Last updated 5.9.2018

## **This letter contains important information and clarification for MAHs about FiMVO invoicing and the change-over period**

Please also refer to the FiMVO website <https://www.laakevarmennus.fi/en> and follow us on LinkedIn <https://www.linkedin.com/company/fimvo-finnish-medicines-verification-organisation/> .

FiMVO will start invoicing MAHs that have products on the Finnish market in August 2018. First payments will be due in September. Please find below some Questions & Answers to clarify the invoicing procedure.

**Q1: What are the fees based on?**

A1: The fees are based on the FiMVO budget. FiMVO applies the flat-fee/MAH model recommended by EMVO so the number of MAHs on the Finnish market will affect the fee per MAH. Currently we are unable to estimate the exact number of MAHs Finland will have in August 2018.

Please note that the fee is based on marketing authorization holders, not marketing authorisations. If a company represents more than one MAH, the fee will be charged according to the number of MAHs.

**Q2: How much are the fees?**

A2: Annual fee 6 800 euro/MAH
The fee will be charged annually in January. However, the first payment has been charged starting in August 2018 covering September – December 2018 and the annual fee for 2019.

Set-up fee, range estimation 5 000 – 8 000 euro/MAH

The set-up fee will be charged in two instalments (one half of the set-up fee) in January 2019 and January 2020. The fee will be decided in December 2018.

**Q3: What are the two different fees?**

Q3: There is an annual fee and a set-up fee.

The annual fee covers the yearly running costs of FiMVO. This includes the running costs of the Finnish Medicines Verification System (FiMVS), FiMVO’s share of the European Hub
 costs and FiMVO governance costs.

The set-up fee will cover for the costs of setting up the system in 2016-2018. The setting up has been funded by pharmaceutical industry stakeholders by means of a loan. To be able to pay back these loans, FiMVO will charge a set-up fee from all MAHs.

**Q4: What is the FiMVO invoicing period?**

A4: FiMVO will invoice annually in the beginning of the year.

 If new MAHs enter the market, a second set of invoices will be sent out annually in June to cover for the second half of the year.

 Please note that the first invoices in August 2018 will cover for both Q4 and 2019.

**Q5: If a company will not have serialized packs on the market after February 9th 2019 but still has unserialised packs on the market, will fees be charged?**

A5: If the MAH has no other serialised products on the market and does not intend to have such products on the market, a contract and the resulting fees are not necessary.

**Q6: If an MAH is represented by multiple companies, who is responsible for the fees?**

A6: This depends on how the companies have contracted between themselves. It is sufficient to pay the FiMVO fees only once, but it is the responsibility of the companies to decide who will list the MAH in the Annex 2 of the FiMVO contract.

**Q7: What should be done if a new MAH enters or leaves the market?**

A7 If you already have a valid contract with FiMVO, you should update Appendix 2 to your current MAH list. If you do not have a contract with FiMVO, you should contact FiMVO: info@laakevarmennus.fi .

**If you have any further questions, do not hesitate to contact us!**

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