EUROPEAN COMMISSION

Brussels, 15.10.2015
C(2014) 7286 final

In the published version of this decision, some information has been omitted, pursuant to articles 24 and 25 of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty, concerning non-disclosure of information covered by professional secrecy. The omissions are shown thus […].		PUBLIC VERSION This document is made available for information purposes only.

Subject: **State aid SA. 37624 – Slovakia**

Alleged illegal State Aid to Imuna Pharm

Sir,

1 PROCEDURE

(1) On 21 October 2013 the Commission received a complaint concerning alleged aid to Imuna Pharm ("IP"). A reply to the complainant[1] finding no state aid within the meaning of Article 107(1) TFEU in his allegations and inviting the possible submission of new facts was sent on 26 November 2013, to which he replied on 20 December 2013. The Commission forwarded his submission to Slovakia together with a request for information on 30 January 2014. Slovakia replied on 21 February 2014. A preliminary assessment letter confirming the finding that no state aid was apparent was sent to the complainant on 23 April

[1] The complainant did not want his identity to be revealed.

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2014. The complainant replied on 23 May 2014 disputing again the Commission's findings and calling to take position on its allegations. The Commission now considers it appropriate to adopt a decision.

2 ISSUES RAISED IN THE COMPLAINT

(2) The alleged beneficiary - IP is engaged in collecting human plasma in Slovakia and exporting it in 2011-2012. The export of human plasma was allowed on the basis of one-year export licence issued by the Slovak Ministry of Health. IP was the only company involved in the export of human plasma until September 2011 when another export licence was granted to Sanaplasma SK. In September 2012, however, the individual export licence was extended only for IP. Sanaplasma SK was not granted an extension of the export licence for another year, a decision which Sanaplasma SK appealed in Slovakia. In early 2013, the Ministry argued in the appellate proceedings that it could not grant a plasma export licence to Sanaplasma SK because Slovakia was facing a constant insufficiency of human plasma for therapeutic use. The complainant disputes this insufficiency argument with figures from 2007-2011 which show that the export of plasma for fractionation represented more than 44% of the blood collected in each of those years. As a result of the ministerial decision, Sanaplasma SK was forced to terminate its business operations in Slovakia.

(3) The complainant focuses its allegations on State aid on two issues. Firstly, the complainant alleges that the granting of the export license to IP resulted in a *de facto* exclusive right to the beneficiary, because IP was then the only operator with an export license for human plasma in Slovakia. This right was allegedly granted in a discriminatory and non-transparent manner and without ensuring that the beneficiary is only left with a minimum return necessary for an average company to cover its operational and capital costs, including a reasonable rate of profit. Thus, Slovakia has allegedly foregone resources by letting the beneficiary benefit from all possible profits, that is, by not curbing sales revenues.

(4) The complainant asks the Commission to review its allegations regarding the exclusive license grant in light of the existing Commission guidance – Communication from the Commission on the application of the European Union State aid rules to compensations granted for the provision of services of general economic interest, point 33 and applicable case law.[2] Also, the complainant asked the Commission to address its concerns regarding the effects of the objected measures.

(5) Secondly, the complainant alleges that IP, as a result of the exclusive position which it enjoys, buys human plasma from Slovak hospitals and transfusion centres at a price significantly below market value, and thus receives state aid

[2] Bouygues SA and Bouygues Télécom SA v Commission of the European Communities (Case T-475/04 [2007] ECR II-02097) paras 101, 104, 105 and 111 and Connect Austria gesellschaft fur Telekommunikation GmbH v Telekom-Control-Kommission, and Mobilkom Austria AG (case C-462/99 [2003] ECR I-05197) paras 92 and 93. See also Commission Decision C(2012) 6777 final in State aid case SA.33988 (2011/N) – Greece, para 28.

in the form of foregone profits that would have been made by the hospitals if the plasma was sold at a market price. These allegations are based on a press article submitted to the Commission.[3]

(6) The article states that the price paid by IP to National Transfusion Service and State or municipal hospitals is EUR 16-19 per litre of human plasma, which is below-cost. The complainant further indicated that the minimal costs incurred by the National Transfusion Service and hospitals before selling the human plasma to the beneficiary amount to at least EUR 30 per litre.

