KOWAL KRAJOWA ORGANIZACJA WERYFIKACJI AUTENTYCZNOŚCI LEKÓW
POLISH MEDICINES VERIFICATION ORGANISATION plmvo

Press release *Monday, 10 February 2020*

FIRST ANNIVERSARY OF

THE EUROPEAN MEDICINES VERIFICATION SYSTEM

The European Medicines Verification System (EMVS or the System) that went live on 9 February 2019 is celebrating its first year of operations.

The System represents a pioneer undertaking in managing multinational risk by private-public alliance of regulators and participants of the pharmaceutical market across European Union and European Economic Area.

EMVS had been established pursuant to the publication of the Commission Delegated Regulation (EU) 2016/161 stipulating detailed rules for the safety features appearing on the packaging of medicinal products for human use (the Regulation).

The reason for the introduction of the System had been outlined in the preamble to the Regulation, in particular in recitals (19) and (24) that read:

"*Past incidents of falsification show that certain medicinal products […] are at higher risk of being falsified. The authenticity of those medicinal products should therefore be subject to additional verifications…*"

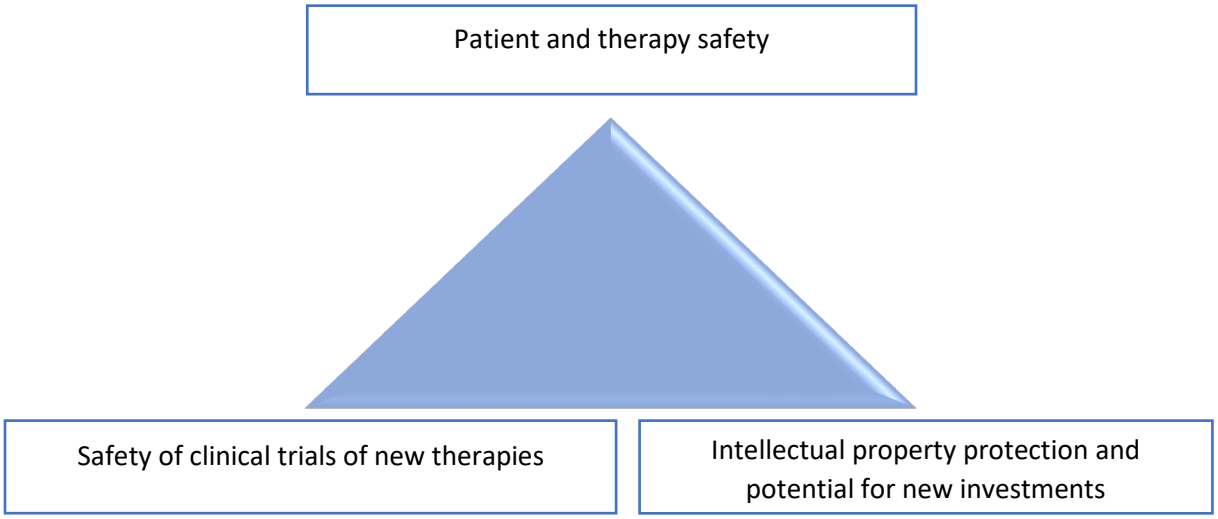
"*The verification of the authenticity of a unique identifier is not only paramount to the authentication of a medicinal product but also informs the person performing the operation of whether that product is expired, recalled, withdrawn or indicated as stolen"*.

The System represents a response to the known fact that fighting of falsified medicines via border controls is no more feasible. Europe is not only a target market for over 30 billion single packages of medicines per annum but also an important distribution hub for other continents where medicines are supplied to patients. If we match the volume figure with alarming reports of World Health Organisation quoting the scale of falsified medicines ranging from 1% through 30% across the globe, we are coping with dangerous threat not only for public health but also economies and societies. We also cannot forget that profitability of medicines falsification exceeds by far trafficking of narcotics or other traditional economic crime.

Taking all the above into consideration the European Commission decided that inherent risk of falsification embedded in manufacturing and distribution of medicines for Europe needs to be mitigated. Moreover, the decision was made that the mitigation measure must encompass wide range of benefits for the stakeholders of the project so that the cost-benefit equation brings measurable surplus to all and each of them. EMVS had been decided to become an answer to the unmet need of enhanced safety for all - patients, healthcare system, medicine supply chain participants and regulators. Obviously, patients remaining in the heart of the project.

Fundacja "Krajowa Organizacja Weryfikacji Autentyczności Leków"
ul. Stępińska 9, 00-739 Warszawa. KRS: 0000685283 NIP: 5252716278 REGON: 367739353

When we speak about the enhanced safety we need to remember that this term refers to the multidimensional aspect of it, taking into consideration patient safety, safety of therapies and clinical trials and last but not least intellectual property protection of those who invest in innovation and development of safe and efficient medicine therapies for society.



After first year of operations we can see that the System engaged over two hundred thousand users across Europe, including: manufacturers of medicines, marketing authorisation holders, community pharmacies, dispensing doctors, hospitals, wholesalers and National Competent Authorities across European Union and European Economic Area. Moreover, we must not forget thousands of IT suppliers supporting all the above mentioned. All of them had to learn how to cooperate under join IT platform developed according to stakeholder management concept, and only supervised by regulatory bodies.

Obviously, as expected with the system of this scale and complexity the first year was not easy for neither of the stakeholders. It is also difficult to expect that after a first year of operations it could have proved all its expected deliverables. We need to bear in mind that the European Commission in its 2015 Impact Assessment of the, draft at the time, Regulation indicated that the System assessment should have taken place at the latest five years after the date of application of the delegated acts. Hence, we need some patience.

This does not mean that the System did not prove already its broader benefits. For instance, due to implementation of the GS1 2D Data Matrix coding standard across all the supply chain participants, the transparency of business processes improved, and first instances of automation have been observed. This observation seems to be particularly evident in the area of wholesale operations and some hospital locations. The process had been started but it is progressing and is expected not only to increase patient safety but also shorten time of single pack of medicine handling, for instance in case of returns or quality recalls.

As Andreas Walter, the General Manager of the European Medicines Verification Organisation, when asked by KOWAL Foundation about European perspective of the project, has said that: *"On top of the fact that the System has already been used for the detection of attempted falsification of medicines,*

we have also observed several other major advantages of the EMVS. Amongst them particularly satisfactory is the fact that our stakeholders are using the system as an opportunity for the revision and enhancement of their manufacturing and distribution processes across Europe and beyond. These experiences bring benefits not only concerning patient safety but also for sustainability and the operational efficacy of supply chain of medicines, and not only in Europe but also other destinations. Nevertheless, This does not mean that we did not encounter some mid-term challenges with a project of this size and complexity, although we needn't focus on the past but rather the overwhelming opportunities going forward".

Poland is particularly proud celebrating the first anniversary of EMVS. We started our journey with some delay, comparing to the mainstream of EMVS implementations across Europe, nonetheless due to great European collaboration and support of stakeholders of the project, we managed to achieve the position of a leader in Robotic Process Automation in certain areas of EMVS operations.

Celebrating the first year of operations of EMVS across Europe but in particular in Poland, Polish Medicines Verification Organisation would like to thank all of our European and Polish stakeholders, amongst them the European Medicines Verification Organisation, National Competent Authorities, pharmacists, wholesalers and manufacturers of medicines for their tremendous effort and commitment in reaching this point of our common journey towards safer and better patient therapies.

Fundacja "Krajowa Organizacja Weryfikacji Autentyczności Leków"
ul. Stępińska 9, 00-739 Warszawa. KRS: 0000685283 NIP: 5252716278 REGON: 367739353