve public health. According to Article 168(1) TFEU, EU action must complement national policies and must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. The aim of the proposed Council Recommendation is to support EU Member States in addressing the cancer risks linked to HPV and HBV infections by increasing the uptake of and ensuring access to vaccination.

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

Vaccination policies, programmes and services are a national competence and responsibility. Nevertheless, viral infections, including those causing cancers, do not respect borders, and all EU Member States face public health challenges in the field. There is therefore a clear added value in addressing vaccine-preventable cancers with a set of recommendations at EU level.

- **Proportionality**

This proposal for a Council Recommendation takes into account that EU action, which must, as set out in Article 168 of TFEU, complement national policies (including policies on vaccination), must be directed towards protecting public health. As mentioned above, the aim of the initiative is to support EU Member States in addressing the cancer risks linked to HPV and HBV infections by increasing the uptake of and ensuring access to vaccination. The proposal fully respects that vaccination is a national competence and responsibility and does not go beyond what is needed to reach its objectives.

⁴⁵ <https://webgate.ec.europa.eu/dyna/bp-portal/>

⁴⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an EU strategy on the rights of the child, COM/2021/142 final.

⁴⁷ Council Recommendation (EU) 2021/1004 of 14 June 2021 establishing a European Child Guarantee (OJ L 223, 22.6.2021, p. 14).

⁴⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health, COM(2023) 298 final.

- **Choice of instrument**

The instrument chosen for this initiative, namely a proposal for a Council Recommendation, fully respects the principles of subsidiarity and proportionality, allowing EU Member States to adapt their approach to national needs.

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

- ***Ex-post* evaluations/fitness checks of existing legislation**

This proposal for a Council Recommendation is a new initiative. Therefore, *ex-post* evaluations/fitness checks of existing legislation have not been carried out.

- **Stakeholder consultations**

Input for the proposed Council Recommendation was gathered through a call for evidence on ‘Cancer prevention – action to promote vaccination against cancer-causing viruses’⁴⁹, which ran from 9 January 2023 to 6 February 2023. Out of a total of 367 responses received, 331 were valid. Of the 331 valid responses, 300 responses came from EU citizens.

Input was also gathered through targeted consultations of key stakeholder groups other than EU citizens, such as EU Member State representatives, European Non-Governmental Organisations and experts participating in EU-funded projects. The targeted consultations were carried out from February 2023 to April 2023. As part of these consultation activities, a dedicated Stakeholder Webinar on the initiative was held on the Commission’s Health Policy Platform⁵⁰ on 23 March 2023.

300 responses were received from EU citizens. Out of these responses, 260 focused on misperceptions regarding alleged lack of safety of vaccination in general. However, almost all responses with concerns came from EU citizens from one EU Member State whose population size accounts for only around 1 % of the EU population. In addition, the responses with concerns were similar, albeit not identical, and this suggests a coordinated campaign promoting a position that is not necessarily representative for EU citizens but reiterates the need to increase public confidence in vaccines, including by debunking false narratives.

The key stakeholder groups other than EU citizens had a positive attitude towards the initiative. Stakeholders stressed the importance of integrating HPV and HBV vaccination in national immunisation programmes. In addition, stakeholders stressed that improved monitoring of vaccination coverage rates is needed to better inform public health action aimed at increasing uptake. Moreover, stakeholders invited the Commission to coordinate EU Member States’ efforts to implement the General Data Protection Regulation in relation to the collection of vaccination data as the national approach creates issues in some countries. They also stressed that there could be an added value in coordinating vaccination and cancer registries, including to eventually increase the cost-efficiency of cancer screening programmes. Stakeholders also stressed the importance of increasing public confidence in vaccines, including by monitoring and addressing mis- and disinformation, and of ensuring easy access to

⁴⁹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13529-Cancer-prevention-action-to-promote-vaccination-against-cancer-causing-viruses_en

⁵⁰ https://health.ec.europa.eu/eu-health-policy/interest-groups/eu-health-policy-platform_en

vaccination, including by providing vaccination free of charge to those for whom vaccination is recommended. Some stakeholders pointed to issues in relation to the national procedures for obtaining parental consent to vaccinate minors, having a possible negative impact on the uptake. Some stakeholders also mentioned supply issues and stressed the importance of sufficient supply of vaccines. It was suggested that the Commission could facilitate the sharing of best practices to increase vaccination uptake.

