Are your supplies of blood plasma VAT exempt?

Recent developments related to blood plasma supplies in the EU and a comparison to the Swiss VAT treatment

Does human blood plasma fall within the scope of the VAT exemption applicable to blood?

- ***In the European Union (EU)***

On 5 October 2016, the Court of Justice of the European Union (CJEU) issued its decision to a German case (C-412/12, TMD)[1] , in regards to whether the supply of blood plasma used for manufacturing of medicinal products should be VAT exempt or not.

With its decision CJEU, confirmed that although not explicitly listed in the EU VAT Directive's[2] article, which provides for the VAT exemption of supplies of blood and human organs[3], the supply of plasma derived from human blood **falls under the exemption, but only when the plasma is actually intended for direct therapeutic use.**

Additionally, CJEU ruled that where **the human blood plasma is intended to be used for the manufacture of medicinal products** (i.e. plasma intended for industrial use) **it should be subject to VAT**. In this latter case, the question remains **"Which VAT rate applies – the standard rate or the reduced rate?"** The answer to this question depends on the national VAT rules of the country where the blood plasma sale, intra-community acquisition or import takes place.

- ***In Switzerland***

Swiss VAT law provides for a VAT exemption of supplies of blood and human organs[4]; however, only the supplies of **whole blood** by persons possessing the required license are eligible to the VAT exemption.

Therefore, the supply of blood plasma, which is a component of human blood, but does not qualify as whole blood itself, is subject to Swiss VAT. Such an interpretation has been confirmed by the Federal Tax Authority (FTA) in their written guidelines.

The FTA has also confirmed that if the human blood plasma can qualify as "medication"[5], then the **reduced VAT rate of 2.5% applies**.

Contacts

Patricia More
Partner, Indirect Tax
PwC Geneva
patricia.more@ch.pwc.com
+41 58 792 95 07

Sandra Ragaz
Indirect Tax Leader for Pharma & Life Science in Switzerland
PwC Zurich
sandra.ragaz@ch.pwc.com
+41 58 792 44 69

Gergana Chalakova
Manager, Indirect Tax
PwC Geneva
gergana.chalakova@ch.pwc.com
+41 58 792 92 02

Implications your business should consider

As the CJEU's decision becomes directly applicable legislation in all EU member states, it is expected that the CJEU's decision would trigger changes to the current tax authorities' practices in some countries, particularly with respect to the VAT treatment of blood plasma for industrial use. This new EU legislation would mainly affect the specialized laboratories selling blood plasma, the pharmaceutical companies using plasma for the manufacture of medicinal products, as well as the intermediaries involved in the supply chain.

In view of the above, if you are involved in transactions with blood plasma (as either a supplier or a purchaser) it is recommended that you continue to monitor for local country developments triggered by the TMD case (C-412/12), and assess the impact of the CJEU's decision in the light of both the EU and local legislation applying to your current supply chain.

We have provided a list below of impacts/actions to consider, depending on your role in the plasma transaction:

- ***When you are the Supplier***

Future *What you should consider going forward*	**Past** *Considerations assessing past impact*
Check if there are any local country regulations that could prevent the tax authorities from limiting the scope of the VAT exemption to blood plasma for direct therapeutic use (i.e. assess if the local VAT legislation and jurisprudence and/or practice of the tax authorities can secure your VAT position)	
Review your current customers' portfolio and define if you are allowed to continue applying a VAT exemption or should start charging VAT with respect to your future sales	Review your past customers' portfolio and define if you were allowed to apply a VAT exemption or should consider adjusting/correcting your past position
Define which VAT rate you should apply to your sales of plasma for industrial use (i.e. standard or reduced) to avoid being challenged by the local tax authorities	Balance the opportunities versus risks when assessing your past VAT position and whether a regularization of it is required, taking into account the VAT recovery possibility of your customers, the time limit for claiming input VAT deduction, the periods opened for tax audit, etc.
Identify the ERP system set-up and map the accounting changes needed due to a different VAT treatment (e.g. review and amend customers and materials tax classification, tax codes, tax condition records, invoice templates, VAT compliance processes, etc.)	Investigate whether you are able to re-charge to your customers the VAT amount you may be required to charge with respect to the regularization of your VAT situation. Evaluate the amount of your potential exposure to additional tax liabilities, penalties and late payment interest.
Consider informing your customers if you will need to start charging VAT on your sales to them	Consider informing your customers if you decide to re-charge them the VAT due further to your VAT adjustment/correction procedure
Make sure you are not missing an opportunity: Assess the impact on your input VAT deduction right, considering that a requalification of your sales between exempt and taxable does not necessarily decrease but could also lead to an increase of your input VAT recovery right. Evaluate the amount of your additional VAT recovery right	

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- ***When you are the Customer***

Future	Past
Anticipate that you could be charged VAT in case you are involved in the transaction with blood plasma as customer and you purchase it for industrial use	Check your agreements to see if your suppliers are entitled or not to recharge you with the VAT due on supplies of blood plasma for industrial use (especially pay attention if the price has been agreed gross or net of VAT)
Check your agreements with suppliers of blood plasma to see if your price has been agreed gross or net of VAT to be able to foresee the impact on your costs	Investigate whether or not you are entitled to claim recovery of any such VAT recharged to you by your supplier (in particular take into account if the statutory period during which you are entitled to claim input VAT deduction expired and whether this period is closed for tax audit)
Make sure you are not missing an opportunity: Assess the impact on your input VAT recovery right. Consider that a requalification of your purchase between exempt and taxable does not necessarily negatively impact your VAT recovery right. It could also lead to an increase of your input VAT recovery right. Evaluate the amount of your additional VAT recovery right (if any)	

- ***When you are Importer or Intermediary***

If you are involved in the supply chain as an intermediary or importer, please note that the implications of the TMD case are not clear. Therefore, it is recommended that you start to analyze your situation as soon as possible in order to be able to anticipate and estimate the likely implications to your past and future VAT position.

If you would like to discuss the above in more detail and assess the implications for your business, please do not hesitate to contact us.

[1] C-412/15 (TMD Gesellschaft für transfusionsmedizinische Dienste mbH v Finanzamt Kassel II – Hofgeismar)
[2] Directive 2006/112/EC
[3] The VAT exemption on blood is laid down in Article 132(1)(d) of Directive 2006/112/EC.
[4] The VAT exemption on blood is laid down in Article 21(2)(5) of Swiss VAT Law of 12 June 2009.
[5] Definition of "Medication" is provided with Article 49 of the Ordinance to the Swiss VAT Law