



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL  
TAXATION AND CUSTOMS UNION  
Indirect Taxation and Tax administration  
**Value added tax**

**taxud.c.1(2016)680818 – EN**

Brussels, 28 January 2016

**VALUE ADDED TAX COMMITTEE**  
**(ARTICLE 398 OF DIRECTIVE 2006/112/EC)**  
**WORKING PAPER NO 891**

**QUESTION**  
**CONCERNING THE APPLICATION OF EU VAT PROVISIONS**

**ORIGIN:** Poland

**REFERENCE:** Article 132(1)(b)

**SUBJECT:** VAT treatment of services provided under bone marrow transplantation procedure

## **1. INTRODUCTION**

Poland has submitted four questions (annexed) concerning the VAT treatment of services provided under the bone marrow transplantation procedure in Poland. The transplantation procedure is described in detail in the annexes but a short description of the relevant parts will also be given in connection with the analysis of every separate question. In addition, a diagram of the procedure, based on the information provided by Poland, is featured before the Commission services' analysis (see section 3.3).

## **2. SUBJECT MATTER**

Poland seeks to establish the scope of the exemption for medical services in Article 132(1)(b) of the VAT Directive<sup>1</sup>, which reads as follows:

*"Article 132*

*1. Member States shall exempt the following transactions:*

*[...]*

*(b) hospital and medical care and closely related activities undertaken by bodies governed by public law or, under social conditions comparable with those applicable to bodies governed by public law, by hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature;*

*[...]"*

Other provisions that should be considered are the following:

*"Article 133*

*Member States may make the granting to bodies other than those governed by public law of each exemption provided for in points (b), (g), (h), (i), (l), (m) and (n) of Article 132(1) subject in each individual case to one or more of the following conditions:*

*(a) the bodies in question must not systematically aim to make a profit, and any surpluses nevertheless arising must not be distributed, but must be assigned to the continuance or improvement of the services supplied;*

*(b) those bodies must be managed and administered on an essentially voluntary basis by persons who have no direct or indirect interest, either themselves or through intermediaries, in the results of the activities concerned;*

---

<sup>1</sup> Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1).

*(c) those bodies must charge prices which are approved by the public authorities or which do not exceed such approved prices or, in respect of those services not subject to approval, prices lower than those charged for similar services by commercial enterprises subject to VAT;*

*(d) the exemptions must not be likely to cause distortion of competition to the disadvantage of commercial enterprises subject to VAT.*

[...]"

"Article 134

*The supply of goods or services shall not be granted exemption, as provided for in points (b), (g), (h), (i), (l), (m) and (n) of Article 132(1), in the following cases:*

- (a) where the supply is not essential to the transactions exempted;*
- (b) where the basic purpose of the supply is to obtain additional income for the body in question through transactions which are in direct competition with those of commercial enterprises subject to VAT."*

### **3. THE COMMISSION SERVICES' OPINION**

#### **3.1. The interpretation of exemptions in the VAT Directive in general**

According to case-law from the Court of Justice of the European Union (CJEU) the exemptions in Article 132 of the VAT Directive are independent concepts of EU law whose purpose is to avoid divergences in the application of the VAT system from one Member State to another<sup>2</sup>. The CJEU has consistently held that the exemptions are to be interpreted strictly since they constitute exceptions to the general principle that VAT is to be levied on all services supplied for consideration by a taxable person<sup>3</sup>. Nevertheless, the interpretation must be consistent with the objectives pursued by those exemptions and comply with the requirements of the principle of fiscal neutrality inherent in the common system of VAT. Thus, the requirement of strict interpretation does not mean that the exemptions should be construed in such a way as to deprive the exemptions of their intended effect<sup>4</sup>.

#### **3.2. The exemption as provided for in Article 132(1)(b) of the VAT Directive**

##### *3.2.1. The objective of that exemption and the scope of "hospital and medical care"*

The objective of the exemption in Article 132(1)(b) is to reduce the cost of medical care and to make that care more accessible to individuals<sup>5</sup>. The concept of "hospital and medical care" covers services that are intended to diagnose, treat or cure diseases or health disorders or to protect, maintain or restore human health<sup>6</sup>. The therapeutic purpose of the

---

<sup>2</sup> See, *inter alia*, case C-349/96, *CPP*, paragraph 15.

<sup>3</sup> See, *inter alia*, case C-2/95, *SDC*, paragraph 20, and case C-141/00, *Kügler*, paragraph 28.

<sup>4</sup> See, *inter alia*, case C-86/09, *Future Health Technologies*, paragraph 30.

<sup>5</sup> Case C-45/01, *Dornier*, paragraph 43, and *Kügler*, paragraph 29.

<sup>6</sup> Case C-91/12, *PFC*, paragraph 28, and case C-106/05, *L.u.P.*, paragraph 27.

medical care should not necessarily be interpreted narrowly. The CJEU has in that regard held that it is consistent with the aim of reducing healthcare costs to include examinations or preventive medical treatment even when it is clear that the person concerned is not suffering from any disease or health disorder<sup>7</sup>.

3.2.2. *The scope of "closely related activities"*

The CJEU has on several occasions discussed the scope of "closely related activities" in relation to the exemption for hospital and medical care. As a rule, services fall within the concept only when they are actually supplied as a service ancillary to the hospital or medical care received by the patients in question and constituting the principal service<sup>8</sup>.

In *Commission v France*<sup>9</sup>, the CJEU reached the conclusion that closely related activities included the transfer of a blood sample, by the laboratory that took it, to another laboratory for the purpose of analysis<sup>10</sup>. It stated that:

*"...where a duly authorised health-care worker orders, for the purpose of making his diagnosis and with a therapeutic aim, that his patient should undergo an analysis, the transmission of the sample, which logically takes place between the taking of the sample and the analysis itself, must be regarded as closely related to the analysis and must therefore be exempt from VAT..."*<sup>11</sup>

In *Ygeia*<sup>12</sup>, the CJEU reached the conclusion that the supply of telephone services and the hiring out of televisions to in-patients and the supply of beds and meals to people accompanying in-patients do not amount, as a general rule, to activities closely related to hospital and medical care. It could be otherwise only if those supplies would be essential to achieve the therapeutic objectives sought by the hospital and medical care and their basic purpose is not to obtain additional income for the supplier by carrying out transactions which are in direct competition with those of commercial enterprises liable for VAT<sup>13</sup>. The CJEU stated that:

*"...only the supply of services which are logically part of the provision of hospital and medical-care services, and which constitute an indispensable stage in the process of the supply of those services to achieve their therapeutic objectives, is capable of amounting to 'closely related activities' within the meaning of that provision. Only such services are of a nature to influence the cost of health care which is made accessible to individuals by the exemption in question."*<sup>14</sup>

In *CopyGene*<sup>15</sup>, a privately owned bio-bank offered the collection, transportation, analysis and storage of cord blood of new-born children with a view to using the cord stem cells contained in it to treat the child in the event of serious disease<sup>16</sup>. The CJEU stated that the

---

<sup>7</sup> Case C-212/01, *Unterpertinger*, paragraph 40.

<sup>8</sup> *Dornier*, paragraph 35, and joined cases C-394/04 and C-395/04, *Ygeia*, paragraph 18.

<sup>9</sup> CJEU, judgment of 11 January 2001 in case C-76/99, *Commission v France*.

<sup>10</sup> *Commission v France*, paragraph 30.

<sup>11</sup> *Commission v France*, paragraph 24.

<sup>12</sup> CJEU, judgment of 1 December 2005 in joined cases C-394/04 and C-395/04, *Ygeia*.

<sup>13</sup> *Ygeia*, paragraph 35, cf Article 134 of the VAT Directive.

<sup>14</sup> *Ygeia*, paragraph 25. See also case C-334/14, *De Fruytier*, paragraph 29, where this is referenced.

<sup>15</sup> CJEU, judgment of 10 June 2010 in case C-262/08, *CopyGene*.