Specifically on HPV vaccination, stakeholders suggested to: 1) offer vaccination free of charge as part of national immunisation programmes; 2) offer vaccination (also) in schools/educational settings; 3) carry out targeted catch-up campaigns and/or extend eligible age groups in the wake of the COVID-19 pandemic; 4) increase public knowledge on the cancer risks linked to HPV infection for both girls and boys and the importance of HPV vaccination for both genders; and 5) de-sexualise communication efforts, promoting, together with health professionals and/or youth influencers, HPV vaccination as a cancer prevention tool in addition to being a tool to sexual/reproductive health.

Stakeholders also invited the Commission to look into a possible reassessment of the marketing authorisation conditions of the HPV vaccines currently on the EU market in view of allowing for a one-dose schedule, as this could reduce costs for EU Member States and make vaccination a one-step procedure, possibly increasing the uptake among disadvantaged groups. It was suggested to define a specific goal for the percentage of the EU target population of boys that should be vaccinated by 2030, parallel to the one for girls.

Specifically on HBV, stakeholders suggested to: 1) offer vaccination free of charge to all eligible population groups, reaching out to groups at high risk and sometimes in disadvantaged situations, such as people who inject drugs, prison populations, men having sex with men, trans gender persons and migrants, asylum seekers and refugees from countries where HBV is endemic; and 2) carry out targeted catch-up campaigns in the wake of the COVID-19 pandemic. Stakeholders also called for studies to monitor progress towards the WHO hepatitis elimination targets, including those related to childhood vaccination and prevention of vertical transmission of HBV.

The opinions put forward by stakeholders were analysed and taken into consideration in the initiative to the extent possible. The following elements were considered particularly pertinent to reach its objectives:

- ensuring easy access to vaccination, with a particular focus on disadvantaged groups;
- increasing public confidence in vaccines, including by monitoring and addressing mis- and disinformation;
- improving monitoring of vaccination coverage rates to better inform interventions, including by solving issues experienced by some EU Member States in relation to the collection of vaccination data in the context of the national approach to the implementation of provisions of the General Data Protection Regulation which can be further specified by EU Member States;
- streamlining parental consent procedures to vaccinate minors in respect of national legislation in the field;

- integrating vaccination in cancer prevention programmes, at operational level but also to provide integrated health communication on cancer prevention;
- coordinating vaccination and cancer registries, including to eventually increase the cost-efficiency of screening programmes;
- sharing of best practices.

As regards a possible reassessment of the marketing authorisation conditions of the HPV vaccines currently on the EU market, it should be noted that a one-dose schedule can be seen as more relevant in a situation of general vaccine shortage that is not the case within the EU. Stakeholders' call for studies to monitor progress towards the WHO hepatitis elimination targets, including those related to childhood vaccination and prevention of vertical transmission of HBV, was taken into consideration to the extent that the ECDC is already supporting countries in the monitoring of progress towards those targets.

In addition to the consultation activities directly linked to this proposed Council Recommendation, the public consultation, the targeted consultations and other consultation activities carried out in relation to the Cancer Plan⁵¹ informed it. Multi-faceted cancer prevention efforts and the protection of children and young people against cancers that can occur later in life were priorities for those who provided input to those consultation activities. Vaccination, such as against HPV and HBV, was also identified as a high priority.

