NOTE

From: General Secretariat of the Council
To: Council
Subject: Council Recommendation on vaccine-preventable cancers
        (legal basis proposed by the Commission : Article 168(6) TFEU)
        - Adoption

1. On 1 February 2024, the European Commission submitted to the Council a proposal for a Council Recommendation on vaccine-preventable cancers\(^1\), based on Article 168(6) TFEU.

2. The proposal includes a series of recommendations notably as regards vaccination targets for human papillomaviruses (HPV) and for the Hepatitis B virus and as regards measures to counter mis- and dis-information on vaccination. This Council Recommendation forms part of Europe’s Beating Cancer Plan.

3. Following an optional consultation by the European Commission, the European Economic and Social Committee adopted its opinion on this Council Recommendation at its Plenary session on 30 May 2024\(^2\).

4. The Working Party on Public Health examined the proposal at its meetings on 19 February, 11 March and 15 April 2024 and reached agreement on the text\(^3\).

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\(^1\) 6062/24
\(^2\) 10656/24
\(^3\) 7217/2/24 REV2 and WK 7431/24 INIT
5. On 5 June 2024, the Permanent Representatives Committee (Part I) confirmed the agreement reached in the Working Party on Public Health and agreed to submit the corresponding text\(^4\) to the EPSCO Council of 21 June 2024 for adoption.

6. The Council is invited:

- to adopt, at its session on 21 June 2024, the Council Recommendation on vaccine-preventable cancers, as set out in the Annex to this note;

- to enter into the minutes of the Council the statement in the addendum to this note.

7. After the Recommendation has been adopted, it will be published in the Official Journal of the European Union.

\(^4\) 9901/24
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,

Having regard to the opinion of the European Economic and Social Committee,*

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.

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(3) Some types of precancerous conditions and 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 Plan⁶ (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 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 implementing Regulation (EU) 2016/679⁷, the Union’s General Data Protection Regulation.

(6) Some Member States have encountered issues in relation to the national procedures for obtaining the necessary parental or legal guardian 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. This provision allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

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(8) It is envisaged to give Union support to Member States to develop or upgrade electronic vaccination registries or equivalents 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 optimise procedures for parental or legal guardian consent, 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 precancerous conditions of the cervix and 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 year⁸. 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 men⁹. This emphasises the importance and need of vaccinating all adolescent and preadolescent girls and boys against HPV and of enabling equitable access to vaccination to reach high vaccination coverage rates not only in girls, but also in boys.

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⁸ 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.

⁹ Ibid.
(10) Risk-based screening in line with the Council Recommendation on strengthening prevention through early detection: a new EU approach on cancer screening\(^{10}\) can help prevent cervical cancer in women. However, no organised population-based or targeted screening programme is currently recommended in 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 recommended for men. Furthermore, secondary prevention programmes can be an important contribution to reducing HPV-related cancer burden, especially in at-risk population groups.

(11) Vaccination against HPV within national immunisation programmes is crucial for cancer prevention in both women and men but also ensuring access beyond this framework is essential for broader coverage and protection.

(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 are needed for those age groups\(^{11}\) this figure remains low, below 50\%, in other Member States\(^{12}\). Only limited data are currently available for vaccination uptake in boys as well as in young adults.

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\(^{11}\) Three doses are needed for older young people.

\(^{12}\) https://immunizationdata.who.int/pages/coverage/hpv.html?CODE=EUR&ANTIGEN=PRHPV1_F&YEAR=&ADVANCED_GROUPINGS=EURO
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 States.\(^{13}\)

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 or legal guardians, should also be addressed by continuing communication efforts and by monitoring and addressing mis- and disinformation related to HPV infection and HPV vaccination.\(^{13}\)

Access issues in relation to HPV vaccination should be addressed through low-threshold vaccination offers and education. This could involve free vaccination, for example, in schools and educational settings, a structured invitation and reminder system and 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 persons with disabilities, people experiencing homelessness, migrants, asylum seekers and refugees, displaced persons from Ukraine, Roma, people with high risk sexual behaviour (e.g. sex workers) and LGBTI\(^{14}\) persons.

In 2022, the joint action PartnERship to Contrast HPV (PERCH)\(^{15}\), was launched, bringing together European countries to fight cancers caused by HPV infection from a wide range of perspectives.


\(^{14}\) See the Commission’s LGBTIQ Equality Strategy 2020-2025 (COM(2020) 698 final)

\(^{15}\) https://www.projectperch.eu/
(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 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 chronic. 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 Member States and EEA countries are living with a chronic HBV infection.

(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 with high risk sexual behaviour (e.g. sex workers), people who inject drugs and men who have 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 infected.

(21) Vaccination against HBV as part of national immunisation programmes is key to prevent disease caused by chronic infection with HBV, including liver cancer.

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18 Ibid.
(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, people with high risk sexual behaviour (e.g. sex workers), men who have sex with men, transgender 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 2030 19.

(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) 20.

(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 vaccination 21.

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20 Ibid.

