VAT RATES ON MEDICAL DEVICES: FOREIGN EXPERIENCE AND UKRAINIAN PRACTICE

STAWKI VAT NA WYROBY MEDYCZNE: DOŚWIADCZENIA ZAGRANICZNE ORAZ PRAKTYKA STOSOWANA NA UKRAINIE

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ABSTRACT

Introduction: In Ukraine differentiated VAT rates is a matter of debate. Today the Cabinet approved a list of medical products that has been changed three times resulting in changed VAT rates for specific products. European Union provides another method of regulation of VAT rates on medical devices. The abovementioned demonstrates the relevance of this study.

Material and methods: Comparative analysis of Ukrainian and European Union legislation based on dialectical, comparative, analytic, synthetic and comprehensive research methods were used in this article.

Discussion: In Ukraine general rate of VAT for all business activities is 20 %. But for medical devices, Tax Code of Ukraine provides special rules. VAT rate of 7% for transactions supplies into Ukraine and imported into the customs territory of Ukraine of medical products on the list approved by the Cabinet. The list generated by the medical product name and nomenclature code that does not correspond to European experience and Council Directive 2006/112/EC.

Conclusion: In our opinion, reduced VAT rates should to be established for all medical devices that are in a stream of commerce, have all necessary documents, that proved their quality and safety and fall under definition of medical devices.

KEY WORDS: medical devices, medical equipment, VAT rates, pharmaceutical products.

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INTRODUCTION

Some of the goods that are in a stream of commerce has a high level of value for people. Medical devices unconditionally belong to this category of goods. That is one of the reason of their special law regulation and providing for manufactures specific rules to production and trading. Legislation on value added tax (VAT) is not an exception from this point of view.

MATERIAL AND METHODS

Article is based on analysis of Ukrainian legislation, in particular, Tax Code of Ukraine, Law of Ukraine "On prevention of financial catastrophe and creating conditions for economic growth in Ukraine", orders of the Cabinet of Ministers; European Union`s Directives (2006/112/EC and 2001/83/EC) and judicial practice. The research is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

DISCUSSION

In Ukraine, general rate of VAT for all business activities is 20 %. However, for medical devices Tax Code of Ukraine provides special rules.

VAT - excise tax form that retains the benefits of multi-tax turnover tax on all levels of the movement of products, which includes the price of goods and fully paid by the end user, which is the vast majority of patient health institution.

In Ukraine differentiated VAT is a matter of debate, but since April 1, 2014 in accordance with Law of Ukraine of 27.03.2014 p. Number 1166-VII "On prevention of financial catastrophe and creating conditions for economic growth in Ukraine" [1] was made the first attempt to differentiate VAT, along with what regime was abolished exemptions in the supply of medicines and medical devices. At the same time from April 1, 2014 in accordance with Art. 193 Tax Code of Ukraine introduced tax treatment of such products at the rate of 7% [2].

On April 26, 2014 in Ukraine applied VAT rate of 7% for transactions supplies into Ukraine and imported into the customs territory of Ukraine of medical products on the list approved by the Cabinet; supplies into Ukraine and imported into the customs territory of Ukraine of medical devices and/or medical devices approved for use within clinical trials, permission for which is provided by the Ministry of Health of Ukraine.

Today the list of medical products, approved by Cabinet, has changed three times resulting in specific products has also changed VAT rate.

The current list of medical products supply operation in the customs territory of Ukraine and imported into the customs territory of Ukraine are subject to value added

tax at the rate of 7%, approved by Cabinet of Ministers of 3 September 2014 [3]. Number 410, which entered into force on 10 September 2014

The list generated by the medical product name and nomenclature code that does not correspond to European experience and Council Directive 2006/112/EC [4], as according to Art. Directive 98 reduced tax rates apply only to the goods or services in the categories set out in Annex III, which among other things provided for pharmaceutical products, medical equipment and other assistive devices, not individual names (names) of goods or services from a single category.

It does not include "baby products" range of medical products for babies (diapers, pacifiers, silicone and the like for children), bottles, vials, bottles, lids for sealing medicines, blood products bandage preoperative and postoperative, capsules and so on. Thus, on September 10, 2014 is automatically led to the use of the full 20% VAT rate.

We believe that selective tax breaks led to including more medical devices within the 20% VAT rate, therefore it restricts access to medicines for the benefit of private and public commercial interests. Such situation is morally unjust and unethical from any point of view. [4, p. 588]

In the Verkhovna Rada of Ukraine there is a draft law which provides the amendments to article 193 Tax Code of Ukraine, particularly provides that the reduced rates 7 % of VAT shall apply to all medical devices with no exceptions[5]. But for today this law is not promulgated.

