Direct Healthcare Professional Communication (DHPC)

<Date>

EMOCLOT®, KLOTT®, PLASMACLOT® (Coagulation Factor FVIII), UMAN COMPLEX®, KEDCOM® (Prothrombin Complex), AIMAFIX®, KEDRIFIX® (Coagulation Factor FIX), ATKED® (Antithrombin III): Potential risk linked to incorrect sterilization of medical devices included into their secondary packaging

Dear Healthcare professional,

Kedrion S.p.A. in agreement with AIFA would like to inform you of the following:

Summary

- **Potential risk linked to incorrect sterilization of the BUTTERFLY NEEDLE (DEHP FREE) used for the administration of the medicinal product after its reconstitution with the solvent**
- **Potential risk linked to incorrect sterilization of the FILTER NEEDLE 16X3/4" used for the filtration of the reconstituted medicinal product before administration to the patient.**
- **As a precautionary measure it is requested to stop the use of such medical devices.**
- **Only the butterfly needle/filter needle included in the packaging is affected by the quality defect; the medicinal product itself can be used safely with an other device.**
- **Pharmacies should ensure that no medicinal products packs containing the butterfly needle (DEHP FREE)/filter needle 16X3/4" are given to doctors or patients.**
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Background on the safety concern

Kedrion S.p.A. received by the supplier F.M. S.p.A. of the mentioned devices the “Safety Notice FSN-01-2021” in relation to a potential risk linked to the sterilization step of the above-mentioned Medical Devices provided. This entails that, to date, the device sterility cannot be guaranteed.

The butterfly needle/filter needle are used by Kedrion S.p.A. for the packaging of its lyophilized products (Coagulation Factor VIII and IX, Prothrombin Complex and Antithrombin III).

As a consequence of this devices issue, patients may be at risk of developing infections/sepsis.

Up to now F.M. S.p.A. (the medical devices provider) and Kedrion S.p.A. Pharmacovigilance have not identified any notice of Adverse Drug Reaction which may be linked to this issue.

We are informing you to prevent any potential risks connected with the use of potentially unsterilized devices.

Therapeutic indication of such medicinal products is presented to follow:

Coagulation Factor VIII: Treatment and prophylaxis of bleeding in patients with haemophilia A. Management of acquired factor VIII deficiency. Treatment of haemophiliacs with antibodies against factor VIII.

Coagulation Factor IX: Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency). This product may be used in the management of acquired factor IX deficiency.

Prothrombin Complex: Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. Treatment of bleeding and perioperative prophylaxis in congenital deficiency of any of the vitamin K dependent coagulation factors when purified specific coagulation factor product is not available.

Antithrombin III: Patients with congenital or acquired antithrombin deficiency. Prophylaxis of deep vein thrombosis and thromboembolism in clinical risk situations (especially during surgery or during the peri-partum period), in association with heparin if indicated. Prevention of progression of deep vein thrombosis and thromboembolism.

It is recommended that:

- **<u>Do not use the butterfly needle/filter needle potentially involved in the issue.</u>**
- It is important to underline that the presence of a potentially unsterilized device in the secondary package does not affect safety and efficacy of the medicinal products. You must discard the butterfly needle and / or filter needle included into the product and use standard needle

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

- Please refer to: Segnalazioni reazioni avverse | Agenzia Italiana del Farmaco (aifa.gov.it)

For biological medicinal products it is important to report not only the product name but batch details as well.

Company contact point

<Contact point details for access to further information, including relevant website address, telephone numbers and a postal address >