<sup>16</sup> Case C-262/08, *CopyGene*, paragraph 16.

concept of closely related activities did not cover activities such as the collection, transportation and analysis of umbilical cord blood and the storage of stem cells contained in it, where the medical care to which those activities were merely potentially related had not been performed, commenced or yet envisaged<sup>17</sup>. It made the following analysis:

*"...in the case of the majority of the recipients of the activities at issue... there is not and probably never will be a principal service coming within the concept of 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive. Thus, the first question is based on the premise that, when services such as those at issue in the main proceedings are supplied, there is usually no hospital or medical care which has been performed, commenced, necessitated or determined, or even envisaged in its major aspects.*

*Indeed, it is only in the double eventuality that, first, the state of medical science enables or requires the use of cord stem cells for the treatment or prevention of a given illness and, second, that illness presents or is likely to present in a specific case that a sufficiently close link would exist between, on the one hand, the hospital and medical care which would constitute the principal service and, on the other hand, the activities at issue in the main proceedings.*

*In those circumstances, even accepting that the activities at issue in the main proceedings could have no purpose other than that of using the cord stem cells thus preserved in connection with medical care provided in a hospital environment and could not be diverted to other uses, those activities cannot be regarded as actually being supplied as services ancillary to the hospital or medical care received by the patients in question and constituting the principal service.*

*Therefore, those activities do not fall within the concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive. Indeed, since the hospital and medical care have not been performed, commenced or yet envisaged, activities such as those at issue in the main proceedings are merely liable, if certain eventualities come to pass, to be closely related to medical care provided in a hospital environment."<sup>18</sup>*

The CJEU reached the same conclusion in *Future Health Technologies*<sup>19</sup>, where the supplies of services at issue were similar to those in *CopyGene*. It found that closely related activities do not cover activities consisting in the dispatch of a kit for collecting blood from the umbilical cord of new-born children and in the testing and processing of that blood and, where appropriate, in the storage of stem cells contained in it for possible future therapeutic use to which those activities were merely potentially related and which had not been performed, commenced or yet envisaged<sup>20</sup>.

### *3.2.3. The bodies undertaking the care or the closely related activities*

In accordance with the wording of Article 132(1)(b), hospital or medical care and the closely related activities must be "undertaken by" one of the bodies listed in the provision,

---

<sup>17</sup> *CopyGene*, paragraph 52.

<sup>18</sup> *CopyGene*, paragraphs 47-50.

<sup>19</sup> CJEU, judgment of 10 June 2010 in case C-86/09, *Future Health Technologies*.

<sup>20</sup> *Future Health Technologies*, paragraph 52.

i.e. “bodies governed by public law, hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature”.

The CJEU has recently, in *De Fruytier*<sup>21</sup>, made clear that closely related activities to medical care have to be carried out by one of the bodies listed in the provision to qualify for the VAT exemption, as the wording already suggests<sup>22</sup>. Ms De Fruytier was engaged, in a self-employed capacity, in transporting human organs and samples of human origin for various hospitals and laboratories, under the authority and responsibility of a medical doctor<sup>23</sup>. The CJEU found that a transporting company such as hers could not be classified as any of the bodies listed in the provision<sup>24</sup>. Unlike a laboratory governed by private law and undertaking diagnostic medical tests with a therapeutic purpose, a self-employed transporter is not an individualised entity performing the same type of particular function as hospitals or centres for medical treatment or diagnosis and can therefore not be characterised as "an establishment of a similar nature" to the other bodies listed in the provision<sup>25</sup>.

A question that arises in this context is whether the closely related activity needs to be performed by the *same* body as the one carrying out the hospital or medical care. The case-law of the CJEU would seem to suggest that that is not a requirement. It is true that in early case-law where the concept of ancillary supplies was first dealt with, the main activity and the ancillary supply were both provided by the same entity, even though this fact in itself was not specifically discussed<sup>26</sup>. However, as regards case-law on the exemption for medical care, in *Commission v France*, the closely related activity (the transport of the blood sample) was performed by another body than the one performing the primary activity (the analysis of the blood sample), but this did not change the conclusion of the CJEU that both were exempt<sup>27</sup>. Moreover, in *De Fruytier*, the CJEU spends a number of paragraphs discussing whether Ms De Fruytier's company is one of the bodies listed in Article 132(1)(b)<sup>28</sup> – an analysis that would have been redundant had the requirement instead been that the closely related activity must be performed by the same body as the one performing the hospital or medical care. On the other hand, it must also be mentioned that in the recent judgment *Mapfre*<sup>29</sup> regarding insurance transactions, the CJEU gave relevance to the fact that the main insurance supply and the alleged ancillary supply were made by different providers.

#### 3.2.4. *The recipient of the care and the closely related activities*

In most CJEU case-law regarding ancillary supplies, the premise has been that the recipient that receives/purchases the main supply and the ancillary supply is the same. For example, in *CPP*, the question was whether the taxable person was supplying the same customer with several services or with a single service<sup>30</sup>. In *Dornier*, regarding the

---

<sup>21</sup> CJEU, judgment of 2 July 2015 in case C-334/14, *De Fruytier*.

<sup>22</sup> See *De Fruytier*, paragraph 27.

<sup>23</sup> *De Fruytier*, paragraph 7.

<sup>24</sup> *De Fruytier*, paragraphs 32-36.

<sup>25</sup> *De Fruytier*, paragraph 36.

<sup>26</sup> See *CPP*, paragraphs 29-32.

<sup>27</sup> See *Commission v France*, paragraphs 28-30.

<sup>28</sup> *De Fruytier*, paragraphs 27-36.

<sup>29</sup> CJEU, judgment of 16 July 2015 in case C-584/13, *Mapfre*, paragraphs 56-57.

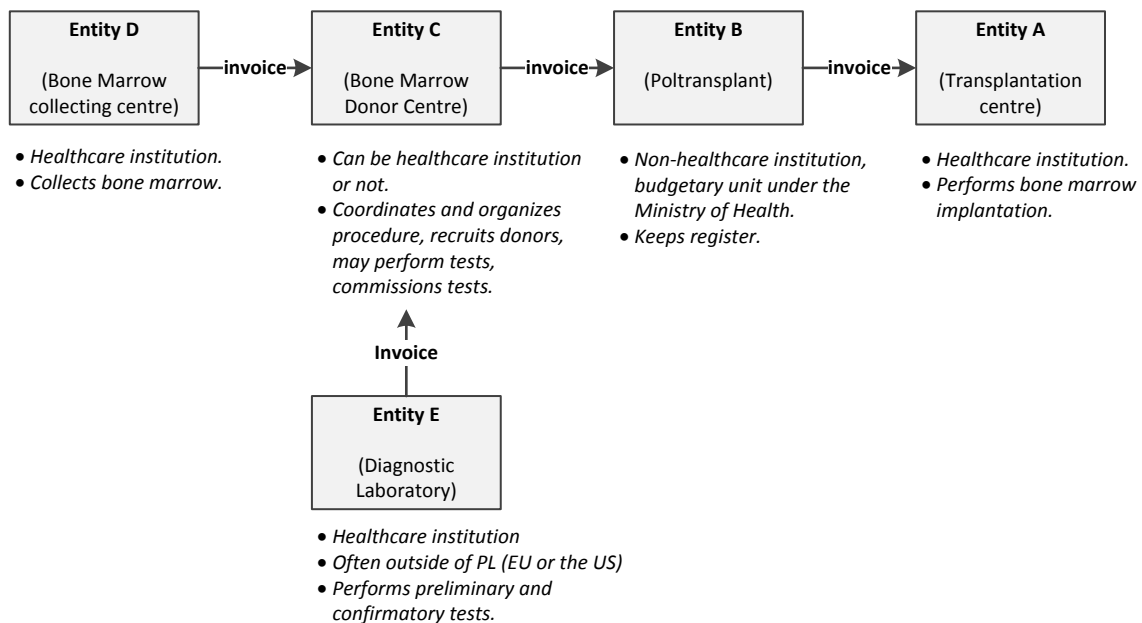
<sup>30</sup> *CPP*, paragraph 29.

exemption for medical care, the premise was that the patients were the direct recipients of both the main and the ancillary supply<sup>31</sup>.

