



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA raises awareness of clinical care recommendations to manage suspected thrombosis with thrombocytopenia syndrome

EMA's COVID-19 taskforce (COVID-ETF)¹ is advising healthcare professionals in the EU to consider recommendations by learned societies when assessing people with signs and symptoms of thrombosis with thrombocytopenia syndrome (TTS) following vaccination with Vaxzevria and COVID-19 Vaccine Janssen. In this context it is highlighting guidance from the International Society on Thrombosis and Haemostasis (ISTH).²

TTS requires rapid identification and urgent clinical management. National and international recommendations have been updated with evolving experience from managing TTS and heparin-induced thrombocytopenia and thrombosis (HITT), a condition with some similarities to TTS.

The taskforce acknowledged that there are differences between the guidelines available (mostly concerning the assays and imaging used for diagnosis and for guiding treatment, as well as treatment options with non-heparin anticoagulants, intravenous immunoglobulins and glucocorticoids). For the management of suspected TTS, especially if no local guideline is available, the taskforce recommends that healthcare professionals consider the ISTH interim guidance on vaccine-induced immune thrombotic thrombocytopenia (VITT),² which is based on ongoing international collaboration of healthcare professionals. As the management of TTS is evolving, the guidance may be further updated in future.

Examples of learned societies with treatment recommendations

- International Society on Thrombosis and Haemostasis (ISTH): <https://www.isth.org/page/covid19>
- Belgian Society on Thrombosis and Haemostasis (BSTH): <https://bsth.be/covid19-resources>
- Czech Society of Thrombosis and Haemostasis (CSTH): <https://csth.cz/>
- Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie (DGHO): <https://www.dgho.de/covid-19>

¹ COVID-ETF is a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

² International Society on Thrombosis and Haemostasis (ISTH): <https://www.isth.org/page/covid19>



Examples of learned societies with treatment recommendations

- Federación de Asociaciones Científico Médicas Españolas (FACME): <https://facme.es/covid-19/covid-19-documentos/>
- Groupe d'etude sur l'hémostase et la thrombose (GETH): <https://site.geht.org/docutheque/>
- Gesellschaft für Thrombose- und Hämostaseforschung (GTH): <https://gth-online.org/covid-19-info/>
- Società Italiana per lo Studio dell'Emostasi e della Trombosi (SISSET): <https://www.siset.org/linee-guida/linee-guida-siset>
- Svenska sällskapet för Trombos och Hemostas (SSTH): <https://www.ssth.se/lankar>
- British Society for Haematology (BSH): <https://b-s-h.org.uk/about-us/news/covid-19-updates/>
- American Society of Hematology (ASH): <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>

The advice from the taskforce follows EMA's review of TTS, a very rare event following vaccination with Vaxzevria and COVID-19 Vaccine Janssen. The conclusions reached are based on EMA's safety signal evaluations, which led to updates of the product information for both [Vaxzevria](#) and [COVID-19 Vaccine Janssen](#). Healthcare professionals have been informed through [dear healthcare professional communications \(DHPCs\)](#) of the signs and symptoms of TTS with either vaccine, so that people affected can be diagnosed and treated as soon as possible using the available guidelines.

The Agency recognises and supports the extensive work by healthcare professionals and learned societies, which is essential to optimise the management of people with suspected TTS following vaccination with Vaxzevria or COVID-19 Vaccine Janssen.