As for European Union ('EU') it also has special rules for applying VAT to medical devices. So, under EU law on VAT, Member States may apply a reduced rate of VAT to pharmaceutical products and certain medical devices. In accordance with Article 98 of Council Directive 2006/112/EC of 28 November 2006 on the common system of VAT Member States may apply either one or two reduced rates. The reduced rates shall apply only to supplies of goods or services in the categories set out in Annex III. When applying the reduced rates to categories of goods, Member States may use the Combined Nomenclature to establish the precise coverage of the category concerned.

Paragraphs 3 and 4 of the Annex III establishes next categories of medical devices to which the reduced rates referred to in article 98 may be applied:

– pharmaceutical products of a kind normally used for health care, prevention of illnesses and as treatment for medical and veterinary purposes, including products used for contraception and sanitary protection;
– medical equipment, aids and other appliances normally intended to alleviate or treat disability, for the exclusive personal use of the disabled, including the repair of such goods, and supply of children's car seats [5].

As we can see EU legislation allows to apply reduced rates of VAT only to medical devices that fall under the categories defined in Annex III to Council Directive 2006/112/EC and not to all medical devices that are in a stream of commerce.

Interesting position described in the judgment of the Court of Justice of the European Union handed down on 17 January 2013 in Case C-360/11 (European Commission & Kingdom of Spain). The Commission appealed to the court because it thinks that Kingdom of Spain has applied a reduced VAT rate on broader categories of goods than what is provided for in points 3 and 4 of Annex III to Council Directive 2006/112/EC on the common system of VAT. In this case Advocate General Jääskinen has formulated conditions to which medical devices has to fulfill for applying reduced rates.

So, point 3 allows Member States to apply a reduced rate of VAT to goods which fulfil two conditions. First, they have to be 'pharmaceutical products', and second, these products have to be 'normally used for health care, prevention of illnesses and as treatment for medical and veterinary purposes'.

The wording of category 4 attributes the following criteria to medical equipment to which a reduced rate of VAT can be applied: such goods have to be 'for the exclusive personal use of the disabled'. Two observations can be made of this wording: first, category 4 refers to medical devices used exclusively by humans, with no mention of veterinary use. Second, the application of a reduced rate of VAT to medical devices is reserved for 'exclusive *personal* use', excluding general use.

After analysis of Spanish legislation for compliance with the above conditions he made a decision that Kingdom of Spain has failed to fulfil its obligations under Article 98 of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax, in conjunction with Annex III [7].

But he remarked that for understanding what kind of goods, including medical devices, applied under low rates, he had to use a few other EU directives. One of them is Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [6]. The concept of pharmaceutical product should be likened to medicinal product defined in Article 1 of this Directive as follows:

"Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product."

Most language versions use different expressions in category 3 and in Article 1 of Directive 2001/83. For example, in the German versions, however, the term 'Arzneimittel' is used in both provisions. This is indeed a narrower term than 'pharmaceutical product', but it seems to be an exception to the more general trend of using differing expressions. Abovementioned raises the issue of defining the scope of medical devices in modern context, that we discussed in previous articles [8, 9] but it require specific scientific research and goes far beyond the scope of this review.

CONCLUSION

We think that it is clear that medicinal products are pharmaceutical products, but the two directives pursue rather different objectives, and without an express reference to a definition in another directive. We agree with Mr. Jääskinen that between them have to be a connection. Moreover, the

definition of medicinal product in Article 1 of Directive 2001/83 ties the concept to the medical care of human beings. For its part, the concept pharmaceutical product in category 3 covers also veterinary use. It seems to me that the expression pharmaceutical product used in category 3 is intended to be broader than the term medicinal product as it is defined in Directive 2001/83 [10].

Thus, as we can see, applying reduce rates for medical devices in EU for Member States is not easy. As a result, reduce rates could be apply to goods that are not medical devices at all and on the contrary not apply to some medical devices that fall under the paragraphs 3 and 4 of the Annex III.

For our view regulation of VAT rates applying to medical devices should be clear and closely defined. In our opinion reduced rates should to be establish for all medical devices that are in a stream of commerce, have all necessary documents, that proved their quality and safety and fall under definition of medical devices. We believe that it will be fairly both for end users and for manufactures that provided and trading medical devices. Moreover, this will equate to do medical devices readily available for people and preventive abusing governmental bodies their rights in connection with list of medical devices to which can be applied such reduced rates. All that will contribute to the general conception of balance between standard of living and health for people of different social groups without any discrimination [11, p. 565].

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