However, it is important to note *Horizon College*<sup>32</sup>, concerning the exemption for education (now Article 132(1)(i) of the VAT Directive). The CJEU found that the making available, for consideration, of a teacher to an educational establishment in which that teacher temporarily carried out teaching duties under the responsibility of that establishment, may constitute a transaction that is exempt from VAT on the basis of it being a supply of services closely related to education, if such a teacher placement is a means of better enjoying the education deemed to be the principal service, and the supply fulfils the requirements in Article 134 of the VAT Directive<sup>33</sup>. The CJEU specifically pointed out that it did not matter that there was no direct relationship between the establishment making teachers available and the students of the host establishment<sup>34</sup>.

### 3.3. Analysis of the questions submitted by Poland

The questions submitted may be specific to the transplantation procedure as it is carried out in Poland but they raise issues of wider interest. A diagram of the transplantation procedure, based on the information provided by Poland and used for the purposes of the more detailed analysis, is featured below:




---

<sup>31</sup> See *Dornier*, paragraphs 33-35.

<sup>32</sup> CJEU, judgment of 14 June 2007 in case C-434/05, *Horizon College*.

<sup>33</sup> *Horizon College*, paragraph 46.

<sup>34</sup> *Horizon College*, paragraphs 31-32.

3.3.1. *Should individual services within the transplantation procedure, i.e. testing services, be treated as "closely related activities"?*

According to the information provided by Poland, testing services are performed on at least three separate occasions within the transplantation procedure. First, preliminary tests to determine histocompatibility<sup>35</sup> are performed when a potential donor has been recruited and before the donor is placed in the register. Second, additional testing is performed to confirm histocompatibility if a compatible donor to a specific patient has been found in the register. Finally, a blood test is done to ultimately test the compatibility between the donor and the patient and to perform virological tests. The described tests are performed by either Entity E, a diagnostic laboratory (sometimes in another Member State or in the United States), or by Entity C, a bone marrow donor centre (in Poland), in case it has its own laboratory.

The opinion of the Ministry of Finance of Poland is that all testing services should be considered closely related activities to the transplantation services because they are an indispensable, inherent element of the transplantation procedure, within which none of the stages may be practically performed separately from the others. Reference is made by Poland to *VTSI*<sup>36</sup>, where the CJEU found that the extraction of cartilage cells and the subsequent multiplication of the cells for re-implantation for a therapeutic purpose fell within the concept of "provision of medical care" in Article 132(1)(c) of the VAT Directive<sup>37</sup>. Reference is also made by Poland to *De Fruytier* and *Ygeia* where it is stated that the closely related activity must be an "indispensable stage" in the process of the supply of the medical care services<sup>38</sup>.

3.3.1.1. Qualification of the testing services in themselves

First, it is the view of the Commission services that the testing services carried out as part of the transplantation procedure do not constitute "hospital and medical care" as such, as provided for in Article 132(1)(b), because they do not in themselves have as their direct purpose the diagnosis, treatment or cure of diseases or health disorders, or the protection, maintenance or restoration of health. This has not been suggested by Poland either. The question is thus whether these testing services constitute activities that are closely related to medical care (i.e. the actual transplantation of the bone marrow). As a first step, the Commission services will analyse only the services as such, without taking into account the entity that is carrying them out.

As described in *CopyGene* and *Future Health Technologies*, activities that are only potentially related to medical care having not been performed, commenced or even envisaged cannot be considered closely related activities to that care. Thus, any testing that is done in the Polish transplantation procedure and that does not relate to a specific individualised transplantation of bone marrow should in the Commission services' view

---

<sup>35</sup> Histocompatibility, or tissue compatibility, is the property of having the same, or mostly the same, alleles of a set of genes called human leukocyte antigens (HLA). Histocompatibility is thus a measure of how similar two people's HLA alleles or tissue types are.

<sup>36</sup> CJEU, judgment of 18 November 2010 in case C-156/09, *Verigen Transplantation Service International (VTSI)*.

<sup>37</sup> *VTSI*, paragraph 27.

<sup>38</sup> *Ygeia*, paragraph 25, and *De Fruytier*, paragraph 29.



not qualify for a VAT exemption. In *VTSI*, referenced by Poland, cartilage cells were extracted from a patient with the specific purpose of being treated and then re-implanted in the same patient. The CJEU considered that the whole procedure had a therapeutic objective<sup>39</sup>. The case is therefore not really comparable to the one at hand, where the link between most of the testing activities (all the preliminary tests) and any medical care is only a distant possibility.

However, the assessment is different for the confirmatory testing that is done at the later stage, to confirm that a specific donor is a match with a specific patient to whom a transplant procedure will surely be done. For that testing, the Commission services consider that there is a clear link between the testing activity and a concrete medical treatment. Indeed, the final compatibility testing (including the blood test) could be considered an indispensable stage in the process of transplanting bone marrow. Nevertheless, in order to avoid a non-justified extension of the exemption and in line with the principle of strict interpretation, it should be emphasised that the testing services must be related to an individual transplantation procedure.

#### 3.3.1.2. Qualification of the entities providing the testing services

As regards the entities performing the testing services (Entity E and sometimes Entity C), the information from Poland provides that they are in fact bodies meeting the requirements laid down in Article 132(1)(b) of the VAT Directive. This is indeed a pre-requisite for any of the testing services to be considered closely related to the medical care provided by Entity A. In line with the case-law discussed in section 3.2.3 it is however not necessarily a requirement that the closely related activities are performed by Entity A. Finally, it does not affect the Commission services' assessment that Entity E is established in another Member State, or even in the United States. The supplies would in any event have to be assessed in accordance with the rules of the country in which the supply is deemed to take place, in this case Poland given that the recipient is another taxable person established there (cf. Article 44 of the VAT Directive<sup>40</sup>).

To sum up, the Commission services consider that in the scenario described by Poland the final testing services to confirm compatibility that are linked to an individualised and specific transplantation, can be considered closely related activities pursuant to Article 132(1)(b) of the VAT Directive, provided that the services are supplied by a body meeting the criteria in that provision, but not necessarily the same body as the one supplying the medical care. However, the final VAT qualification of these services will also be affected by the way the transplantation procedure is organised, which will be analysed in the next two sections, sections 3.3.2 and 3.3.3.

---

<sup>39</sup> *VTSI*, paragraphs 25-27.

<sup>40</sup> Article 44 of the VAT Directive: "*The place of supply of services to a taxable person acting as such shall be the place where that person has established his business. However, if those services are provided to a fixed establishment of the taxable person located in a place other than the place where he has established his business, the place of supply of those services shall be the place where that fixed establishment is located. In the absence of such place of establishment or fixed establishment, the place of supply of services shall be the place where the taxable person who receives such services has his permanent address or usually resides.*"

3.3.2. *Would the aforementioned services be exempt from VAT even when they are invoiced by an intermediary not classified as a health care institution, which then passes on the cost of purchased services to another entity that is also an intermediary not classified as a healthcare institution?*

According to the information provided by Poland, the testing services, while being performed by bodies meeting the criteria set out in Article 132(1)(b) of the VAT Directive (Entity E or C), are not purchased directly by the patient or even by the transplantation centre (Entity A), but rather by an intermediary (Entity B, or Entity C, if testing performed by Entity E) who coordinates the process and then re-invoices costs to the next intermediary in the chain (Entity B), who in turn re-invoices to the transplantation centre (Entity A).

The opinion of the Ministry of Finance of Poland is that closely related activities can be exempt from VAT even when they are re-invoiced by intermediaries who are not classified as any of the bodies listed in Article 132(1)(b). Poland makes reference to the principle of fiscal neutrality, the objective pursued by the exemption, and to Article 28 of the VAT Directive<sup>41</sup>.