- **Collection and use of expertise**

To prepare for this policy initiative, the Commission, in spring 2022, sent a formal request to the ECDC, working with EMA and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), for scientific input on HPV and HBV, focusing on vaccination. The ECDC, the EMA and the EMCDDA were consulted again during the actual preparation of the proposal. The contributions from the ECDC, the EMA and the EMCDDA added to the scientific base of the initiative.

- **Impact assessment**

An impact assessment was not carried out as a Council Recommendation implies non-binding measures and will allow EU Member States to adapt their approach to national needs.

- **Regulatory fitness and simplification**

Not applicable.

- **Fundamental rights**

As mentioned above, this policy initiative complements the EU Strategy on the Rights of the Child and the European Child Guarantee, in which access to vaccination is a key element in terms of ensuring the right to healthcare for all children.

⁵¹ Commission Staff Working Document – Stakeholder Consultation – Synopsis Report – Accompanying the Communication from the Commission to the European Parliament and the Council on the Europe's Beating Cancer Plan, COM(2021) 44 final.

4. BUDGETARY IMPLICATIONS

This policy initiative will not generate any budgetary impact for the Commission.

5. OTHER ELEMENTS

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

The Commission intends to invite EU Member States to regularly provide information to allow to monitor the implementation of the recommendations contained in the proposed Council Recommendation. It envisages to do so through the Public Health Expert Group established in 2022⁵². This expert group has a subgroup on vaccination and one on cancer.

The recommendations to EU Member States are oriented towards the achievement of the 2030 goals and targets set for HPV and HBV vaccination coverage rates in the Cancer Plan and by the WHO⁵³ respectively.

The Commission intends to monitor progress towards the HPV and HBV vaccination coverage rates by requesting, by the end of 2024, that the ECDC displays available national data on HPV and HBV vaccination coverage rates in EU Member States in a dedicated dashboard together with national monitoring methodologies and goals and targets to be met. Progress indicators would relate to vaccination coverage rates in countries. The level of completeness of the data displayed by the ECDC would depend on the monitoring and reporting of vaccination coverage rates by EU Member States. It may improve as national monitoring systems are strengthened through the implementation of related individual recommendations in the initiative.

The reporting on the implementation of recommendations to EU Member States would happen through updates to EU Member States in the Public Health Expert Group after 4 years and again in 2030.

The reporting and monitoring is envisaged to continue until 2030.

- **Explanatory documents (for directives)**

Not applicable.

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

Not applicable.

⁵² Commission Decision of 7 December 2022 setting up a Commission expert group on public health and repealing Commission Decision setting up a Commission expert group ‘Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases’, C(2022) 8816 final.

⁵³ The targets set by WHO for HBV also include the target of 95 % of pregnant women screened for HBsAg. This target is also considered for the purposes of implementation and monitoring in the context of the proposed Council Recommendation.

Proposal for a

COUNCIL RECOMMENDATION

on vaccine-preventable cancers

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) Under Article 168 of the Treaty on the 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 illnesses and diseases, and obviating sources of danger to physical and mental health, including cancer.
- (2) Vaccination policies, programmes and services are the competence and responsibility of Member States. However, the Commission supports and coordinates national efforts due to the cross-border nature of vaccine-preventable diseases. It does this, amongst others, through communication efforts such as setting up the European Vaccination Information Portal, where people can find reliable information about vaccination and vaccines, and developing information and awareness-raising campaigns, such as the ongoing #UnitedInProtection campaign, which is adaptable to national challenges and needs.
- (3) Some types of cancers, namely cancers caused by Human papillomaviruses (HPV) and Hepatitis B virus (HBV), can be prevented by vaccination. Vaccination remains one of the most powerful and efficient public health measures at Member States' disposal.
- (4) In Europe's 2021 Beating Cancer Plan¹ (the Cancer Plan), the Commission put forward the objective to fully vaccinate at least 90 % of the Union target population of girls against HPV and significantly increase the vaccination of boys against HPV by 2030. In addition, the Commission announced that it would help ensure access to vaccination against HBV in order to increase vaccination uptake.
- (5) Some Member States have centralised, population-based Immunisation Information Systems in place to monitor vaccination coverage rates in their country, including at subnational level. However, monitoring is fragmented in other Member States, and some of the countries report issues in collecting vaccination data as part of the monitoring of vaccination programmes in the context of the national approach to

¹ Communication from the Commission to the European Parliament and the Council on the Europe's Beating Cancer Plan, COM(2021) 44 final, 3.2.2021.

implementing Regulation (EU) 2016/679 of the European Parliament and of the Council², the Union's General Data Protection Regulation.

