# FREE MOVEMENT OF GOODS (PHARMACEUTICALS) IN THE EUROPEAN UNION VERSUS PROTECTION OF HEALTH OF POPULATION

**Tomas Peracek**
*Faculty of management, Comenius University in Bratislava, Slovak Republic*
*tomas.peracek@fm.uniba.sk*

**Alexandra Mittelman**
*Faculty of management, Comenius University in Bratislava, Slovak Republic*
*alexandra.mittelman@fm.uniba.sk*

**Lubomira Strazovska**
*Faculty of management, Comenius University in Bratislava, Slovak Republic*
*lubomira.strazovska@fm.uniba.sk*

***ABSTRACT***

*The topic of the paper belongs into the area of management, however, it also offers overlaps into the area of constitutional and administrative law and it directs to the multidisciplinary research of problematics of reexport of chosen products, mainly pharmaceuticals. The concept and legal regulation of reexport remains to a large extent unfinished, after years of professional discussions (not only) in the slovak legal environment. The restriction of reexport of chosen products and the protection of consumer against the inappropriate impacts of this performance should represent the main aim of legal regulation in this area of law. The essential legal enactments except the Constitution of the Slovak Republic are mainly law no. 362/2011 of Journal of Laws on pharmaceuticals and medical aids and on the change and completion of some laws subsequently amended (herein after referred to as „Law on pharmaceuticals) and law no. 363/2011 of Journal of Laws about the range and conditions of payment of pharmaceuticals, medical aids and dietetic groceries on the basis of public health insurance and on the change and completion of some laws subsequently amended. The aim of this paper is to analyze this issue whose legislative solution is necessary for the protection of life and health of population in near future.*

***Keywords:*** *freedom of trade, management, movement of goods, protection of life and health, reexport*

## 1. INTRODUCTION

The reexport of pharmaceuticals is the unusual name of increasingly conventional condition in the Slovak Republic. Companies that deal with the distribution of pharmaceuticals, they do not place them to the slovak pharmacies and hospitals after importing them, but they export them again abroad. The reason? Profit. Therefore more pharmaceuticals have been sent abroad this year than a year before, when it was more than a million packages. It results from the data of the State institution for the control of pharmaceuticals (SICP), to whom the planned export has to be announced. As it follows from the data available of SICP, 589 pharmaceuticals were exported in 2015 from the Slovak Republic, in the amount almost 1.4 million packages, that is almost 400,000 more than in 2014. These pharmaceuticals go most frequently to the countries of Western Europe, where is its price uncomparably higher. Czech Republic fights with the same problem, too. (Nováčková, Milošovičová, 2011, pp. 88-99) State institution for the control of pharmaceuticals has legal competence to ban export of pharmaceutical, but only in case of the threat of its unavailability on the domestic market. This happened 182 times in 2014. As SICP states, on the basis of information about export, consumption and planned export,

SICP identified in 2014, 27 pharmaceuticals, whose export would have threatened availability of the pharmaceutical and provision of healthcare. 182 decisions have been made for those pharmaceuticals, that represent 57,446 packages. The problems that cause unavailability of pharmaceuticals consist in, according to Ministry of Health, mainly in the bad logistics between pharmacy and distributor, in the problems in production of pharmaceuticals or production chain and also when are pharmaceuticals imported to the Slovak Republic the subject of reexport. Mainly pharmaceuticals for the treatment of serious diseases, for example epilepsy, schizophrenia, Parkinson's disease or many pharmaceuticals determined for the treatment of oncological diseases head abroad. The reexport is according to Ministry of Health the reason for unavailability of some pharmaceuticals in the Slovak Republic. Slovak pharmaceutical society calls attention for a long time to the unvailability of some pharmaceuticals. It claims that significantly lower prices in comparison to other member states of EU, the possibility of pharmacies to deliver pharmaceuticals to other subjects, not only to patients and the possibility of distributors to export pharmaceuticals abroad is the basis for the developed export of pharmaceuticals, that then slovak patients miss. As Association of innovative pharmaceutical industry (AIPI) states, this situation is caused by the fact that in the Slovak Republic, there are the one of the lowest prices of pharmaceuticals and therefore the slovak market is becoming attractive for distribution companies. The member companies of AIPI do not participate in reexports and they always import enough pharmaceuticals to the Slovak Republic, according to the statistic estimation of morbidity. The Slovak Republic as one of the member states of EU has adopted in legislation the possibility of the ban of export of pharmaceuticals and therefore its export has been monitored since 2013. However, according to the opinion of European Commission is this legislative measure inconsistent with the legal order of EU, whose consequence was the beginning of action about the infringement of legal rules against the Slovak Republic. In march 2015, European Commission requested the Slovak Republic by the letter, to provide the answer where the Slovak Republic can give reasons for its statement and show accordance of the slovak legislative with the law of EU, where it mainly deals with the rules about the free movement of goods.