First, against Poland's opinion it could be argued that activities closely related to medical care should have the same direct recipient as the medical care itself. In this case, the principal supply of medical care is provided in the relationship between Entity A and the patient, but the testing services of Entity E or C are being invoiced to the next entity in the chain (and then onwards) and not directly to the patient. However, it is not certain to what extent this would be an obstacle given the approach of the CJEU in *Horizon College*, where there was no direct relationship between the recipient of the services and the provider either. Furthermore, it is true that for the patient it does not matter whether the closely related activity is invoiced to someone else before the cost reaches him. On the other hand, exemptions are generally to be interpreted strictly and it is not clear to which extent the rationale in *Horizon College* regarding the exemption for education can be applied to the exemption for medical services.

In addition to this uncertainty, the contractual relationships between the different entities in the chain will be decisive for the assessment, and on this point we do not have any information<sup>42</sup>. The Commission services assume however for the purpose of the analysis that in the relationships between Entities A and B, and B and C, both B and C are required to provide testing services, i.e. that this is an obligation of their contracts. Assuming that this is the case, the entity actually performing the testing services can be seen as a sub-contractor to the entity that is required to supply the testing services, and this would then be the meaning of "re-invoicing".

The Commission services consider that if an entity is required by contract to provide testing services, and these services in themselves qualify as closely related activities (see

---

<sup>41</sup> Article 28 of the VAT Directive: "*Where a taxable person acting in his own name but on behalf of another person takes part in a supply of services he shall be deemed to have received and supplied those services himself.*"

<sup>42</sup> It is not entirely clear what is meant by "re-invoicing" and what the contractual obligations of every entity in the chain are.

analysis in section 3.3.1) and the entity is a body meeting the requirements in Article 132(1)(b) of the VAT Directive, the services can be exempt from VAT even if they are performed by a sub-contractor as a way for the supplier to fulfil the requirements of the contract. However, the Commission services do not agree with Poland that such services can be VAT exempt even when the entity that is obliged to provide them according to the contract is not a body listed in Article 132(1)(b) of the VAT Directive<sup>43</sup>. The principle of fiscal neutrality cannot extend the scope of an exemption in the absence of clear wording to that effect, given that it is a principle of interpretation to be applied concurrently with the principle of strict interpretation of exemptions<sup>44</sup>.

To sum up, it is not certain whether it is a requirement in case-law anymore that the closely related activities should have the same direct recipient as the medical care. Assuming that this is not required, and that Entities B and C are required by contract to provide testing services, the Commission services consider that such services can qualify as closely related activities if they are connected to an individual transplantation (see analysis in section 3.3.1), even if they are performed by a sub-contractor and then re-invoiced forward. However, this can only be the case when the entity under contractual obligation to provide testing services is a body meeting the requirements in Article 132(1)(b) of the VAT Directive, which excludes for example that the exemption applies in the supply made by C to B where the former is not a body meeting the aforementioned requirements.<sup>45</sup>

*3.3.3. Would such services be exempt if, as part of the remuneration, the intermediary adds additional costs associated with establishing and maintaining the infrastructure enabling the transplantation?*

According to the information provided by Poland, Entity C adds additional costs when it re-invoices the testing services to the next entity in the chain. These costs are associated with establishing and maintaining the infrastructure enabling the transplantation, and include administrative costs, the costs of gathering donors (due to the fact that in several hundred donors only one becomes an actual donor), the costs for contacts with donors, the costs of information meetings and the costs of donor hospitalisation and medication for the donor before bone marrow collection.

The opinion of the Ministry of Finance of Poland is that the testing services being re-sold are a component of a comprehensive service consisting in coordinating and organising the collection and provision of bone marrow. According to Poland, "although it has been purchased VAT exempt and is re-invoiced in the amount of the exact cost, it will be

---

<sup>43</sup> Or a body that the Member States has granted exemption to in accordance with Article 133 of the VAT Directive.

<sup>44</sup> Cf. *De Fruytier*, paragraph 37, and CJEU, judgment in case C-366/12, *Klinikum Dortmund*, paragraph 40.

<sup>45</sup> It might be of interest here to note that Poland has referred to Entity B as a "non-healthcare institution". However, for a body to fulfil the requirements in Article 132(1)(b) it needs to be a body governed by public law according to the objective criterion (which seems to be the case), that performs hospital or medical care or closely related activities according to the subjective criterion. It is thus not self-evident that Entity B would not be covered by Article 132(1)(b) even though it is a "non-healthcare institution".

subject to VAT, like other services sold by the intermediary with added additional costs". Reference is made to *BGZ Leasing*<sup>46</sup>.

Again, the contractual relationships will be decisive. It is not clear what the final product is that Entity C has to supply according to the contract but we assume again that it is testing services. If Entity C in the calculation of the consideration also includes general (administrative) costs that can be attributed to the particular tests, it is still a question of one supply and the whole price that Entity C is charging to Entity B could in the Commission services' view be exempt from VAT.

However, the description provided by Poland leaves the impression that Entity C is adding costs that have nothing to do with a specific transplantation but that are rather general costs that relate to all of the tasks that Entity C is performing. If it is then a question of Entity C owing another supply according to the contractual relationship, besides the testing services (i.e. general organisation and maintaining of the infrastructure for the transplantation procedure) then such a separate second supply would not be tax exempt.

3.3.4. *On what basis should the status of a provider of medical or closely related services to an entity established in the EU (taxable services bought from outside the EU in accordance with Article 44) be determined if the provider is established outside the EU?*

According to the information provided by Poland, Entity E is sometimes established outside of the EU, often in the United States and will be set up in the form of a limited liability company operating in the field of molecular biology. Poland is therefore asking whether such a body can be considered an institution "of a similar nature" and on what basis: the laws of the country of the recipient or that of the provider.

The opinion of the Ministry of Finance of Poland is that if an entity registered outside of the EU provides services that meet the subjective criterion in Article 132(1)(b) of the VAT Directive, and which in Poland are performed by entities having the status of a healthcare institution, it should be regarded as such an entity. Reference is in that respect made to *CopyGene*.

As mentioned in section 3.3.1, when a service is bought from the United States by a taxable person in the EU, the place of supply is where the taxable person has established his business (see Article 44 of the VAT Directive). Entity C in Poland buys testing services from Entity E in the United States and the place of supply will thus be Poland. The Commission services are of the opinion that the assessment of Entity E should be made with reference to the VAT Directive. Thus in a scenario as this one it needs to be established whether Entity E is a body as listed in Article 132(1)(b), or a body to which the Member State has extended the exemption according to Article 133, and whether it is performing medical care or closely related activities.

---

<sup>46</sup> CJEU, judgment of 17 January 2013 in case C-224/11, *BGZ Leasing*.

### **3.4. Conclusions**

- In general, "closely related activities" to medical care must be connected to a specific individualised medical care that has been performed or will surely be performed. They cannot merely be potentially related to medical care that has been neither performed nor commenced or envisaged.
- "Closely related activities" must, as is the case with hospital or medical care, be performed by one of the bodies listed in Article 132(1)(b) of the VAT Directive to be exempt, but it does not necessarily have to be the same body as the one performing the hospital or medical care.
- If an entity is required by contract to provide testing services and these services in themselves can qualify as closely related activities and the entity is a body meeting the requirements in Article 132(1)(b) of the VAT Directive, the services provided by that body can be exempt from VAT even if they materially are performed by a subcontractor. However, the service supplied by the subcontractor itself for the body in question will not be exempt if that subcontractor does not meet the conditions in Article 132(1)(b).
- If an entity is required by contract to provide one supply consisting of testing services, general costs referring to those testing services may be added in the calculation of the price and still the testing services will be VAT exempt. However, if an entity is required by contract to provide a second supply consisting of administrative services, that second supply will not be VAT exempt.
- The assessment of an entity providing "closely related activities" from outside the EU to a taxable person within the EU should be made with reference to the VAT Directive.

### **4. DELEGATIONS' OPINION**

The delegations are requested to give their opinion on this matter.