(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 coverage rates in many Member States must still be improved to reach even the 2020 interim targets. 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, people with high risk sexual behaviour (e.g. sex workers), men who have 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, or 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 and people experiencing homelessness, 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 Union, the ECDC is tasked to monitor the level of vaccination coverage in Member States based on reliable data available from countries.

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The Council takes note that, 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 targets\textsuperscript{24} to be met. Coordination with relevant international bodies should be encouraged and double reporting should be avoided.

There is a need to better integrate HPV and HBV vaccination in 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, screening and cancer registries or equivalents 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.

The Council takes note that 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, scientific partners 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, at Union level. Nevertheless, communication campaigns need to take into account national specificities of the Member States.

\textsuperscript{24} 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.
(35) The Council takes note that 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) The Council takes note that, in line with its comprehensive approach to mental health\textsuperscript{25}, and taking the EU Strategy on the Rights of the Child\textsuperscript{26} and the European Child Guarantee\textsuperscript{27} into account, the Commission intends to develop a prevention toolkit addressing the links between mental and physical health in children, including physical health linked to vaccination, and thus making an impact in the most vulnerable and formative years of their lives.

(37) Vaccination data should also be provided in digital, structured and reusable form and Union citizens’ access to their vaccination data should be further facilitated via existing initiatives and taking into account emerging infrastructures. 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.

\textsuperscript{25} 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.

\textsuperscript{26} 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) 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 and health inequities linked to access to and availability of vaccination.

(40) The Council takes note that the Commission intends to support the development of modelling tools and analysis in order 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 prevention programmes, especially for cancer. 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 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 Council takes note that the Commission intends to invite Member States to regularly provide information (using, unless otherwise justified, existing data, indicators and submission dates, including those used for international organisations) 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, in line with national vaccination recommendations, and by ensuring access and promoting uptake for groups at high risk and/or in disadvantaged situations.

2. Strengthen the integration of HPV and HBV vaccination in prevention programmes, especially for cancer, at operational level but also to provide integrated health communication on cancer prevention.

3. Measure the overall impact of vaccination, including in view of increasing the cost-efficiency of cancer screening programmes, in respect of the Union’s data protection law. Explore, strengthen, and, where appropriate, establish links between vaccination, screening and cancer registries or equivalents.

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 in an evidence-based approach, including in the context of the Public Health Expert Group, established in 2022\(^\text{28}\), and its subgroups on vaccination and cancer, and through targeted calls for practices on the Commission’s Best Practice Portal\(^\text{29}\).


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 or equivalents that enable the availability and analysis of data at national and subnational level and to which data recorded by different vaccine and vaccination providers can be seamlessly transferred, to inform efficient, data-driven public health action.

6. Optimise national procedures for obtaining parental or legal guardian 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 provide vaccination data also in digital, structured and reusable form and 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 taking into account existing and emerging infrastructures.

8. Actively participate, if appropriate, 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, provided that there is a need and necessity of the network and it is based on adequate legal provisions.

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 and health inequities linked to access to and availability of vaccination.
**Human papillomaviruses (HPV)**

10. 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, for example by offering vaccination to adolescent and preadolescent girls and boys in schools and educational settings or by implementing or strengthening invitation and reminder systems for vaccination in accordance with the national context.

11. Address structural barriers for those adolescent and preadolescent girls and boys belonging to disadvantaged groups, such as persons with disabilities, people experiencing homelessness, migrants, asylum seekers and refugees, displaced persons from Ukraine, Roma, people with high risk sexual behaviour (e.g. sex workers) and LGBTI persons, and, in line with national procedures to also cover, via targeted catch-up campaigns, young adults who did not get vaccinated or fully vaccinated during adolescence or preadolescence.

12. 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 by unfragmented electronic vaccination repositories at national level.

13. 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.

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30 See the Commission’s LGBTIQ Equality Strategy 2020-2025 (COM(2020) 698 final)
**Hepatitis B virus (HBV)**

14. Strengthen national efforts to reach the 2030 goal of elimination of viral hepatitis, including HBV, as a public health threat in the WHO European Region, including by strengthening efforts to reach the 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, and by reinforcing the monitoring of progress towards those targets and by making use of available support from ECDC if needed.

15. Facilitate childhood vaccination and prevention of vertical transmission of HBV.

16. 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 which can include people who inject drugs, prison populations, people experiencing homelessness, people with high risk sexual behaviour (e.g. sex workers), men who have sex with men, transgender persons and migrants from, asylum seekers from and refugees from countries where HBV is endemic, as well as health professionals. Some of these may also be in disadvantaged situations. Ensure monitoring of the uptake by unfragmented electronic vaccination repositories at national level.

17. Pay special attention to people who inject drugs, including efforts to provide low-threshold vaccination services, to make 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.
Communication

18. Implement, when available, the model for evidence-based awareness-raising campaigns on the importance of HPV and HBV vaccination aimed to improve cancer prevention and fight against mis- and disinformation and with the overall goal of increasing health literacy.

Monitoring and reporting

19. 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