- (6) Some Member States have encountered issues in relation to the national procedures for obtaining parental consent to vaccinate minors, having a possible negative impact on the uptake.
- (7) Any processing of personal data by Member States for vaccination purposes should comply with EU data protection law, in particular the General Data Protection Regulation, with a focus on the provisions governing the processing of special categories of personal data within the meaning of Article 9 of the General Data Protection Regulation. These provisions can be further specified by Member States.
- (8) It is envisaged to give Union support to Member States to develop or upgrade electronic vaccination registries in line with the General Data Protection Regulation, without prejudice to the tasks of the national data protection authorities and in respect of any relevant guidance of the European Data Protection Board, as well as to streamline parental consent procedures, in respect of national legislation in the field. This would, amongst others, happen by mapping national approaches across the Union and discussing successful ones with Member States.
- (9) HPV infection can lead to cervical cancer in women. In the Union and the European Economic Area (EEA), there are around 28 600 cases of and 13 700 deaths from cervical cancer every year³. Infection with HPV can also lead to other anogenital cancers in both women and men (vulvar, vaginal, penile and anal cancers) as well as head-and-neck cancers, such as oropharyngeal cancers, of which there were around 19 700 cases in the Union and the EEA in 2022, mostly (around 15 000) in men⁴.
- (10) While risk-based screening in line with the Council Recommendation on strengthening prevention through early detection: a new EU approach on cancer screening⁵ can help prevent cervical cancer in women, no high-quality screening programme is currently available in all Member States and EEA countries for women to prevent other cancers caused by HPV infection. And so far, there is no organised screening for such cancers available for men.
- (11) Vaccination against HPV as part of national immunisation programmes provides a benefit in preventing cancers in both women and men.
- (12) All Member States recommend vaccination of adolescent and preadolescent girls against HPV. Many Member States also recommend it for boys of those age groups, some of the countries extending recommendations to also cover, via targeted catch-up campaigns, young adults who did not get vaccinated or fully vaccinated during adolescence or preadolescence.
- (13) Data for vaccination uptake show that whereas a few Member States have vaccinated more than 90 % of adolescent or preadolescent girls with one out of the two doses that

² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

³ [ECIS - European Cancer Information System](#), accessed on 27/10/2023. EU/EEA figures computed as the sum of values for [EU-27](#), [Norway](#), and [Iceland](#).

⁴ *Ibid.*

⁵ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: a new EU approach on cancer screening replacing Council Recommendation 2003/878/EC (OJ C 473, 13.12.2022, p. 1).

are needed for those age groups⁶ this figure remains low, below 50 %, in other Member States⁷. Only limited data are currently available for vaccination uptake in boys as well as in young adults.