\*

\*   \*

**QUESTION FROM POLAND**

According to Article 398 of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1, with subsequent amendments), hereinafter “the Directive”, the Ministry of Finance of the Republic of Poland is kindly requesting to discuss the following issues with the VAT Committee (if possible within the 105<sup>th</sup> meeting):

In connection with the provisions of Article 132(1)(b) of the Directive doubts have arisen concerning the taxation of services provided under the bone marrow transplantation procedure which, in Poland, is as follows:

1. Centres for Bone Marrow Donors (hereinafter referred to as the "BMD"), classified under Polish regulations as medical care entities (meeting the subjective criterion stipulated in Article 132(1)(b) of the Directive) or foundations that are not classified as medical care entities under Polish regulations (not meeting the subjective criterion stipulated in Article 132(1)(b) of the Directive), recruit potential bone marrow donors for the purpose of combating leukaemia and other blood diseases. To this end, BMD commissions a third party (usually from other Member State or from the USA) to conduct preliminary typification tests in terms of HLA antigens (blood test or oral mucosa swabs) in individuals who reported their willingness to become potential donors. The data of the potential donor are entered to the Central Register of Unrelated Donors of Bone Marrow and Cord Blood maintained in Poland by Poltransplant (a budgetary unit, not classified as a medical care entity, reporting to the Minister of Health).
2. In case the transplant centre (Polish or foreign) finds for its patient an initially matching donor in the Central Register, it applies to the BMD, through Poltransplant, for conducting additional tests. The BMD performs (and in case it does not have its own diagnostic laboratory, it commissions the tests to other entity) additional tests (repeated typification confirming the donor/recipient match in terms of HLA) and issues an invoice to Poltransplant, whereas Poltransplant subsequently issues an invoice to the transplant centre.
3. If the compatibility exists, the transplant centre, through Poltransplant, asks for a donor's blood sample in order to finally test the recipient and donor match. The BMD performs the virological examination (in case it does not have its own diagnostic laboratory, it commissions the examination to other entity) and sends the blood sample with the results directly to the transplant centre (e.g. in other Member State). The invoice for the virological examination performed and the shipment is issued to Poltransplant which subsequently issues the invoice to the transplant centre.
4. If the transplant centre, after having examined the sample, confirms full compatibility, Poltransplant contacts the transplant centre with the BMD. The recovery centre performs the so-called medical clearance, i.e. examines the donor thoroughly in all respects and performs the recovery. 10 years ago only bone marrow was transplanted, currently, in the majority of cases (4/5) haematopoietic

progenitor cells are procured from peripheral blood. The recovery centre issues an invoice to the BMD for the recovery and the medical clearance.

5. The BMD issues an invoice to Poltransplant which subsequently issues an invoice to the transplant centre for the overall process (the major part of costs is settled at that moment). The invoice comprises not only the cost of bone marrow recovery but, first of all, the reimbursement of all costs associated with establishing and maintaining of the infrastructure enabling to perform such transplantation, i.e. the costs of collecting donors, contacts with donors. It is associated with the fact that among several hundred potential donors, only one turns out to be the real donor.

In this context, the following doubts have arisen:

1. should individual services within the comprehensive transplantation procedure, i.e. testing services, bone marrow recovery, as well as import of those services from outside the EU / from the EU territory, be treated as closely related to the transplantation service and, accordingly, exempt from VAT?
2. would the aforementioned services be exempt from VAT also when they charge entities not classified as medical care entities (intermediaries), subsequently transferring the cost to the consecutive entity (also an intermediary not classified as a medical care entity),
3. would such services be exempt if, within the remuneration the intermediary accrues additional costs associated with establishing and maintaining of the infrastructure enabling to perform such transplantation, i.e. administrative costs, costs of donor collection (due to the fact that among several hundred potential donors, only one turns out to be the real donor), contacts with donors, costs of information meetings concerning the surgery, costs of donor hospitalisation and medication for the donor necessary before bone marrow recovery.

The CJEU judgement in case C-262/08 CopyGene implies that “*the concept of activities ‘closely related’ to ‘hospital and medical care’ (...) is to be interpreted as meaning that it does not cover activities such as those at issue in the main proceedings consisting in the collection, transportation and analysis of cord blood and the storage of stem cells contained in it, where the medical care provided in a hospital environment to which those activities are merely potentially related has not been performed, commenced or yet envisaged.*”.

On the other hand, in the judgement in case C-156/09 VTSI concerning the removal and multiplication of cartilage cells for the purpose of re-implantation in the patient, the CJEU presented the position stating that “*the specific services provided by VTSI form, admittedly, only part of that overall process. However, as the Advocate General observed at point 23 of her Opinion, they are an essential, inherent and inseparable part of the process, none of the stages of which can usefully be performed in isolation from the others.*”.

*It follows from the foregoing that the extraction of joint cartilage cells from cartilage material taken from a human and the subsequent multiplication of the cells for re-implantation for a therapeutic purpose falls within the concept of ‘provision of medical*

*care' referred to in Article 13(A)(1)(c) of the Sixth Directive. Such an interpretation is also consistent with the objective of reducing the cost of health care referred to in that provision".*

Analogically, in the judgement in case C-334/14 the CJEU stated that taking into consideration the purpose of the exemption envisaged in Article 13(A)(1)(b) of the Sixth Directive, only the supply of services which are logically part of the provision of hospital and medical-care services, and which constitute an indispensable stage in the process of the supply of those services to achieve their therapeutic objectives, is capable of amounting to 'closely related [...] activities' within the meaning of that provision, given that only such services are of a nature to influence the cost of health care which is made accessible to individuals by the exemption in question (see: paragraph 29 of the aforementioned judgement).

The purpose of (preliminary) typification tests in terms of HLA antigens purchased by the BMD from an entity established in other Member State or outside the EU (USA) is to identify a potential donor (determining antigens of histocompatibility) and to enter the donor's data to the Central Register. Although the ultimate use of bone marrow, i.e. its transplantation, will not occur in each case (the probability of identifying a genetically matching donor ranges from 1:25.000 to 1:several million), undoubtedly, without such tests it is impossible to proceed to further stages of the transplantation procedure, i.e. determining the histocompatibility between the recipient and the potential donor (additional test, the so-called repeated typification), bone marrow recovery and transplantation and, as a consequence, treatment of a patient suffering from cancer.

According to the opinion of the Minister of Finance of the Republic of Poland, although at the moment of performing the aforementioned preliminary typification tests the potential donor may become a real donor only hypothetically, the medical care has not started yet (no specific recipient exists), nevertheless, the said service should be considered as closely related to the transplantation (which has unquestionably a therapeutic objective), since it constitutes an indispensable, inherent element of the transplantation procedure, within which none of the stages may be practically performed separately from others.

However, in this context, it should be noted that the service closely related (i.e. the typification test, whether the preliminary or the repeated) is not purchased directly by the entity providing the underlying (in the meaning of major) service (the transplant centre is the last entity in the transaction chain), but by the intermediary (BMD), coordinating the process of recovery and supply of bone marrow to the patient's hospital, and subsequently re-invoicing costs to the consecutive intermediary in the chain (Poltransplant). Thus, the entity providing the underlying (major) service (the transplant centre) purchases the closely related service indirectly (through their re-invoicing by intermediaries).

In this scope, the case law of CJEU does not provide the answer to the question whether the closely related service must be purchased directly by the entity supplying the underlying (basic) service (in the context of the case under analysis – the transplant centre), or it may be the entity – intermediary (in the context of the case under analysis – BMD) re-invoicing costs of services purchased to the entity providing the underlying (major) service, or the consecutive intermediary (in the context of the case under analysis – Poltransplant), subsequently invoicing to the entity providing the underlying (major) service.



Assuming that the closely related service may be purchased by an intermediary (as in the case under analysis), the next issue to be resolved is the status of the purchaser – intermediary, re-invoicing the "closely related" service (e.g. typification tests), i.e. whether it should be a medical care entity (meeting the subjective criterion stipulated in Article 132(1)(b) of the Directive).

In the judgement in case C-334/14 Nathalie De Fruytier, concerning the activity consisting in transporting human organs and samples of human origin for hospitals and laboratories, the Court of Justice recognised that "services closely related" may qualify for VAT exemption pursuant to Article 132(1)(b) of the Directive if they are carried out either by a body governed by public law or, under social conditions comparable to those applicable to bodies governed by public law, by hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature (see: paragraph 27 of the aforementioned judgement).

