

The European coalition for vaccination calls on healthcare professionals to get vaccinated against COVID-19

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In February 2021, the Coalition for Vaccination has published a manifesto to encourage healthcare professionals to get vaccinated against COVID-19.

The manifesto highlights three key reasons why all healthcare professionals should get vaccinated against COVID-19 when they have the opportunity to do so and why they should help promote the vaccination against COVID-19 among the general public.

1. You protect yourself from illness and possible severe or life-threatening complications
2. COVID-19 vaccines are safe and effective
3. You help safeguard healthcare capacity

The Coalition for Vaccination brings together European associations of healthcare professionals and relevant students' associations in the field, as well as associated professional organisations working in the field of public health and immunisation. It was convened by the European Commission in 2019 to deliver accurate information to the public, to combat myths and to exchange best practices. The Coalition is co-led by the Standing Committee of European Doctors (CPME), the European Federation of Nurses Associations (EFN) and the Pharmaceutical Group of the European Union (PGEU).

UPDATES FROM THE EUROPEAN MEDICINES AGENCY

The European Medicines Agency (EMA) published a direct to healthcare professional communication for Vaxzevria (previously COVID-19 Vaccine AstraZeneca), a plain-language description of medical terms related to medicines use and communications advising against the use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials and on the precautionary marketing suspension of the thalassaemia medicine Zynteglo.

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COVID-19 vaccine AstraZeneca – direct healthcare professional communication

EMA has released a direct healthcare professional communication (DHPC) on the risk of thrombocytopenia and coagulation disorders with the COVID-19 Vaccine AstraZeneca. It contains important information for healthcare professionals prescribing, dispensing or administering this vaccine. As noted in the DHPC:

- ▶ Benefits of the COVID-19 Vaccine AstraZeneca outweigh the risks despite the possible link to very rare blood clots with low blood platelets.
- ▶ A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca.
- ▶ Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia.

Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

EMA's medical terms simplifier

EMA has created a medical terms simplifier that provides public-friendly descriptions of medical terms used for side effects of medicines and mechanisms of action. The 'EMA medical terms simplifier' has been assembled over many years by EMA's medical writers, who use these plain-language descriptions to prepare public-friendly communications. Having become increasingly aware that there was no single resource for describing common medical terms found in medicines information, the team worked to produce a public-domain version of this resource.

Please note that the medical terms simplifier does not cover rarely used terms, most disease states, very specialised areas or the broader field of medical science. EMA will continue to maintain and further develop this resource over time.

EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that the available data do not support its use for COVID-19 outside well-designed clinical trials.

In the EU, ivermectin tablets are approved for treating some parasitic worm infestations while ivermectin skin preparations are approved for treating skin conditions such as rosacea. Ivermectin is also authorised for veterinary use for a wide range of animal species for internal and external parasites.

Ivermectin medicines are not authorised for use in COVID-19 in the EU, and EMA has not received any application for such use (Czechia and Slovakia, have allowed the temporary use of the medicine for COVID-19 within the remit of their national legislation).

Following recent media reports and publications on the use of ivermectin, EMA reviewed the latest published evidence from laboratory studies, observational studies, clinical trials and meta-analyses. Laboratory studies found that ivermectin could block replication of SARS-CoV-2 (the virus that causes COVID-19), but at much higher ivermectin concentrations than those achieved with the currently authorised doses. Results from clinical studies were varied, with some studies showing no benefit and others reporting a potential benefit. Most studies EMA reviewed were small and had additional limitations, including different dosing regimens and use of concomitant medications. EMA therefore concluded that the currently available evidence is not sufficient to support the use of ivermectin in COVID-19 outside clinical trials.

Although ivermectin is generally well tolerated at doses authorised for other indications, side effects could increase with the much higher doses that would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus. Toxicity when ivermectin is used at higher than approved doses therefore cannot be excluded.

EMA therefore concluded that use of ivermectin for prevention or treatment of

COVID-19 cannot currently be recommended outside controlled clinical trials. Further well-designed, randomised studies are needed to draw conclusions as to whether the product is effective and safe in the prevention and treatment of COVID-19.

This EMA public health statement has been endorsed by the COVID-19 EMA pandemic Task Force (COVID-ETF), in light of the ongoing discussions on the use of ivermectin in the prevention and treatment of COVID-19.

