

## TO WHOM IT MAY CONCERN

30<sup>th</sup> August 2017

Dear Madame, Dear Sir,

We would like to refer to the Falsified Medicines Directive (FMD), being of application as from February 9<sup>th</sup>, 2019.

The Luxembourg National Medicines Verification Organisation (LMVO) has selected the IT service provider to build the Luxembourg verification system in co-operation with the Belgian National Medicines Verification Organisation (BeMVO). The implementation of this supra-national verification system is starting now. Today we have a view on the organisation model and the budget of the LMVO.

As stipulated in the FMD and the related Delegated Regulation, the system and its operations must be financed by the MAH's acting within the Luxembourg scope of FMD. The LMVO requests:

- A one-off registration fee (see further)
- A yearly flat fee, in line with the recommendations of EMVO, will be invoiced as from February 2019.

### What is the scope of FMD in Luxembourg?

The Luxembourg scope of FMD is defined as follows:

- All products under prescription according to the Luxembourg legislation
- Plus the black list products as identified in annex 2 of the Delegated Regulation
- Minus the white list products as identified in annex 1 of the Delegated Regulation
- Plus all products defined by the Luxembourg Competent Authorities.

### The one-off registration fee

All MAH companies distributing products within above defined scope in Luxembourg on February 9<sup>th</sup> 2019 are subject to the FMD legislation and must contribute in the overall costs of the system via the one-off registration fee and the yearly flat fee.

On February, 9<sup>th</sup> 2019 the FMD legislation will be of application and the Medicines Verification System will give the LMVO an accurate view on all active MAH having products in scope.

To be able to fulfil your duties and to pay the compulsory one-off registration fee a contract between your MAH and the LMVO must be concluded beforehand.

Please find the registration form and the contract attached.

---

## What should you do?

- Check if your MAH Company has products that are within the scope of FMD in Luxembourg. Even if only one product in your portfolio has to be FMD-compliant, a contract is necessary.
- Pay attention: Fill out a separate form for each MAH company being active in Luxembourg on February 9<sup>th</sup>, 2019 and indicate the wave you want to participate in.
- Send the completed and scanned registration form by email to **info@lmvo.lu** or by postal services.
- Properly complete the contract:
  1. Fill out the official identity of the MAH and contact credentials.
  2. Sign properly the contract by mandated person and provide us with the proof of mandate in a separate document.
  3. Send back ASAP – and ideally before registration deadline – the signed contract (1 copy)
  4. In return you will receive an invoice and an invitation to pay (in the period of your choice)

	Registration deadline	Payment deadline	FEE (VAT excl)	Discount	Amount to pay (VAT excl)
Wave 1	30-09-17	15-12-17	4.000,00	50%	2.000,00
Wave 2	31-03-18	30-06-18	4.000,00	25%	3.000,00
Wave 3	31-07-18	31-10-18	4.000,00	-	4.000,00
Existing MAH's registering <b>later than 31 July 2018</b> will have to pay an extra admin fine.					

Please follow these instructions to avoid supplementary costs for the LMVO and for your MAH(s).

### More specific

1. Do not miss the registration deadline for you to be able to receive in time the registration invoice;
2. Do not miss the payment deadline. All MAH's that miss their payment deadline, will automatically be transferred to the following wave. A supplementary invoice will be sent to be able to fulfil your payment in accordance with the adapted wave.
3. Although we urge all MAH's to start the preparation to be compliant with all aspects of FMD (packaging, internal organisation, on boarding on European Hub), there are no conditions regarding the status of your preparation to register and pay the one-off registration fee.

Chairman of LMVO  
Jan Janssens