While transposing the above interpretation to the background of the case under analysis it should be stated that the service closely related (e.g. typification) is actually performed by a medical care entity whereas at the subsequent stages of the transaction chain, it is only re-invoiced. It arises from the specific nature of the bone marrow transplantation procedure.

In this context, it should be also reminded that the established case law of CJEU implies that the terms used for describing the exemptions specified in Article 13 of the Sixth Directive should be interpreted strictly, since they constitute exceptions to the general principle that VAT is to be levied on all goods and services supplied for consideration by a taxable person. The interpretation of those terms must be consistent with the objectives pursued by those exemptions and comply with the requirements of the principle of fiscal neutrality inherent in the common system of VAT. Thus, the principle of strict interpretation does not mean that the terms used to specify the exemptions referred to in Article 13 must be construed in such a way as to deprive the exemptions of their intended effects. In relation to the "medical care" term contained in Article 13(A)(1)(b) of the Sixth Directive and the "provision of medical care" term, within the meaning of Article 13(A)(1)(c) of this Directive, the Court of Justice ruled on many occasions that the above two terms refer to the provision of services aimed at diagnosing, treatment and, to the extent possible, curing diseases or health disorders.

The next significant issue is the method of defining the status of an entity providing medical services, or services closely related thereto (i.e. whether the entity meets the subjective criterion stipulated in Article 132(1)(b) of the Directive) for an entity established in the EU (import of services subject to taxation in accordance with Article 44 of the Directive) in case if the service provider is established outside the EU. In the context of the case under analysis the typification services are provided by a limited liability company established in the USA (certified by the American Society for Histocompatibility and Immunogenetics and the New York State Department of Health), conducting activities in the area of molecular biology, consisting in performing typification under laboratory conditions. A question arises whether such an entity may be recognised as an institution "of nature similar" to hospitals as well as medical and diagnostic centres?

In the judgement in case C-262/08 CopyGene, the CJEU ruled that " *since diagnostic medical tests, in the light of their therapeutic purpose, come within the concept of 'medical care' as referred to in Article 13A(1)(b) of the Sixth Directive, a laboratory governed by private law and undertaking analyses must be regarded as being an establishment 'of a similar nature' to 'hospitals' and 'centres for medical treatment or diagnosis' within the meaning of that provision (see L.u.P., paragraphs 18 and 35).*".

Therefore, considering the above rule it seems that if an entity established outside the EU provides services meeting the subjective criterion arising from Article 132(1)(b) of the Directive (i.e. the services are covered by the scope of the medical care term, or are closely related thereto), which are performed in Poland by entities with the status of a medical care entity, it should be classified as such an entity. However, such an approach may cause that foreign entities lose their overall interest in gaining the status of a medical care entity.

**QUESTION FROM POLAND (SUPPLEMENTING INFORMATION)**

With reference to the e-mail of 29 September 2015, with a request for supplementing a letter no PT1.9001.2.2015.KMA.479 of 21 August 2015, the Ministry of Finance provides additional information on the procedure of bone marrow transplantation along with the position in this case.

The bone marrow transplant procedure involves the following entities:

1. **A Transplanting Centre (subject “A”)** under the Polish legislation is a healthcare institution (which meets subjective criteria provided for by Article 132(1)(b) of the Directive of the Council no 2006/112/EC of 28 November 2006 on the common system of value added tax (EU Journal of Laws L 347 of 11.12.2006, p. 1, as amended)
  - performs bone marrow implantation
2. **Poltransplant (B)** – under the Polish legislation, a budgetary unit subordinate to the Minister of Health, a non-healthcare institution (fails to meet the subjective criterion of Article 132(1)(b) of the Directive)
  - keeps the Central Register of Unrelated Bone Marrow and Cord Blood Potential Donors (hereinafter referred to as “the Register”) in Poland
  - passes information on donors to the world register
3. **Bone Marrow Donor Centres (hereinafter referred to as “BMDC” or C)** under Polish law are:
  - a. healthcare institution (meeting the subjective criteria provided for by Article 132(1)(b) of the Directive ) or
  - b. foundations, not being healthcare institutions (failing to meet subjective criterion of Article 132(1)( b) of the Directive)

Coordinate the process of collecting and implanting bone marrow, organize particular stages of the procedure. Their tasks include:

- recruitment of potential bone marrow donors in order to fight leukemia and other blood disorders,
- organizing tests, commissioning an external entity (usually from another Member State or from the USA) to perform preliminary histocompatibility tests (a blood test or a swab of the oral mucosa) in people who have volunteered to become a potential donor, repeat tests of histocompatibility, virological tests and blood sampling.

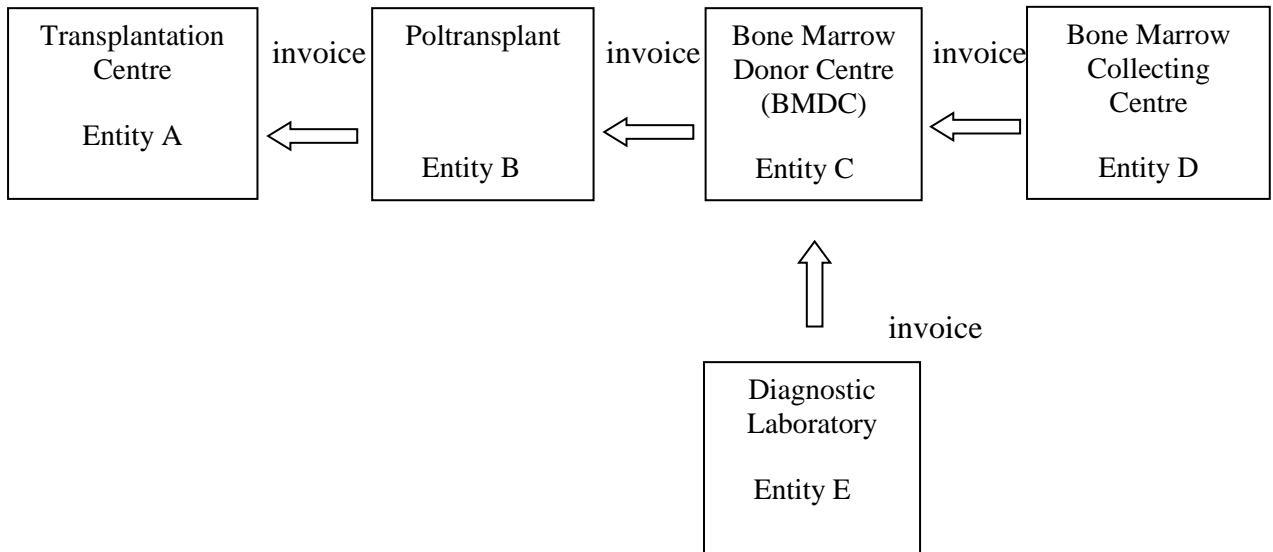
4. **Bone Marrow Collecting Centre (D)** – under the Polish legislation, a healthcare institution, based in Poland, meeting the criteria provided for by Article 132 (1)(b) of the Directive
  - Collects bone marrow
5. **Diagnostic Laboratory (E)** usually from another MS or the United States – no data whether it is an entity meeting the criteria provided for by Article 132(1)(b) of the Directive; if it is established in Poland, it is a healthcare institution which meets the abovementioned criterion:
  - performs preliminary histocompatibility tests (a blood test or a swab of the oral mucosa) in people who have volunteered to become a potential donor,
  - carries out repeated (confirmatory) histocompatibility tests.