Precautionary marketing suspension of thalassaemia medicine Zynteglo

The company that markets the gene therapy medicine Zynteglo for treating the rare blood condition beta thalassaemia has suspended sales pending investigation of a safety concern. The company, bluebird bio, notified EMA that a related medicine it was developing, which uses the same technology as Zynteglo, may have been associated with a case of cancer. Although no cases of cancer have been reported with Zynteglo itself, the company suspended marketing of Zynteglo until the possibility that the same risk might apply to the licensed medicine has been investigated.

The concern arose with the medicine, bb1111, intended to treat another blood disorder, sickle cell disease. This medicine uses the same viral vector as Zynteglo, based on a type of virus known as a lentivirus, to insert a working gene into the patient's blood cells. One patient treated with bb1111 developed acute myeloid leukaemia, a cancer of the blood, that might have been related to treatment, and a different blood disorder, myelodysplastic syndrome, was reported in another patient.

Cancer caused by this type of treatment (insertional oncogenesis) was already identified as a potential risk with Zynteglo, so patients who receive the medicine are followed up and monitored in a registry. So far no cases of cancer have been reported with Zynteglo treatment. Nonetheless, since bb1111 works in the same way, it was thought prudent to suspend clinical studies with bb1111 and pause sales of Zynteglo while the evidence is examined more thoroughly.

EMA is liaising closely with the company and experts within the regulatory network, and will now examine the evidence at EU level and decide on any relevant regulatory action for Zynteglo or any similar medicines under evaluation. No other authorised medicines use the

same viral vector so no direct implications are foreseen for other licensed medicines.

Zynteglo was granted conditional marketing authorisation on 29 May 2019. Currently it is only marketed in Germany, and because of limited availability and the rarity of the condition it is intended to treat, only a very small number of patients have received or would have been eligible to receive treatment. However, if treated patients do have any concerns they should contact the specialist supervising their Zynteglo treatment. EMA will communicate further once additional information becomes available.

For more information please visit EMA's website at <https://www.ema.europa.eu>.

FIP RELEASES MEDICINES RECONCILIATION TOOLKIT

To support pharmacists' contributions to the WHO's third Global Patient Safety Challenge — 'Medication without harm' – the International Pharmaceutical Federation (FIP) created a toolkit on medicines reconciliation for its members.

The medicines reconciliation toolkit outlines the principles and important processes that pharmacists should follow when providing this professional service. It summarises the definitions, impact and procedures for the implementation of pharmacist-led medicines reconciliation in both community and hospital health-care settings, and offers a set of tools to support practice. A webinar will be organised by FIP in the next month to present the toolkit.

MDR INFOGRAPHIC – IDENTIFYING MEDICAL DEVICE SOFTWARE

Medical devices are an essential part of the delivery of high-quality healthcare and their procurement and management in the European hospital setting is often under the authority of hospital pharmacist. With the full application of the new Medical Device Regulation only weeks away and the one on InVitro Devices following in May 2022, the European Commission has released an infographic that helps those working with devices with determining if their software is a medical device.

EUROPE'S BEATING CANCER PLAN RELEASED

On the day before World Cancer Day – which is celebrated every year on the fourth of February – the European Commission presented 'Europe's Beating Cancer Plan' to the public. The plan is

structured around four key action areas with ten flagship initiatives and multiple supporting actions spanning from employment, education, social policy and equality, through marketing, agriculture, energy, the environment and climate, to transport, cohesion policy and taxation.

The four key action areas touch on prevention, early detection of cancer, diagnosis and treatment as well as improving the quality of life of cancer patients and survivors. Particular attention will be paid to children. The 'Helping Children with Cancer Initiative' seeks to ensure that children have access to rapid and optimal detection, diagnosis, treatment and care. In the area of prevention, Europe's Beating Cancer Plan will address risk factors such as smoking, alcohol consumption, environmental pollution and hazardous substances as well as promote healthy diets and physical activity. The EU-supported Cancer Screening Scheme is one of the tools for improving access, quality and diagnostics to increase the early detection of cancer. In the field of diagnosis and treatment, the cancer plan puts forward actions for addressing unequal access to quality care and medicines. These actions will be targeting the National Comprehensive Cancer Centres and innovative cancer diagnosis and treatments. The 'Better Life for Cancer Patients Initiative' will cover all aspects of the recovery and follow-up care including rehabilitation, potential tumour recurrence, metastatic disease, and measures to support social integration and re-integration in the workplace.

On 12th of February, the European Commission organised a webinar on Europe's Beating Cancer Plan. This webinar aimed to inform the public in more detail about the Cancer Plan, to have an exchange on the content and to discuss how stakeholders can support the implementation of the Plan and its actions.

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