LFB safety alert on the quality of water vials used in the preparation of coagulation factor concentrates for infusion

18 June 2018

Dear NMOs,

On 6th June the pharmaceutical company LFB informed the French Medicines Agency ANSM of some quality issues concerning the water vials used to prepare coagulation factor concentrates.

Please note that at the moment it has been estimated that this represent a **low safety risk** for patients. However, it is advised for those having the affected vials to **return them to your usual pharmacy and ask for a replacement**.

Here below, you will find the official statement from LFB as well as the products affected and the European countries in which they are marketed.

The EHC team

Safety alert from LFB

ALERT ON THE USE OF VIALS OF WATER FOR INJECTION (2.5ml, 5ml and 10ml) included in some LFB BIOMEDICAMENTS products - 14 June 2018

LFB BIOMEDICAMENT, declares today, in agreement with the French authorities ANSM, a quality appearance defect (possible presence of translucent particles on the scale of the micron), which may appear randomly over time, in the water for injection vials, provided by a LFB subcontractor. It concerns all batches of vials of water for injection (vials 2.5 ml, 5 ml and 10 ml) packaged in the products listed below and for all valid batches.

In this context, and as precautionary measure, LFB BIOMEDICAMENTS has changed the vials of water for injection with new batches of 10ml and 5ml vials, for the future manufactured batches.
It should be noted that all of the results of release tests for all of the concerned batches of water for injection are compliant. No pharmacovigilance case or complaint related to this defect has been reported to date.

Because the quality of the freeze-dried powder is not concerned, the vials of freeze-dried product are not subject to this alert.

For batches currently on the markets, LFB BIOMEDICAMENTS has requested not to use the vial of water for injection packed in the same box as the freeze-dried product and has requested its distributors to contact hospitals informing this situation. LFB BIOMEDICAMENTS is going to evaluate the impact with its distributors and discuss the potential measures.

It is reminded that in France it has been suggested to hospitals to reconstitute the freeze-dried powder with another vial of water for injection different to the one provided by LFB, available in the hospital with the same format. No alternative diluent except water for injection can be used.

Products and European countries affected	
Products	**Countries**
WILFACTIN 100 UI/ml, powder and solvent for injection - 1000 UI/10 ml	Belgium, Finland, Greece, Italy, the Netherlands, Russia and the UK
BETAFACT 50 UI/ml, powder and solvent for injection - 500 UI/10 ml	Greece and Turkey
FACTANE 100 UI/ml, powder and solvent for injection - 500 UI/5 ml	Turkey
FACTANE 100 UI/ml, powder and solvent for injection - 1000 UI/10 ml	Belgium and Turkey
HEMOLEVEN 100 UI/ml, powder and solvent for injection 1000 U/10 ml	Belgium, Germany, Italy, Luxembourg, the Netherlands, Spain, Switzerland and the UK