**The course of the various stages of the bone marrow collection procedure:**

1. The BMDC (entity C) recruits a potential donor and commissions the laboratory (entity E) to perform a preliminary test – to determine histocompatibility antigens. E issues the invoice for a test to the entity C.
2. Potential donor's data are placed in the register kept in Poland by Poltransplant (entity B).
3. A Transplanting Centre (entity A) finds a compatible donor in the Polish register, contacts Poltransplant (entity B) and asks for verification and confirmation of this information.
4. The Transplanting Centre (entity A) asks for “extra selection” – performing confirmatory histocompatibility tests.
5. Poltransplant (entity B) transmits the request of the BMDC (entity C), which takes care of the potential donor.
6. The BMDC (entity C) commissions a laboratory (if it does not have its own laboratory) to perform additional laboratory tests (entity E); the laboratory issues an invoice to the entity C. The BMDC (entity C) issues an invoice (re-invoices the cost of tests) to Poltransplant (entity B), and, in turn, Poltransplant – to the Transplanting Centre (entity A).
7. In the event of histocompatibility between a recipient and a potential donor, the Transplanting Centre (entity A) asks for a sample of donor's blood to ultimately test the compatibility of the recipient and the donor. Contacts with Poltransplant (entity B), which commissions the BMDC (entity C) to collect blood and perform virological tests.
8. The BMDC (entity C) performs tests for viruses (if it does not have its own laboratory, it commissions an external entity) and sends blood sample results to the Transplanting Centre (entity A). The invoice for performing virological tests and

shipment is issued to Poltransplant (entity B), which issues the invoice to the Transplanting Centre (entity A).

9. If, having tested the sample, the Transplanting Centre (entity A) finds full histocompatibility, Poltransplant (entity B) puts the Transplanting Centre (entity A) in touch with the BMDC (entity C).
10. The BMDC (entity C) arranges the date of bone marrow collection with the Transplanting Centre (entity A).
11. A Collecting Centre (entity D) performs so-called medical clearance i.e. examines the donor carefully and comprehensively.
12. The Collecting Centre (subject D) collects marrow. Currently, in most cases (5/4) hematopoietic cells are collected from peripheral blood (donors get an agent which activates the peripheral blood hematopoietic cells). The procedure involves filtering donor's blood through a device that "returns" blood after extraction of the hematopoietic cells, which will be subject to the transplant.
13. The collected marrow is passed to the Transplanting Centre (entity A).
14. If the Transplanting Centre (entity A) is located out of Poland, the Collecting Centre (entity D) requests Poltransplant (entity B) for permission to export material from Poland (in the reverse situation, a consent to import the material to Poland for a Polish patient is also required).
15. The Collecting Centre (entity D) issues an invoice to the BMDC (entity C) for collection and clearance. It should be noted that one clinic usually hosts both transplantation centre and the tissue and cell bank, which does not only collect, but performs all operations on hematopoietic cells from bone marrow or peripheral blood. If the Collecting Centre (entity D) does not operate in a larger structure (hospital), where there also is a bank, this centre has to sign a contract with the bank to perform activities provided for by Article 25 of the Act of 1 July 2005 on the collection, storage and transplantation of cells, tissues and organs. The collected marrow requires cleansing, elimination of the inconsistency of different blood groups, etc. The bank also purifies and transforms autologous bone marrow – for auto-transplantation.
16. The BMDC reissues an invoice issued by the Collecting Centre (entity D) for collecting and clearance of BMDC (entity C) to Poltransplant (entity B), which, in turn, issues an invoice for the whole process to the Transplantation Centre (entity A). A lot of the costs associated with the transplantation procedure, unreconciled at previous stages are re-invoiced by the BMDC. Re-invoicing includes not only the cost of collecting, but primarily reimbursement of all costs incurred by the BMDC (entity C) associated with creation and maintenance of the infrastructure to make such a transplantation, i.e. the cost of gathering donors, contacts with donors. This is due to the fact that hundreds of potential donors one appears to be an actual donor.



Taken the actual state into consideration, there are the following concerns:

1. whether the individual services within the transplant procedure, i.e. the services of tests, as well as import of services from outside the EU/from the EU, should be considered as closely associated with the transplant service, and therefore exempt from VAT?
2. whether the abovementioned benefits will be exempt from VAT even if they are invoiced by an intermediary (BMDC – entity C) not being a healthcare institution, which then passes on the cost of purchased services to another entity (entity B) – also an intermediary not being a healthcare institution.
3. whether they will be exempt if, as part of the remuneration, the intermediary adds additional costs associated with creation and maintenance of the infrastructure to make such a transplantation, i.e. the administrative costs, the costs of gathering donors (due to the fact that in several hundred donors one becomes an actual donor), contacts with donors, the costs of treatment information meetings, costs of donor hospitalization and medication for a donor, which are necessary before bone marrow collection.
4. on what basis should the status of a provider of medical or closely related to medical services to an entity established in the EU (import of taxable services pursuant to Article 44 of the Directive) be determined (i.e. whether the entity meets the subjective criterion in the meaning of Article 132(1)(b) of Directive) if the provider is established outside the EU.

Ad. 1

The CJEU judgement in case C-262/08 CopyGene implies that “*the concept of activities ‘closely related’ to ‘hospital and medical care’ (...) is to be interpreted as meaning that it does not cover activities such as those at issue in the main proceedings consisting in the collection, transportation and analysis of cord blood and the storage of stem cells contained in it, where the medical care provided in a hospital environment to which those activities are merely potentially related has not been performed, commenced or yet envisaged.*”

On the other hand, in the judgement in case C-156/09 VTSI concerning the removal and multiplication of cartilage cells for the purpose of re-implantation in the patient, the CJEU presented the position stating that “*the specific services provided by VTSI form, admittedly, only part of that overall process. However, as the Advocate General observed at point 23 of her Opinion, they are an essential, inherent and inseparable part of the process, none of the stages of which can usefully be performed in isolation from the others.*”

*It follows from the foregoing that the extraction of joint cartilage cells from cartilage material taken from a human and the subsequent multiplication of the cells for re-implantation for a therapeutic purpose falls within the concept of ‘provision of medical care’ referred to in Article 13(A)(1)(c) of the Sixth Directive. Such an interpretation is also consistent with the objective of reducing the cost of health care referred to in that provision”.*

Analogically, in the judgement in case C-334/14 the CJEU stated that taking into consideration the purpose of the exemption envisaged in Article 13 part A paragraph 1(b) of the Sixth Directive, only the supply of services which are logically part of the provision of hospital and medical-care services, and which constitute an indispensable stage in the process of the supply of those services to achieve their therapeutic objectives, is capable of amounting to ‘closely related [...] activities’ within the meaning of that provision, given that only such services are of a nature to influence the cost of health care which is made accessible to individuals by the exemption in question (see: paragraph 29 of the aforementioned judgement).

The purpose of (preliminary) typification tests purchased by the ODS from an entity established in other Member State or outside the EU (USA) in terms of HLA antigens is to identify a potential donor (determining antigens of histocompatibility) and to enter the donor's data to the Central Register. Although the ultimate use of bone marrow, i.e. its transplantation, will not occur in each case (the probability of identifying a genetically matching donor ranges from 1:25.000 to 1:several million), undoubtedly, without such tests it is impossible to proceed to further stages of the transplantation procedure, i.e. determining the histocompatibility between the recipient and the potential donor (additional test, the so-called repeated typification), bone marrow recovery and transplantation and, as a consequence, treatment of a patient suffering from cancer.

According to the opinion of the Ministry of Finance of the Republic of Poland, although at the moment of performing the aforementioned preliminary typification tests the potential donor may become a real donor only hypothetically, the medical care has not started yet (no specific recipient exists), nevertheless, the said service should be considered as closely

related to the transplantation (which has unquestionably a therapeutic objective), since it constitutes an indispensable, inherent element of the transplantation procedure, within which none of the stages may be practically performed separately from others. As a result, these services (both preliminary tests and confirming histocompatibility), according to the opinion of the Ministry of Finance of the RP should be exempt from VAT pursuant to Article 132(1)(b) of the Directive.