## 2. THE PROPOSAL OF THE LEGISLATIVE MEASURE

Despite the EU objection, Ministry of Health of the Slovak Republic made the proposal of the bill amending the law from the area of administrative law, that:

- changes and amends Law no. 362/2011 of Journal of Laws on pharmaceuticals and healthcare devices and about the amendment of some acts subsequently amended and
- changes Law no.363/2011 of Journal of Laws on the range and conditions of payment of pharmaceuticals, healthcare devices and dietetic groceries on the basis of public health insurance and about the amendment some acts subsequently amended.

The aim of this proposal is to prevent reexport of pharmaceuticals and to remove the reservations of European Commission expressed in the legitimate statement – Infringement no.2014/4141 C(2016) 3065 final from 26.05.2016 and to synchronize slovak legal enactments regarding humane pharmaceuticals with The Treaty on the Functioning of the European Union. The content of the prepared Amendment is to amend law on pharmaceuticals with the expression „medical prescription in anonymised form". It deals with the copy of the issued medical prescription where the person that is the holder of the permission for the provision of pharmaceutical care in public pharmacy or hospital pharmacy or the person authorized by the holder of the permision for the provision of medical care in public pharmacy or hospital pharmacy anomymises personal data about patient. Pharmacy should enclose this copy of medical prescription to the order addressed to the holder of the registration by means of information system for the arrangement of the automatic electronic placing, accepting and confirming orders for humane pharmaceuticals placed in the list of categorized pharmaceuticals

created and run by the holder of the registration.(Capandová, 2015, pp 1-8) The Amendment proposed tightens penalties, where after repeated infringements of the obligations imposed by this law, the issued permission will be withdrawn from the holder of the permission for the wholesale distribution of humane pharmaceuticals and the holder of the permission for the provision of pharmaceutical care in public pharmacy or hospital pharmacy. Then, the expression as „exporter of pharmaceutical" will be withdrawn from the law, because the applicant for the certificate about the fact that the producer of the pharmaceutical is the holder of the permission for the production of pharmaceutical and about the fact that the holder of the permission for the pharmaceuticals' production meets the valid provisions of The World Health Organization regarding the production of pharmaceuticals determined for the export to third states and can only be the holder of the permission for pharmaceuticals' production. It is put more precisely, by which subject the holder for wholesale distribution of humane pharmaceuticals can deliver humane pharmaceuticals placed in the list of categorized pharmaceuticals. The obligation imposed to the holder of the permision for the wholesale distribution of humane pharmaceticals to deliver to pharmacy pharmaceutical within 24 hours is deleted. This obligation is imposed only to the holder of the registration of the ordered pharmaceutical. The new obligations are imposed to the holder of the permission for the wholesale distribution of humane pharmaceuticals. The holder of the permission for the wholesale distribution of humane pharmaceuticals will be as well as the holder of the registration of the pharmaceutical obliged to deliver the categorized pharmaceutical only to the holder of the permission for the provision of pharmaceutical care in public or hospital pharmacy or other holder of the permission for the wholesale distribution of humane pharmaceuticals. The holder of the permission for the wholesale distribution of humane pharmaceuticals is authorized within the frame of resale to return redundant categorized pharmaceuticals to the holder of its registration, what will be the only exception when these pharmaceuticals will be able to head somewhere else than to pharmacy or to other wholesale distributor. The holder of the permission for the wholesale distribution of humane pharmaceuticals will be obliged to submit upon the request to Ministry of Health of the Slovak Republic the records about the revenues of humane pharmaceuticals placed in the list of categorized pharmaceuticals and its deliveries:

- to holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy
- to other holders of the permission for the wholesale distribution of humane pharmaceuticals and
- to the holders of the registrations of these pharmaceuticals in case of its resale

or data from these records in electronic version enabling automatic processing. The holder of the permission for the wholesale distribution of humane pharmaceuticals should then be obliged to administer and store documents about the authorized subjects whom he delivered categorized pharmaceuticals and he will also be obliged to submit this documents or requested data from it to Ministry of Health upon request. These new obligations imposed to the holder of the permission for the wholesale distribution of humane pharmaceuticals regarding categorized pharmaceuticals should according to the amendment avoid the export of these pharmaceuticals. These obligations have the character of the obligation imposed in the public interest according to the Article 81 of the EU Directive and the Council no.2001/83/ES, that establishes Code of Law of Society on humane pharmaceuticals. This enactment does not oppose the application of stricter requirements established by the member states in relation to wholesale distribution of:

- narcotic drugs or psychotropic substances on its area
- drugs made from blood
- immunological drugs
- radioactive drugs

The criticised enactment by European Commission of §19a of the law on pharmaceuticals that amends the question about the export of human pharmaceutical is replaced by new statutory text from which the enactments are omitted, which were most criticized by European Commission. According to the new proposed statutory text, the range of pharmaceuticals whose export is regulated, is narrowed down only to categorized pharmaceuticals. The export of categorized pharmaceuticals can be allowed on to the holder of the registration of pharmaceutical, whose planned export will be announced to SICP till 7 days from the day of its realization. The submitter at the same time proposes to cancel the authorization of SICP to ban the export of the pharmaceutical that is in short supply in the Slovak Republic.

