

LETTER OF ANNOUNCEMENT On-boarding Fee

Friday, 15th of December 2017

Dear (future) On-boarding Partners,

EMVO would like to inform you about the latest adjustments of the On-boarding fees; as from the 15th of January 2018, the On-boarding fee will rise by 50% of the current amount.

As you are all aware, in accordance with the Falsified Medicines Directive (2011/62/EU), the whole European Medicines Verification System has to be in place by the 9th February 2019. EMVO and the NMVOs are undertaking all necessary actions to set up the European Medicines Verification System in time and to ensure that the system will be compliant with the FMD provisions. Still, an important shortage can be noticed with respect to the number of On-boarding Partners (OBPs) going through the On-boarding process and getting connected to the EU Hub.

It is EMVO's pledge to guarantee a smooth On-boarding to all its partners and provide them with due support and assistance in this process. However, due to the small number of On-boarding Partners EMVO counts at the moment, we will most probably be ending up in a bottleneck situation which will cause significant increase in on-boarding connection and support costs. In order to mitigate this risk and cover the increasing on-boarding costs EMVO decided to apply a stepwise rise in the on-boarding fee for late followers. In addition, with this measure EMVO aims to create a positive dynamic among the industry towards every party's compliance, on time, and to give the impulse to the companies to start the on-boarding to the EU Hub as soon as possible.

The application of the 50% rise in the amount to be invoiced to the OBPs will be applicable from the 15th of January 2018 onwards to OBPs that haven't signed a valid EMVO Participation Agreement. All OBPs that will have uploaded a valid Participation Agreement in step 2.3 of the OBP Portal, signed by their named Authorised Representative, and provided a valid copy of proof in the relevant section (step 1.2), before that date, will benefit from the current rate (Early Bird Discount).



In addition, please note that a further rise of 50% of the amount will apply again, from the 15th of June 2018.

Please find below the adjusted table of EMVO's On-boarding fee¹.

	Early Bird	From the 15 th of January 2018	From the 15 th of June 2018
OBPs with more than 12 MAHs in Europe	20,000 €	30,000 €	45,000 €
OBPs with 6 to12 MAHs in Europe	10,000€	15,000 €	22,500 €
OBPs with 3 to 5 MAHs in Europe	8,000€	12,000 €	18,000 €
OBPs with 2 MAHs in Europe	6,000€	9,000€	13,500 €
OBPs with 1 MAH in Europe	3,000 €	4,500€	6,750€

This information can also be consulted from our website **Document Overview** section;



On-boarding Guideline



On-boarding Presentation



Participation Agreement

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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EMVO Team

European Medicines Verification Organisation

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¹ Please note that EMVO reserves its right to potentially apply an additional rise of the On-boarding fee in 2018.