Ad. 2

In this context it should be noted, however, that services closely related (i.e. the preliminary or repeat test) are not purchased directly by the entity providing the underlying (in the meaning of major) service (transplantation centre – entity A – is the last entity in the chain of transactions), but the intermediary (BMDC entity C), which coordinates the process of collecting and delivering bone marrow to the transplantation centre (entity A), and then re-invoices costs to the next intermediary in the chain (Poltransplant – entity B). Thus, the entity providing the underlying (major) service (transplantation service – entity A) indirectly acquires services closely related (through re-invoicing them through intermediaries – entities B and C). The question therefore arises whether these services re-issued by the intermediaries may also benefit from the exemption on the basis of the provision of the Directive.

In order to answer this question, reference should be made to the case law of the ECJ, which in its judgment in Case C-334/14 Nathalie De Fruytier, concerning the activity of transporting human organs and samples of human origin to hospitals and laboratories, decided that “activities closely related” may qualify for VAT exemption pursuant to Article 132 paragraph 1(b) of the Directive if they are carried out either by a body governed by public law or, under social conditions comparable to those applicable to bodies governed by public law, by hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature ( see: paragraph 27 of the aforementioned judgement).

Transferring these considerations to the ground of the case in question, it must be stated that the service closely related (e.g. the initial and repeat histocompatibility test) is actually performed by the healthcare institution (entity E – see question 4), while in the subsequent stages of the transaction chain it is only re-invoiced (this is due the particular nature of this procedure). This raises the question whether it is possible to apply the exemption to the services re-invoiced through an intermediary (entities C and B) a non-healthcare institution (i.e. not meeting the subjective criteria provided for by Article 132(1)(b) of the Directive. According to the consistent case-law of the ECJ, the terms used to describe the exemptions listed in Article 13 of the Sixth Directive must be interpreted strictly, since they constitute exceptions to the general principle that VAT is included in each delivery of goods and all services supplied for a payment by a taxable person.

Assuming only the wording of the provision, there is no possibility of an exemption in respect of the re-invoiced services closely related to medical services by the intermediary (entity B and C) not being a healthcare institution. On the other hand re-invoicing the services in question by the intermediary having a status of a healthcare institution (entity C) will be exempt from VAT.



Taking such an approach, however, implies that the same action (re-invoicing of medical/closely related to medical services services) depending on whether the intermediary has or has not the status of the healthcare institution will once be exempt and once taxed, which is contrary to the principle of fiscal neutrality and undermines the purpose of this exemption (i.e. reducing the cost of medical care), which is a principle pointed out by the Court in its case-law (especially since such an intermediary only buys and resells the service). The Court has repeatedly emphasized that the interpretation of the terms used to describe the exemptions must be consistent with the objectives pursued by those exemptions and must comply with the principle of fiscal neutrality inherent in the common system of VAT. This abovementioned principle of strict interpretation does not mean, therefore, that the terms used to describe the exemptions of Article 13 should be construed in such a way as to deprive the intended effect.

Thus, it appears that in relation to re-invoicing the analysed services Article 28 of the Directive could apply, according to which, where a taxable person acting in their own name but on behalf of another person takes part in a supply of services, it is assumed that the same taxpayer have received and supplied those services, with the result which would be a basis for the exemption of re-invoiced medical/closely related to medical services exempt from VAT provided by the intermediary (not having a status of a healthcare institution).

Ad. 3

While referring to the next question, namely adding expenses incurred by the intermediary (BMDC – entity C), including administrative costs related to obtaining a potential donor, the judgment in Case C 224/11 BGZ Leasing on re-invoicing services of insurance of the leased asset must be cited, in which the Court held that:

“66 *Therefore, the supplies of insurance for the leased item, in respect of which the owner remains the lessor, cannot, in circumstances such as those at issue in the main proceedings, be treated differently according to whether such services are supplied directly to the lessee by an insurance company or whether the latter obtains such insurance cover through the lessor which procures it from an insurer and re-invoices its cost to the lessee for the same amount.*

67 *Moreover, that interpretation is supported by the very purpose of the VAT Directive, which exempts insurance transactions but gives Member States, in Article 401 thereof, the possibility of maintaining or introducing a tax on insurance contracts. Consequently, if ‘insurance transactions’ refers solely to transactions performed by insurers themselves, the final consumer, such as a lessee in a leasing agreement, in circumstances such as those at issue in the main proceedings, might have to pay not only that tax but also VAT. Such a result would be contrary to the purpose of the exemption provided for by Article 135(1)(a) of the VAT Directive (see, to that effect, CPP, paragraph 23).*

68 *Finally it must be stated that that reasoning is based on the assumption that the lessor invoices the lessee for the exact amount of the insurance and that that reasoning cannot apply if the amount invoiced to the lessee for insurance costs is more than that invoiced to the lessor by the insurer.*

69 *It follows that it must be held that, in the context of leasing, a transaction consisting in re-invoicing the exact cost of insurance for the leased item, like that at issue in the main proceedings, constitutes an insurance transaction within the meaning of Article 135(1)(a) of the VAT Directive.”*

Transferring the abovementioned to the ground of analysed procedures of bone marrow transplantation, it seems that only the re-invoiced exact cost of purchased medical/ closely related to medical service could be exempt (assuming that re-invoicing is made by the healthcare institution), with the reservation that it is a separate service, unrelated to the others.

Doubt arises however when the intermediary – entity C (healthcare institution) re-invoicing purchased medical/closely related to medical services adds additional costs (i.e. the costs of obtaining potential bone marrow donors, coordination of the process). Should we in such a situation assume that we deal with two services, i.e.:

- VAT exempt service closely related to a medical service (re-invoiced in the amount of the accurate cost incurred by the intermediary (i.e. the cost of repeat tests confirming the histocompatibility of a particular donor, virological tests, blood sampling) and
- The service of coordination and organization of the process subject to VAT in the amount administrative costs incurred by the intermediary (due to the fact that in several hundred donors one becomes an actual donor, it would cover a fraction of the costs of preliminary test of “inactive” donors exempt from VAT incurred by the intermediary).

Or it should be assumed that the intermediary provides comprehensive service of coordination and organization of the process of bone marrow collection, which consists of all the costs incurred, both these re-invoiced (services of repeat, virological tests, purchased, in the opinion of the Ministry of Finance of the RP, VAT exempt) as well as its own administrative costs and the cost of gathering donors.

In the opinion of the Ministry of Finance of the RP, in view of the guidelines of the Court in this case, the re-sold service (confirmatory testing of histocompatibility, virological tests) is a component of the comprehensive service of coordination and organization of the collection and provision of bone marrow. So, although it has been purchased with VAT exempt and is re-invoiced in the amount of the exact cost, it will be subject to VAT, like other services sold by the service intermediary with added additional costs.

Ad. 4

Another important issue is how to determine the status of the provider of medical or closely related to the medical services (i.e. whether the entity meets the subjective criterion in the meaning of Article 132(1)(b) of the Directive) provided to an entity established in the EU (import of taxable services in accordance with Article 44 of the Directive) if the service provider is established outside the EU. On the basis of the analysed cases, typification services are provided by a limited liability company based in the USA (which has a certificate of the American Society of Histocompatibility and Immunogenetics and Health Department of the New York State), which operates in the field of molecular biology, consisting in laboratory typification. Can such a body be considered as institution “of a nature similar” to hospitals and healthcare or diagnosis

institutions for medical treatment and on what basis: the laws of the State of residence of the service recipient or provider?

In the judgement in case C-262/08 CopyGene, the CJEU ruled that *"since diagnostic medical tests, in the light of their therapeutic purpose, come within the concept of 'medical care' as referred to in Article 13A(1)(b) of the Sixth Directive, a laboratory governed by private law and undertaking analyses must be regarded as being an establishment 'of a similar nature' to 'hospitals' and 'centres for medical treatment or diagnosis' within the meaning of that provision (see L.u.P., paragraphs 18 and 35)."*

Taking the above principle into account, it seems that if an entity registered outside the EU provides services that meet the subject criterion of Article 132(1)(b) of the Directive (i.e. the services fall within the concept of medical care or are closely related to it), which in Poland are performed by entities having the status of a healthcare institution, it should be regarded as such an entity. Such an approach could, however, lead to the situation in which foreign companies will not be at all interested in obtaining a status of a healthcare institution.