The performance of resale of pharmaceuticals, which is nowadays performed by pharmacies as one of the performancies in common should be released from pharmaceutical care from any holder of the permission for the wholesale distribution of humane pharmaceuticals whom was the pharmaceutical bought from by any pharmacy. (Stoličná, 2012, p. 14)

The change of humane pharmaceuticals from the list of categorized pharmaceuticals will be in case of passing the bill enabled between the holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy, but only for the purpose of its dispense in public or hospital pharmacy. These measures restricting the range of performances performed in public or hospital pharmacy are aimed to prevent the export of categorized pharmaceuticals, whose holder of the registration delivered to market in the Slovak Republic for the purpose of its dispensing to patient in the given pharmacies. Nowadays, many holders of permissions for the wholesale distribution of humane pharmaceuticals buy out categorized pharmaceuticals from the holders of the permission for the provision of pharmaceutical care in public or hospital pharmacies and then they export them. The new obligations are imposed to the holder of permission for the provision of pharmaceutical care in public or hospital pharmacy. The most important new intended obligation will be to dispense categorized pharmaceutical to patient. At the same time, it is expected the enabling of:

- the resale of these pharmaceuticals to the holder of the permission for the wholesale distribution of humane pharmaceuticals, who delivered them to the holder of permission for the provision of pharmaceutical care in public or hospital pharmacy
- the changes of humane pharmaceuticals in the list of categorized pharmaceuticals between the holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy for the purpose of its dispensation in public or hospital pharmacy

The next obligation imposed to the holder of the permission for the provision of pharmaceutical care in public or hospital pharmacy is the obligation to order humane pharmaceuticals placed in the list categorized pharmaceuticals from the holder of its registration by means of information system for the provision of automatic electronic entry, receiving and confirming orders of humane pharmaceuticals placed in the list of categorized pharmaceuticals, if he requires from the holder of the registration of humane pharmaceutical, the delivery of this pharmaceutical placed in the the list of categorized pharmaceutical till 24 hours after the order has been accepted. The obligation is to enclose the anonymized medical prescription to the order. (Masár, 2013, p. 20) There will be more obligations of the holder of the registration in the amendmend, as for example creation and operation of information system for ordering pharmaceuticals, whose he has the registration for. The database will enable to the holder of the registration of humane pharmaceuticals to have a survey about the holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy to whom he delivered till 24 hours pharmaceuticals placed in the list of categorized pharmaceuticals on the basis of submitting anonymized medical prescription. This information system will be obliged to keep itself in the state of operation and in case of its failure, it will accept and confirm orders of humane pharmaceuticals from the list of categorized pharmaceuticals also by different way, to provide the delivery of pharmaceutical to pharmacy till 24 hours. Then, he is obliged to deliver