- (14) Public confidence in HPV vaccines is falling across the Union, in particular among young people. Although confidence among health professionals in these vaccines is overall high, it varies between Member States⁸.
- (15) Confidence issues in relation to HPV vaccination should be tackled by addressing persistent safety concerns as well as low perceived risk of getting cancer due to HPV infection. The underestimation of the importance of HPV vaccination as a cancer prevention tool, in particular among boys and their parents, should also be addressed by continuing communication efforts and by monitoring and addressing mis- and disinformation related to HPV infection and HPV vaccination.
- (16) Access issues in relation to HPV vaccination should be addressed by offering free vaccination in schools and educational settings, and through targeted efforts, including by working with health professionals, local associations and trusted individuals at community level, to address structural barriers and increase HPV vaccination uptake among adolescent and preadolescent girls and boys belonging to disadvantaged groups, such as migrants, asylum seekers and refugees, displaced persons from Ukraine, Roma, persons with disabilities and lesbian, gay, bisexual, trans, intersex and queer (LGBTIQ) people.
- (17) In 2022, the joint action PartnERship to Contrast HPV (PERCH)⁹, was launched, bringing together European countries to fight cancers caused by HPV infection from a wide range of perspectives.
- (18) A coordinated approach to HPV-related cancer prevention across the Union, building on the goal put forward in the Cancer Plan as well as the work carried out by the joint action PartnERship to Contrast HPV (PERCH), and taking into account Member States' individual situations in terms of cancer burden from HPV infection, could boost national efforts in the field. Defining a specific goal for the percentage of the Union target population of boys that should be vaccinated by 2030 for public health and gender equality reasons could help in this respect.
- (19) Infection with HBV can become chronic and develop into chronic liver disease, cirrhosis and liver cancer. For 2021, 30 Member States and EEA countries reported 16 187 newly diagnosed HBV infections, a large share of those, 43 %, being classified as chronic¹⁰. Despite a steady decline in the overall incidence of HBV over time due to effective vaccination programmes and other prevention strategies, it is estimated that

⁶ Three doses are needed for older young people.

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https://immunizationdata.who.int/pages/coverage/hpv.html?CODE=EUR&ANTIGEN=PRHP_V1_F&YEAR=&ADVANCED_GROUPINGS=EURO

⁸ A. de Figueiredo, R.L. Eagan, G. Hendrickx, E. Karafillakis, P. van Damme and H.J. Larson, 'State of Vaccine Confidence in the European Union 2022', Luxembourg: Publications Office of the European Union; 2022.

⁹ <https://www.projectperch.eu/>

¹⁰ Hepatitis B. In: ECDC. Annual epidemiological report for 2021. Stockholm: ECDC; 2022.

approximately 3.6 million people in Member States and EEA countries are living with a chronic HBV infection¹¹.

- (20) The burden of infections with HBV in Member States and EEA countries is higher in some population groups, including migrants, asylum seekers and refugees from countries with a high HBV endemicity, prison populations, people who inject drugs and men having sex with men, than in the general population. Heterosexual intercourse, however, remains a common route of HBV transmission in Europe, and even if vertical transmission is now uncommon in this part of the world, prevention strategies are needed as most infants who are infected perinatally will become chronically infected¹².
- (21) Vaccination against HBV as part of national immunisation programmes is key to prevent disease caused by chronic infection with HBV, including liver cancer.
- (22) Most Member States recommend vaccinating all children against HBV. They also have various strategies to prevent mother-to-child (vertical) transmission, including vaccination of infants with the first HBV vaccine dose within 24 hours from birth (also known as 'birth dose'), screening of pregnant women for hepatitis B surface antigen (HBsAg) and post-exposure prophylaxis targeted at infants born to HBV-infected mothers.
- (23) Many Member States have HBV vaccination recommendations for groups at high risk and sometimes in disadvantaged situations, such as people who inject drugs, prison populations, men having sex with men, trans gender persons and migrants, asylum seekers and refugees from countries with a high HBV endemicity, as well as for health professionals. However, data gaps exist in relation to vaccination uptake.
- (24) In 2017, the WHO, in the Action plan for the health sector response to viral hepatitis in the WHO European Region, put forward the goal of eliminating hepatitis as a public health threat in its European Region by 2030¹³.
- (25) Specifically on vaccination, the WHO set interim targets for 2020 of 1) 95 % coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination, and 2) 90 % coverage with interventions to prevent vertical transmission (HBV birth-dose vaccination or other approaches)¹⁴.
- (26) In 2022, the WHO updated the regional Action plan and set 2030 targets of 1) 95 % vaccination coverage (3rd dose) of childhood HBV vaccination, 2) 95 % of pregnant women screened for HBsAg, and 3) 95 % of newborns who received timely (within 24 hours of birth) HBV birth-dose vaccination¹⁵.
- (27) The ECDC supports the monitoring of Member States' progress towards WHO hepatitis elimination targets, including those related to childhood vaccination and prevention of vertical transmission of HBV. Data from 2021 show, despite gaps, that

