EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting of the Competent Authorities on Blood and Blood Components

11th February 2021

Presented by [redacted 5.1.2e]
Blood Products Working Party (BPWP) scientific secretariat and EMA Product Lead
Oncology, Haematology and Diagnostics Office
European Medicines Agency

An agency of the European Union

Plasma supply

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Follow-up survey on impact of COVID-19 on plasma supply

Shortages of immunoglobulins have been notified to EMA in December 2020 and January 2021

- A follow-up survey was sent to Plasma Master File Holders (PMF-Hs) in Oct. 2020 to get an update on the impact of COVID-19 on authorised medicines where plasma is used for its manufacture
- All PMF-Hs confirmed they are monitoring the situation closely, evaluating different scenarios and **have activated mitigations plans** to meet their commitments to patients
- One 3rd of PMF-Hs predict issues of supply for the EU Market in Q1/2 2021

A further survey will be launched in **mid-February 2021** to better understand the expected disruptions of PDMPs in 2021 and ask PMF-Hs for an update on the EU supply of PDMPs

- EMA will continue to monitor through EU-SPOC (Single Point Of Contact) on any notifications of shortages of PDMP. **EMA working closely with EC and EDQM.**

1 Source: EMA report on Impact of COVID-19 on EU supply of plasma derived medicinal products

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Plasma supply

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CHMP position statement on quality and safety assessment for the Plasma Master File (PMF) certification with regards to donor deferral criteria for sexual risk behaviour

CHMP position statement currently being drafted and expected to be published **by February 2021.**

Deferral periods are determined based on an assessment **of country's epidemiological data and scientific considerations.**

In essence, when plasma is collected in accordance with the national recommendations on deferral criteria, the plasma **is accepted** by other European countries.

Source: Based on decisions taken for the granting of initial Marketing Authorisation Application where raw materials/starting materials sourced from plasma have been used in the manufacture of the medicine.

Plasma supply

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Regulatory flexibility on GMP inspection of EEA or Third Country Blood Establishments in PMF

April 2020: EC/EMA/HMA published the Q&A on regulatory expectations for medicinal product for human use during the Covid-19 https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

- UK-EU agreement does not cover the recognition of MHRA inspection outcomes of Blood Establishments in the UK or located in 3rd countries.
- Position statement on risk based approach for BE on 3rd country inspected by MHRA adopted in December 2020.
- In absence of the UK agreement; the Member States can take into consideration the position statement on 3rd countries plasma collection sites inspected by MHRA.
- Compliance letters issued by MHRA are considered valid.

Source: UK withdrawal from the Union: Risk Based Approach for use of Compliance Letters issued by UK Authorities for 3rd country blood establishment sites post Brexit

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COVID-19

CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

bpl Biotest CSL Behring LFB octapharma Takeda

Estimated study completion date: July 2021

News Release

GLOBAL PLASMA LEADERS COLLABORATE TO ACCELERATE DEVELOPMENT OF POTENTIAL COVID-19 HYPERIMMUNE THERAPY

First Patient Enrolled in NIH Phase 3 Trial to Evaluate Potential COVID-19 Hyperimmune Medicine

Osaka, JAPAN and King of Prussia, Pa., USA

- The Alliance's anti-COVID-19 Hyperimmune Globulin (CoVIg-19) medicine is under evaluation as part of the trial and may become one of the earliest treatments for hospitalized individuals at risk for serious complications of COVID-19
- The CoVIg-19 Plasma Alliance urges anyone who has recovered from COVID-19 to consider donating plasma. To learn more, please visit TheFightIsInUs.org

08 Oct 2020

COVID-19 vaccines and treatments: EMA website

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COVID-19

Treatments and vaccines for COVID-19: authorised medicines

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This page contains information on the medicines authorised in the European Union (EU) to treat or prevent COVID-19, following evaluation by the European Medicines Agency (EMA).

EMA's Committee for Medicinal Products for Human Use (CHMP) has evaluated these medicines and issued a scientific opinion on their use in patients with COVID-19.

COVID-19 | ROLLING REVIEW

EMA starts rolling review of Novavax COVID-19 vaccine

COVID-19 | ROLLING REVIEW

EMA starts rolling review of REGN-COV2 antibody combination

COVID-19 | VACCINES

Third COVID-19 vaccine authorised in the EU

COVID-19 | PHARMACOVIGILANCE

First COVID-19 vaccine safety update published

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Any questions?

Acknowledgments:

Inspections: [redacted]@ema.europa.eu
Clinical Studies and Manufacturing Task Force: [redacted]@ema.europa.eu
Donor eligibility criteria: [redacted]@ema.europa.eu
Plasma Master File: [redacted]@ema.europa.eu
COVID-19 Workstream 2 member: [redacted]@ema.europa.eu
Blood Products Working Party: [redacted]@ema.europa.eu, [redacted]@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6123

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