



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2023
EMA/285556/2022 Rev.2¹²
European Medicines Agency

List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123

Regulation (EU) 2022/123 provides the European Medicines Agency with a framework to monitor and mitigate potential and actual shortages of centrally and nationally authorised medicinal products for human use considered as critical to address a given 'public health emergency'^[1] or 'major event'^[2].

As further defined in the Regulation concerning the recognition of a public health emergency, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) is responsible for identifying and publishing a list of medicinal products considered to be critical during the public health emergency (the 'public health emergency critical medicines').

¹ This document was updated in November 2022 to include COVID-19 Vaccine (inactivated, adjuvanted) Valneva, VidPrevtyl Beta and the adapted vaccines Spikevax and Comirnaty (which were authorised after adoption of the list).

² This document was updated in April 2023 to include Bimervax which was authorised on 30 March 2023.

[1] 'public health emergency' means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU

[2] 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply, demand or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection according to Article 2(b) of Regulation (EU) 2022/123.



On 7 June 2022, the MSSG adopted a list of authorised medicines considered critical for the management and prevention of COVID-19 and for which supply and demand will be closely monitored in EU/EEA countries.

Given the current stage of the COVID-19 pandemic, the list of critical medicines includes all authorised COVID-19 vaccines (**Table 1**) and COVID-19 therapeutics (**Table 2**), and will be subject to update when necessary, to take into account any changes in COVID-19 epidemiology in EU/EEA which may give rise to an increased risk of shortages of particular medicines or following the authorisation of new medicines. The list will remain in place until the end of the public health emergency.

The MSSG adopted the list after consultation with the Medicines Shortages SPOC Working Party (SPOC WP), and other relevant groups, including the Emergency Task Force (ETF), EMA's Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) and EU Industry (Trade) Associations.

Supply and demand of the medicines included in the list will be closely monitored so that potential shortages can be avoided or managed early. Marketing authorisation holders for medicines on the list will regularly provide EMA with information on potential existing shortages, including available stocks and forecasts of supply and demand. In addition, national competent authorities through the SPOC Working Party, will provide regular reports on estimated demand for these medicines at national level. Medicines for which demand is likely to exceed supply will be discussed by the MSSG who will decide on the need for further actions.

The list does not pre-empt or reflect national procurement decisions. It should not be read as recommendations on national stockpiles.

The list should not be read as providing guidance on the use of COVID-19 products in individual Member States and also does not reflect recommendations for use to treat or prevent COVID-19 in any particular part of the SARS-CoV-2 virus. Decisions on vaccination campaigns, the choice of vaccine or treatment and how they are allocated remain a national matter.

Table 1. List of critical medicines for COVID-19 public health emergency - authorised COVID-19 vaccines

Product name	International non-proprietary name (INN) or common name	Active substance	Pharmaceutical form(s)	Route of administration	Strengths
Comirnaty	Tozinameran/ riltozinameran and tozinameran/ famtzinameran and tozinameran/ COVID-19 mRNA Vaccine (nucleoside modified)	Single-stranded, 5'-capped messenger RNA produced using a cell-free <i>in vitro</i> transcription from the corresponding DNA templates, encoding the viral spike protein of SARS-CoV-2	Dispersion for injection	Parenteral	All
COVID-19 Vaccine (inactivated, adjuvanted) Valneva	COVID-19 vaccine (inactivated, adjuvanted, adsorbed)	SARS-CoV-2 inactivated strain hCoV-19 / Italy / IMI1 / 2020	Suspension for injection	Parenteral	All
Jcovden (previously COVID-19 Vaccine Janssen)	COVID-19 vaccine (Ad26.COV2-S [recombinant])	Adenovirus encoding the SARS-CoV-2 glycoprotein (Ad26.COV2-S)	Suspension for injection	Parenteral	All
Nuvaxovid	COVID-19 Vaccine (recombinant)	SARS-CoV-2 recombinant spike protein	Dispersion for injection	Parenteral	All
Spikevax (previously COVID-19 Vaccine Moderna)	COVID-19 mRNA vaccine (nucleoside-modified)	CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free <i>in vitro</i> transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2)	Dispersion for injection	Parenteral	All

Product name	International non-proprietary name (INN) or common name	Active substance	Pharmaceutical form(s)	Route of administration	Strengths
Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	COVID-19 Vaccine (ChAdOx1-S [recombinant])	ChAdOx1-SARS-COV-2	Suspension for injection	Parenteral	All
VidPrevtyn Beta	COVID-19 Vaccine (recombinant, adjuvanted)	SARS-CoV-2 prefusion Spike delta TM protein, recombinant (B.1.351 strain)	Suspension emulsion for injection	Parenteral	All
Bimervax	COVID-19 Vaccine (recombinant, adjuvanted)	SARS-CoV-2 virus recombinant spike protein receptor binding domain (RBD) fusion heterodimer – B.1.351-B.1.1.7 strains	Suspension for injection	Parenteral	All

OBSOLETE

Table 2. List of critical medicines for COVID-19 public health emergency - authorised COVID-19 therapeutics

Product name	International non-proprietary name (INN) or common name	Active substance(s)	Pharmaceutical form(s)	Route of administration	Strengths
Dexamethasone-containing medicines ^{3,4}	Dexamethasone	Dexamethasone	Tablet; Oral solution; Injection for injection; Solution for injection/infusion	Oral, Parenteral	All
Evusheld	Tixagevimab/ Cilgavimab	Tixagevimab/ Cilgavimab	Solution for injection	Parenteral	All
Kineret	Anakinra	Anakinra	Solution for injection	Parenteral	All
Paxlovid	PF-07321332/Ritonavir	PF-07321332 ⁵ / Ritonavir	Film-coated tablet	Oral	All
Regkirona	Regdanvimab	Regdanvimab	Concentrate for solution for infusion	Parenteral	All
RoActemra	Tocilizumab	Tocilizumab	Solution for injection; Concentrate for solution for infusion	Parenteral	All
Ronapreve	Casirivimab/Imdevimab	Casirivimab/Imdevimab	Solution for injection/infusion	Parenteral	All
Veklury	Remdesivir	Remdesivir	Powder for concentrate for solution for infusion	Parenteral	All
Xevudy	Sotrovimab	Sotrovimab	Concentrate for solution for infusion	Parenteral	All

³ As per [Article 57. database](#).

⁴ All dexamethasone-containing medicines will be monitored, even though not all have currently an authorisation for COVID-19

⁵ (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido) butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide; Nirmatrelvir