Press release

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Protection of patients against counterfeit medicinal products — Polish Medicines Verification System Foundation

Polish Medicines Verification Organisation was established on 5th July 2017 to create and implement an IT system for verifying the authenticity of medicinal products. The obligation to create this organisation stems from EU regulations aimed at preventing drug falsification that threatens the health and lives of patients. Similar organisations will be established in all EU countries.

The obligation imposed on the representatives of the pharmaceutical industry for individual member states to create a National Medicines Verification Organisations is a direct result of EU Directive 2011/62/EU, the so-called Falsified Medicines Directive, and it is implemented into Polish law by the Act of 19th December 2014 that amends the Act – Pharmaceutical Law and certain other Acts (Journal of Laws of 8th January 2015) and implements these acts to the Directive.

Polish Medicines Verification Organisation was established by four authorised and obligated organisations: the Polish Association of Pharmaceutical Industry Employers (PZPPF), the Employer's Union of Innovative Pharmaceutical Companies INFARMA, the Association of Parallel Importers of Medicinal Products (SIRPL) and the Polish Pharmaceutical Chamber (NIA).

Threat to patients

In recent years the pharmaceutical market has been faced with the rapidly growing and dangerous phenomenon of falsified medicinal products. The scale and severity of the problem is illustrated by the data presented by the World Health Organization (WHO). They show that even 1% of medicines sold in developed countries can be counterfeited, and as many as 50% of medicines sold via the Internet are falsified.

The experiences of the WHO and other organisations involved in combating illicit medicinal product trade show that the phenomenon of falsification is becoming more serious every year. Counterfeit medicines pose a serious threat to health systems in all EU member states, including Poland. Falsified medicines may contain low quality ingredients or inappropriate doses, and therefore pose a serious threat to the health and even the lives of citizens.

Economic problem

In 2016, 1013 preparatory proceedings were initiated, with charges filed in 404 proceedings related to crimes involving the counterfeiting of medicines.

During this time, through international trade inspections, custom services seized 18,628 counterfeit medicinal products with a value of over PLN 830,000. This is only part of the production and sale of counterfeit medicines on the Polish market.

The organisation will protect patients.

The introduction of the so-called Falsified Medicines Directive, and the establishing of national organisations and IT systems linked to a central management centre is necessary to improve the safety of patients using pharmacotherapy in the European Union. These activities are also required to ensure unification of control of the medication market across Europe. The Falsified Medications Directive imposes on the manufacturers of medicinal products the obligation to use additional safety measures on their packaging. Each package will be equipped with a unique code, which, thanks to the system for verifying the authenticity of medicinal products, will be checked for the authenticity of the medication before it is released to the patient from the pharmacy.

— The common goal of the organisation, as well as the public administration, is to ensure patients' safety. The organisation is also open to cooperation with all market participants in order to perform its tasks in the best possible manner. The next few months will be a period of intensive work, aimed at creating a system for verifying the authenticity of medicinal products — says Bogna Cichowska-Duma, General Director of INFARMA.

— The work on the establishment of a national organisation began in May 2015 — says Tomasz Dzitko, President of SIRPL. Further discussions with other stakeholders were dragging on, threatening unpredictable consequences for the medicinal products market in Poland. That is why the decision was made to establish the organisation by the group of four entities that reached an agreement, and the participation of other interested parties was ensured in the statute — emphasises Dzitko.

— It is crucial to ensure that the work on implementing the system starts as soon as possible. The creation of the organisation will enable the completion of the stage of negotiations between organisations, and the transition to a critical stage for the provision of access to medicines for Polish patients, and the creation of a functional IT and procedural solution. Participation in the process for creating the NMVS representation of pharmacists provides a guarantee of correct identification of needs and threats at the retail distribution level of medicines — says Elżbieta Piotrowska-Rutkowska, President of the Polish Pharmaceutical Chamber.

— The priority is to ensure access to medicines for Polish patients after 9th February 2019 (entry into force of the provisions on the serialisation of medicines), therefore it was necessary to set up the Polish Medicines Verification Organisation as soon as possible — says the President of Polish Employer Association of Pharmaceutical Industry, Zdzisław J. Sabiłło. The organisation faces the difficult challenge of creating an efficient medicine verification system — he explains.

Founding Organisations:

The PZPPF brings together pharmaceutical companies operating in Poland, which provide every second drug on the Polish market to patients. The manufacturers belonging to this association guarantee the pharmaceutical security of the country, affect its economic development, and contribute to raising the level of innovation in our economy.

The Employer's Union of Innovative Pharmaceutical Companies INFARMA, represents 28 leading pharmaceutical companies that conduct research and development activities, and manufacture innovative medicines. INFARMA is a member of an international organisation that brings together innovative members of the pharmaceutical industry — the European Federation of Pharmaceutical Industries and Associations (EFPIA), as well as Employers of the Republic of Poland and the Polish Chamber of Commerce. The aim of INFARMA is to take initiatives that positively influence the creation of system solutions in the health care sector in Poland.

The Association of Parallel Importers of Medicinal Products (SIRPL), represents leading companies in the parallel import industry of medicinal products in Poland; it supplies cheaper products from countries in the European Economic Area, and acts to increase the competitiveness of the pharmaceutical sector. SIRPL was established in 2006, and is a member of the European Association of Euro-Pharmaceutical Companies (EAEPC) that promotes the idea of parallel trade in Europe. SIRPL associate companies offer patients nearly 600 different medicinal products.

The Polish Pharmaceutical Chamber is a professional administration body, which unites and represents 34,000 pharmacists practising in general and hospital pharmacies, pharmaceutical wholesalers, offices, and pharmaceutical sector companies. It is a member of the international organisations of pharmacists — PGEU and EAHP.