

06 December 2017.

PASMI Polish Association of Self Medication Industry in connection with the appearing information related to the current practices of the Provincial Pharmaceutical Inspections is in the opinion that the exhibition in pharmacies of medicinal products available without prescription containing nicotine is compliant with the current legal regulations.

Nicotine-containing medicinal products offered for sale in pharmacies are available without a prescription, are not eligible for reimbursement and, most importantly, do not contain abusive or psychotropic substances. It should also be emphasised that nicotine was not included in the list of intoxicants and psychotropic substances under the Act of July 29, 2005 on counteracting drug addiction (consolidated text, Polish Journal of Laws No 2017, item 783). According to Polish Pharmacopoeia VIII, nicotine has been classified as a very potent agent, but it is not in the category of products whose public advertising is forbidden. Thus, referring to the provisions of the Pharmaceutical Law, there are no contraindications concerning exhibitions consisting in the placement of the goods in the pharmacy, which makes it visible to the pharmacy's customers.

Additionally, it should be emphasised that the regulation concerning storage conditions for this type of products, i.e. containing very strong agents, also does not apply to exhibitions. From the literal interpretation of the provision (§4 section 2 point 2 of the Regulation of the Minister of Health of October 18, 2002 on the basic conditions for running a pharmacy), it may not be inferred that separate storage of a medicinal product containing one of the above-mentioned substances, including nicotine, means that such a product could not be exhibited unless it is obviously at the same time stored separately within this exhibition.

In PASMI's assessment, the Pharmaceutical Inspection does not have the authority to clarify or interpret the provisions of existing legal acts, and thus it cannot indicate a single storage standard. Most importantly, the procedure of the Provincial Pharmaceutical Inspections consisting in ordering entrepreneurs running pharmacies to store substances that are very strong in secured conditions under the provisions of the Act on counteracting drug addiction, is an activity that is not reflected in the applicable regulations, and therefore is contrary to the law. Current activities of the Provincial Pharmaceutical Inspectorate authorities, which make it impossible to exhibit products, are

synonymous with the restriction of business operations of entities running pharmacies and entities marketing OTC medicinal products containing nicotine.