¹¹ European Centre for Disease Prevention and Control, 'Prevention of hepatitis B and C in the EU/EEA', Stockholm: ECDC; 2022.

¹² *Ibid.*

¹³ World Health Organization. Regional Office for Europe. (2017). Action plan for the health sector response to viral hepatitis in the WHO European Region. World Health Organization. Regional Office for Europe.

¹⁴ *Ibid.*

¹⁵ Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022-2030 (2023). World Health Organization. Regional Office for Europe.

coverage rates in many Member States must still be improved to reach even the 2020 interim targets¹⁶. For the 2030 targets, the challenge is not less important.

- (28) Public confidence issues in relation to HBV vaccination should be addressed by improving health literacy among groups at high risk and sometimes in disadvantaged situations, such as people who inject drugs, prison populations, men having sex with men, trans gender persons and migrants, asylum seekers and refugees from countries where HBV is endemic, as well as health professionals, and by advocating for HBV vaccination as a cancer prevention tool.
- (29) Access issues in relation to HBV vaccination should be addressed through targeted efforts to understand structural barriers and by offering vaccination in local settings adjusted to target groups in line with their risk profile and situation, for example by making use of mobile units, offering vaccination during other healthcare events, such as medical check-ups, and ensuring that vaccination is provided free of charge.
- (30) Special attention should be paid to older persons and people living in remote areas as well as to people who inject drugs, making HBV vaccination routine in drug treatment, prison and harm-reduction services, in a stigma-free environment, on a voluntary basis, without costs for the person being vaccinated, and with the possibility for accessing an accelerated dosing schedule.
- (31) In the extended mandate given to the European Centre for Disease Prevention and Control (ECDC) under the European Health Union¹⁷, the ECDC is tasked to monitor the level of vaccination coverage in Member States based on reliable data available from countries.
- (32) By the end of 2024, the Commission intends to request ECDC to display available national data on HPV and HBV coverage rates in Member States in a dedicated dashboard together with national monitoring methodologies and goals and targets¹⁸ to be met.
- (33) There is a need to better integrate HPV and HBV vaccination in cancer prevention programmes, at operational level but also to provide integrated health communication on cancer prevention, promoting vaccination as a cancer prevention tool in addition to being a tool to sexual/reproductive health. There is also a need to coordinate vaccination and cancer registries to measure the overall impact of vaccination and cancer prevention programmes, including in view of eventually increasing the cost-efficiency of screening programmes. As the aim is to increase vaccination coverage rates among children and young people, particular attention should be paid to the effect and role of social media and digital platforms.
- (34) The Commission intends to develop a model for evidence-based awareness-raising campaigns on the importance of HPV and HBV vaccination as cancer prevention tools, adaptable to national challenges and needs, and with the involvement of stakeholder associations at European level, including health professionals' associations, and national counterparts, and with an in-built strategy to continue

¹⁶ Prevention of hepatitis B and C in the EU/EEA. Stockholm: ECDC; 2022.

¹⁷ Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1)..

¹⁸ The targets set by WHO for HBV also include the target of 95 % of pregnant women screened for HBsAg. This target is also considered for the purposes of implementation and monitoring in the context of the proposed Council Recommendation.

monitoring and addressing mis- and disinformation specifically related to HPV infection and HPV vaccination, including on social media, at Union level. Nevertheless, communication campaigns need to take into account national specificities of the Member States.