within 24 hours humane pharmaceuticals from the list of categorized pharmaceuticals to the holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy on the basis of the order by means of information system with the enclosed anonymized medical prescription. This obligation must not relate to the holder of the registration of humane pharmaceutical who has against the holder of the permission for the provision of pharmaceutical care in public or hospital pharmacy claims for the delivered pharmaceuticals from the list of categorized pharmaceuticals after the expiry of the twice of contractually agreed repayment term. The holder of the registration will be obliged to provide and announce to Ministry of Health of the Slovak Republic responsible person for the delivery of humane pharmaceuticals in the list of categorized pharmaceuticals with the domicile or residence in the Slovak Republic, if the holder of the registration of humane pharmaceuticals does not have the domicile or residence in the Slovak Republic. The holder of the registration will be obliged to keep the register of the holders of the permission for the wholesale distribution of humane pharmaceuticals and holders of the permission for the provision of pharmaceutical care in public or hospital pharmacy, whom he delivered pharmaceuticals from the list of categorized pharmaceuticals. He has to keep this register for 10 years and to submit it or to provide its data on-demand to Ministry of Health of the Slovak Republic in electronic version enabling automatized data processing. The holder of the registration will be obliged to deliver humane pharmaceutical placed in the list of categorized pharmaceuticals to the holder of the permission for the wholesale distribution of humane pharmaceuticals exclusively for the final delivery to the holder of the permission for the provision of pharmaceutical care in public or hospital pharmacy. The submitted proposal of the legislative change plans to impose to Ministry of Health the new rights to publish on its website name, surname and domicile of the person responsible for the delivery of pharmaceuticals within 24 hours, if it is a natural person or the name or business name and residence of a legal person and its contact information consisiting of e-mail address and mobile telephone number. At the end, the applicant of the Bill proposes to amend the law with other administrative offences for the infringements of the new obligations imposed to the holder of the registration in the provision of §60 of the law on pharmaceuticals but at the same time he proposes to delete the provision on the other administrative offences in connection with the new wording of the provision of §19a, in which it is proposed to delete the notification of export 30 days before the meant export of pharmaceutical. Other administrative offences are amended for the infringements of new obligations imposed to the holder of the permission for the provision of pharmaceutical care in public or hospital pharmacy involved in the provision of §23 ofthe law on pharmaceuticals. Following the new obligations imposed to the holder of the permission for the wholesale distribution of humane pharmaceuticals, the rights of Ministry of Health of the Slovak Republic to impose penalties for other administrative offences are modified, as well. An amendment to the law no.363/2011 of Journal of Laws on the range and conditions of payment of pharmaceuticals, healthcare devices and dietetic groceries is proposed, on the basis of public health insurance and on the amendment to some text of the law no.460/2012 of Journal of Laws and the law no.265/2015 of Journal of Laws. The aim is to harmonise penalties according to this law with other administrative offences according to the law on pharmaceuticals. As the last thimg, the provision is proposed, which expects the date of entry into force of the law from 1st of january 2017.

## 3. THE POSSIBLE CONFLICT BETWEEN AMENDMENT LAW WITH THE EUROPEAN UNION LAW

As defined by the clause of compatibility , the proposed amendment law is according to the Ministry of Health of the Slovak Republic, compatible with the European Union law, according to which is the free movement of goods i.e. also pharmaceuticals the first of the four basic

freedoms of the internal market. This freedom has its legal basis in the provisions of the articles 26, 28 till 37 of the Treaty on the Functioning of teh European Union. It is secured mainly by the abolition of custom duties and quantitative restrictions as well as by means of prohibition of measures with the same effect. For the support of the completion of internal market, the principles of mutual recognition, the abolition of physical and technical barriers and the support standardisation were amended the adoption of the new legislative frame in 2008, significantly reinforced the launching products on the market, free movement of goods, the system of supervision of the European Union market. The right to free movement of goods coming from the member states of EU and the third countries, which in the free circulation in member states is one of the basic rules of the Treaty. (Milošovičová, Nováčková, 2014, p. 75) Originally, the free movement of goods was regarded as the part of the Customs Union between the member states, that involved the abolition of customs duties, quantitative restrictions of the trade and measures with the equivalent effect and creation of the common external rate of duty of the Community. Later, the attention was paid to the abolition of all remaining barriers of free movement with the aim to create the internal market – the area without the internal borders, where goods would move freely in the same way as on the national market.

## 4. CONCLUSION

In relation to objection of the infringement of the European Union law by the prepared amendment law, the European Commission uses more arguments. The freedom to do business should not be understood as an absolute right without any possible restriction. This freedom has also its own content, that can be from the point of view of Community law concerned by the intervention from state which does not have to be necessarily unlawful or discriminatory. From the point of view of exporters of pharmaceuticals it is clear that this intervention of legislature is understood as the mere rejecting of the freedom to do business, when it is banned to export pharmaceuticals from the Slovak Republic or other EU member state. However, this intervention is possible to justify only by the legitimate regard to the general interest of the society as a whole. The right to do business in the area of import and export is not banned in general, it is only restricted in some situations, as the Slovak Republic under Article 40, first sentence of the Constitution of the Slovak Republic guarantees to every person the right to protection of health. This right is not just for the citizens of the Slovak Republic, but also for the foreigners regardless of their citizenship. This basic human right must always take precedence over the right to do business and to make a profit regardless of its possible consequence.

## LITERATURE:

1. Masár, D. (2013) *Problémy marketingu vo verejnom sektore*, Sládkovičovo : Vysoká škola v Sládkovičove
2. Milošovičová, P., Nováčková D., (2014) *Uplatňovanie práva EÚ na Slovensku*, Plzeň: Aleš Čeněk
3. Nováčková D., Milošovičová P., (2011) *Medzinárodné ekonomické právo*, Bratislava: Eurounion
4. Capandová P., (2015) *Selected Issues of Legislation with regard to Operating Pharmacies in the Slovak Republic,* In : Acta Facultatis Pharmaceuticae Universitatis Comenianae, Bratislava: Univerzita Komenského v Bratislave
5. Stoličná Z., (2012) *Vývoj hospodárskej politiky SR od transformačného obdobia roku 1989 až po súčasnosť*, Bratislava: Kartprint