LEGAL FRAMEWORK FOR EXPORT LICENCES AND SELLING PRICES OF HUMAN PLASMA

(7) Act No 362/2011 on medicines and medical appliances sets out the conditions under which the Ministry of Health of the Slovak Republic grants licences to produce transfusion medicines. Under sections 70 (1) and (2) of this act, human plasma can only be exported on the basis of a licence issued by the ministry and eligibility to apply for a licence to export human plasma is restricted to holders of a permit for the comprehensive preparation of transfusion medicines or for the production of human medicines if they have a contract to provide human plasma with the holder of a licence for the comprehensive preparation of transfusion medicines. Under Section 70(3) of the act, a licence to export human plasma can be granted if the authorised applicant demonstrates that:

- he/she has complied with the provisions of Section 69(1) to (4) on the supervision of blood, blood components and transfusion medicines in the acquisition of the human plasma to be exported,
- provided the exported human plasma is surplus to requirements and cannot be used for therapeutic purposes in the provision of healthcare in the Slovak Republic, or further industrial processing in the Slovak Republic for the purposes of making medicines from blood and
- the exported human plasma is intended for industrial processing by a contracted foreign manufacturer of medicines from blood, provided the applicant holds a licence to manufacture human medicines from blood.

(8) Furthermore, Slovakia stated that under Act No 18/1996 on prices, as amended, and implementing Measure of the Ministry of Health No 07045/2003-OAP of 30 December 2003 establishing the scope of prices in healthcare, as amended, the fixed prices of transfusion medicines and the contractual prices of human plasma must be set in such a way that all economically justified costs are included, i.e. all costs of examining the donor, blood donation, blood examination, costs of processing the blood, preparation and storage of transfusion medicines and a reasonable profit.

[3] Article from magazine TREND, "Kto má v rukách krvnú plazmu" dated 06.08.2008 available at http://ekonomika.etrend.sk/ekonomika-slovensko/kto-ma-v-rukach-krvnu-plazmu.html.

3 ASSESSMENT OF EXISTENCE OF STATE AID

(9) By virtue of Article 107(1) of the TFEU, any aid granted by a Member State or through State resources in any form whatsoever, which distorts or threaten to distort competition by favouring certain undertakings or the production of certain goods, shall, in so far as it affects trade between the Member States, be incompatible with the internal market.

(10) The criteria laid down in Article 107(1) TFEU are cumulative. Therefore, in order to determine whether the notified measures constitute State aid within the meaning of Article 107(1) TFEU all of the following conditions must be fulfilled. Namely, the financial support should:

- be granted by the State or through State resources;
- confer an economic advantage on the recipient;
- favour certain undertakings or the production of certain goods;
- distort or threaten to distort competition; and
- affect trade between Member States.

3.1 Granting and/or extension of an existing export license

State resources

(11) The Slovak Republic in its submission clarified the conditions for granting an export license applicable in Slovakia and confirmed that this kind of license is not granted in exchange for any fee. The applicable legal framework in Slovakia, as described in recital (7) is based on objective eligibility criteria which do not include the payment of any fee, whether based on prospective profits or auctioned to the highest bidder among applicants for the licence(s). Moreover, the licence is not tradable on any market. The Slovak legal framework does therefore not confer an economic or financial value to the granting of the licence and this rule is consistently applied. Slovakia has never attached an economic value to the export license, which distinguishes this particular case from the cases cited by the complainant, none of which concerned licences for export of human plasma (see recital (4)).

(12) Therefore, within the currently applicable framework for granting export licenses for human plasma in Slovakia, which is the relevant framework for the assessment, these licenses are granted for free. The number of licences granted does not influence the amount of public resources available to Slovakia. Therefore, the Slovak Republic does not directly forego any State resources which it should otherwise receive when granting such a license.

(13) Thus, the sole act of granting and/or extending an exclusive licence does not constitute an act by which the State foregoes its resources.

(14) As regards the allegation of the complainant that this granting of the export license should be made in line with Communication from the Commission on the application of the European Union State aid rules to compensations granted for the provision of services of general economic interest, the

application of those rules presupposes that a compensation is granted in the first place and, furthermore that it amounts to State aid involving state resources. As stated above, licences for export of human plasma are granted for free at the outset, without any reduction or compensation of a fee set out in the applicable law. Furthermore, Slovakia has a wide discretion to declare the services provided by the alleged beneficiary as services of general economic interest. Slovakia has not done so until now and, therefore, the granting of an export license cannot be assimilated to an exclusive right for a provision of a service of general economic interest. It follows that the rules invoked by the complainant should not be applied in this case.