- (35) The Commission envisages to request the European Medicines Agency and the ECDC to communicate regularly on the outcomes of updated reviews and studies on the safety and effectiveness of the HPV and HBV vaccines in order to provide up-to-date information and address safety-driven acceptance issues faced in the EU, including through the European Vaccination Information Portal.
- (36) In line with its comprehensive approach to mental health¹⁹, and taking the EU Strategy on the Rights of the Child²⁰ and the European Child Guarantee²¹ into account, the Commission intends to develop a prevention toolkit addressing the links between mental and physical health, including physical health linked to vaccination, in children and thus making an impact in the most vulnerable and formative years of their lives.
- (37) Union citizens' access to their vaccination data should be further facilitated. This would empower them to better follow their vaccination history and make decisions on vaccination. The exchange of such data for continuity of care purposes across the Union should also be further facilitated.
- (38) The Commission and the World Health Organization (WHO) have entered a partnership to develop the WHO Global Digital Health Certification Network that takes up the EU Digital COVID Certificate technology. This technology may be used in other cases, such as routine immunisation records in view of delivering better health for Union citizens.
- (39) Continued use by Member States of funding opportunities from the Union's budget, including the European Regional Development Fund, the European Social Fund+ and the EU4Health Programme, in accordance with each instrument's focus and legal basis, to implement HPV and HBV vaccination programmes, including communication activities to promote them, could reduce health inequalities linked to access to and availability of vaccination.
- (40) The Commission intends to support the development of modelling tools and analysis to estimate the cost-effectiveness of preventing cancers caused by HPV and HBV infection by vaccination, to support EU Member States in their decision-making on the integration of these types of vaccination in their national immunisation programmes and cancer prevention programmes. The Commission also intends to promote research, development and innovation in relation to HPV and HBV vaccines at Union level, including through the Horizon Europe programme and its successor programmes.
- (41) It is envisaged to further promote Union action to increase HPV and HBV vaccination at global level, including in terms of identifying behavioural determinants for vaccine

¹⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health, COM(2023) 298 final, 7.6.2023.

²⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an EU strategy on the rights of the child, COM(2021) 142 final, 24.3.2021.

²¹ Council Recommendation (EU) 2021/1004 of 14 June 2021 establishing a European Child Guarantee (OJ L 223, 22.6.2021, p. 14).

uptake and addressing obstacles to vaccination, by working with international partners, such as the WHO, the Organisation for Economic Cooperation and Development (OECD) and the United Nations Children's Fund (UNICEF).

- (42) The Commission intends to invite Member States to regularly provide information to allow to monitor the implementation of the recommendations contained in this Council Recommendation through the Public Health Expert Group and to report on the implementation of recommendations to Member States through updates in the Public Health Expert Group after 4 years and again in 2030.

HEREBY RECOMMENDS THAT MEMBER STATES:

1. Introduce or strengthen the implementation of HPV and HBV vaccination programmes to boost cancer prevention as part of national immunisation programmes, including by providing vaccination free of charge and/or fully reimbursing related costs for those for whom vaccination is recommended, and by ensuring accessibility for groups at high risk and/or in disadvantaged situations.
2. Strengthen the integration of HPV and HBV vaccination in cancer prevention programmes, at operational level but also to provide integrated health communication on cancer prevention.
3. In respect of the Union's data protection law, establish or strengthen links between vaccination and cancer registries to measure the overall impact of vaccination and cancer prevention programmes, including in view of eventually increasing the cost-efficiency of cancer screening programmes.
4. Develop actions to increase the uptake of HPV and HBV vaccination in a cancer prevention perspective, namely by facilitating the identification and transfer of best or promising practices to increase vaccination uptake, including in the context of the Public Health Expert Group, established in 2022²², and its subgroups on vaccination and cancer, and through targeted calls for practices on the Commission's Best Practice Portal²³.
5. In compliance with the General Data Protection Regulation, improve the monitoring of vaccination coverage rates, including for HPV and HBV vaccination, by building or upgrading population-based electronic vaccination registries that enable the availability of data at national level and subnational level and to which data recorded by different vaccine providers can be seamlessly transferred, to inform efficient, data-driven public health action.
6. Streamline national procedures for obtaining parental consent to vaccinate minors in respect of national legislation in the field, including by sharing and discussing national approaches, to facilitate the uptake.
7. Actively participate in efforts to further facilitate Union citizens' access to their vaccination data, empowering them to follow their vaccination history and make decisions on vaccination, as well as to further facilitate the exchange of such data for continuity of care purposes across the Union.

