

Warsaw, 9th July 2018

To whom it may concern,

This letter provides basic information regarding the agreement on financing of the Polish Medicines Verification System (Agreement) by Marketing Authorisation Holders introducing medicinal products subject to safety features into Polish market (MAHs).

The KOWAL Foundation took the responsibility to develop and maintain the Polish Medicines Verification System (PLMVS), according to the EU Directive 2001/83/EC of the European Parliament and of the Council and the Commission Delegated Regulation (EU) 2016/161. The obligation derives directly from the law.

According to the Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, the cost of the PLMVS shall be borne by the MAHs responsible for medicinal products bearing the safety features. The obligation derives directly from the law.

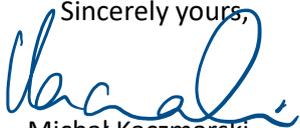
PLMVS is an element of the European Medicines Verification System that is managed by the European Medicines Verification Organisation (jointly the Repositories System, as defined by article 32 item 1 of the Delegated Regulation). The Repositories System stores information on safety features that enable verification of authenticity and identification of medicinal products. The ability to transfer data to the Repositories System is conditioned by signing of an agreement between MAH and the Foundation as well as bearing the fees stipulated in the agreement.

The MAH fee constitutes the Polish share in overall cost of development and maintenance of the Repositories System, divided by all MAHs active in the Polish market, responsible to finance PLMVS

According to the Delegated Regulation the Repositories System starts its operation on the 9th of February 2019. As of the date the obligation to use the Repositories System in order to verify authenticity of the medicinal products bearing safety features comes into force.

The Agreement on financing the PLMVS had been approved by MAH delegates sitting in the Board of KOWAL Foundation.

This Agreement should be considered as standardized terms of engagement with each and every MAH that according to the above mentioned regulations is obligated to sign.

Sincerely yours,

Michał Kaczmarcki

General Manager

Polish Medicines Verification Organisation (KOWAL Foundation)