(15) In addition, in the case at hand, the export license is not an exclusive right for the beneficiary. Indeed, its license is valid for a year and the decision to be granted a license for another year is always reviewable. It is at the discretion of the Slovak authorities to grant as many export licenses as they wish to, in a given year, provided the conditions set out in the relevant national legislation (recital 7) are met.

(16) As stated above in recital (10), the criteria for determining state aid are cumulative. Since the transfer of State resources criterion is not fulfilled, i.e. the granting and/or extension of an existing export licence to IP, does not involve State resources, it is thus not necessary to examine whether the remaining criteria are fulfilled.

(17) In view of the above, the alleged granting and/or extension of an existing export licence does not involve state aid within the meaning of Article 107(1) TFEU.

3.2 Sale of human plasma below cost

Economic advantage

(18) The concept of State aid applies to any advantage granted directly or indirectly, financed out of State resources, granted by the State itself or by any intermediary body acting by virtue of powers conferred on it.[4] Therefore, in order to determine whether a state measure constitutes aid for the purposes of Article 107(1) TFEU, it is necessary to establish whether the recipient undertaking receives an economic advantage which it would not have obtained under normal conditions.[5]

(19) Slovakia alleges that the National Transfusion Service of the Slovak Republic uses its annual plasma production in the following way:

- one third is sold to hospitals in the country for hemotherapy. The price is fixed by the current price list current price list for transfusion medicines published by Measure No 07045/2003-OAP of the Ministry of Health of

[4] Judgement of the Court of 16 May 2002, Case C-482/*99 France v Commission ("Stardust Marine")* [2002] ECR I-4397.

[5] Case C-39/94, SFEI v La Poste, 1996 ECR I-3547, at para. 60.

the Slovak Republic of 30 December 2003, establishing the scope of price regulation in healthcare, as amended.

- while the other two thirds of annual production are sold to IP as surplus production for further processing to make medicines from human blood; this is done on the basis of a purchase contract dated 8.1.2004. The price per litre was EUR 73.03 up to 31.3.2010 and since 1.4.2010 has been EUR 80.

(20) Furthermore, Slovakia confirmed that under the applicable legal framework described in recital 8, the contractual prices of human plasma must be set in such a way that all economically justified costs and a reasonable profit are included. It follows that, contrary to what the complaint alleges, purchase prices for plasma intended for export do in principle remunerate the costs incurred by the sellers in the Slovak Republic.

(21) Furthermore, in that respect, the figures provided by Slovakia indicate that the prices paid by IP for human plasma purchased from the National Transfusion Service since April 2010 amount to, respectively, more than four times the price the complainant alleged and more than two times and half the amount that would cover the processing and supply costs allegedly incurred by the National Transfusion Service and State or municipal hospitals.

(22) Accordingly, whereas the complainant's allegation of purchase prices around EUR 16-19 per litre is not supported in fact, IP does not appear to derive any undue economic advantage when purchasing human plasma from the National Transfusion Service at prices which largely exceed their alleged costs of supply. The Commission was not provided with any additional indication, let alone evidence which would indicate that the information provided by Slovakia is untrue.

(23) In view of the above, it appears that the above mentioned transactions were carried out on market terms and thus did not involve any economic advantage to IP.

(24) As stated above in recital (10), the criteria for determining state aid are cumulative. Since the economic advantage criterion is not fulfilled, i.e. the transactions at hand do not constitute an economic advantage to IP, it is thus not necessary to examine whether the remaining criteria are fulfilled.

(25) In view of the above, the alleged sale of human plasma below cost did not involve state aid.

Conclusion

The Commission has accordingly decided that the measures complained of do not constitute aid within the meaning of Article 107(1) of the TFEU.

If this letter contains confidential information which should not be disclosed to third parties, please inform the Commission within fifteen working days of the date of receipt. If the Commission does not receive a reasoned request by that deadline, you

will be deemed to agree to the disclosure to third parties and to the publication of the full text of the letter in the authentic language on the Internet site: http://ec.europa.eu/competition/elojade/isef/index.cfm.

Your request should be sent by registered letter or fax to:

European Commission
Directorate-General for Competition
State Aid Greffe
B-1049 Brussels
Fax No: +32-2-296.12.42

Yours faithfully,

For the Commission

Joaquín Almunia
Vice-President of the Commission