²² Commission Decision C(2022) 8816 final of 7 December 2022 setting up a Commission expert group on public health and repealing Commission Decision setting up a Commission expert group 'Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases' (OJ C 471, 12.12.2022, p. 8).

²³ <https://webgate.ec.europa.eu/dyna/bp-portal/>

8. Actively participate in efforts to further develop the WHO Global Digital Health Certification Network, including its potential use for routine immunisation records that could support Union citizens for health purposes.
9. Make full use of funding opportunities from the Union budget, including the European Regional Development Fund, the European Social Fund+ and the EU4Health Programme, in accordance with each instrument's focus and legal basis, to implement HPV and HBV vaccination programmes, including communication activities to promote them, to reduce health inequalities linked to access to and availability of vaccination.
10. Specifically for HPV vaccination, strengthen national efforts to reach, by 2030, the objective set in the Cancer Plan of fully vaccinating at least 90 % of the EU target population of girls and significantly increasing the vaccination of boys, including by offering vaccination to adolescent and preadolescent girls and boys in schools and educational settings, addressing structural barriers for those belonging to disadvantaged groups, such as migrants, asylum seekers and refugees, displaced persons from Ukraine, Roma, persons with disabilities and LGBTIQ people, and extending recommendations to also cover, via targeted catch-up campaigns, young adults who did not get vaccinated or fully vaccinated during adolescence or preadolescence.
11. Enhance targeted communication and outreach efforts, by working with stakeholder associations, including health professionals' associations, the education sector and trusted partners at community level, to increase HPV vaccination uptake among the target populations specified in Recommendation 10, while ensuring monitoring of the uptake in a central data repository at national level.
12. Building on the work carried out by the joint action PartnERship to Contrast HPV (PERCH), develop and implement coordinated efforts for HPV-related cancer prevention, taking into account the specific situation in Member States in terms of cancer burden from HPV infections, as well as the status of vaccination and screening programmes, and, as part of such coordinated efforts, define a concrete goal for the percentage of the EU target population of boys that should be vaccinated by 2030.
13. Specifically for HBV, strengthen national efforts to reach the 2030 targets set by WHO of 1) 95 % vaccination coverage (3rd dose) of childhood HBV vaccination, 2) 95 % of pregnant women screened for HBsAg, and 3) 95 % of newborns who received timely (within 24 hours of birth) HBV birth-dose vaccination, including by strengthening systems for the monitoring of progress towards those targets and by making use of available support from ECDC if needed.
14. Facilitate childhood vaccination and prevention of vertical transmission of HBV, and adapt vaccination services to the needs of different target groups, including by offering vaccination in local settings and by continuing targeted efforts to increase the uptake in groups at high risk and sometimes in disadvantaged situations, such as people who inject drugs, prison populations, men having sex with men, trans gender persons and migrants, asylum seekers and refugees from countries where HBV is endemic, as well as health professionals, while ensuring monitoring of the uptake in a central data repository at national level.
15. Pay special attention to people who inject drugs, making HBV vaccination routine in drug treatment, prison and harm-reduction services, in a stigma-free environment, on

a voluntary basis, without costs for the person being vaccinated, with the possibility for accessing an accelerated dosing schedule.

16. Regularly provide information to the Commission to allow to monitor and report on the implementation of the recommendations contained in this Council Recommendation through the Public Health Expert Group.

Done at Brussels,

For the Council
The President