Case C-717/19

Request for a preliminary ruling

Date lodged:

27 September 2019

Referring court:

Fővárosi Közigazgatási és Munkaügyi Bíróság (Budapest Administrative and Labour Court, Hungary)

Date of the decision to refer:

16 September 2019

Applicant:

Boehringer Ingelheim RCV GmbH & Co. KG Magyarországi Fióktelepe

Defendant:

Nemzeti Adó- és Vámhivatal Fellebbviteli Igazgatósága (Appeals Directorate of the National Tax and Customs Authority, Hungary)

[...]

In the administrative tax dispute proceedings brought by Boehringer Ingelheim RCV GmbH & Co. KG Magyarországi Fióktelepe ([...] Budapest, [...]), the applicant, against the Nemzeti Adó- és Vámhivatal Fellebbviteli Igazgatósága (Appeals Directorate of the National Tax and Customs Authority, Hungary) ([...] Budapest, [...]), the defendant, the Fővárosi Közigazgatási és Munkaügyi Bíróság (Budapest Administrative and Labour Court, Hungary) has issued the following

Decision

This court orders that proceedings be suspended and, simultaneously, that the following questions be referred to the Court of Justice of the European Union for a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union:

1) Should Article 90(1) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax be interpreted as precluding a

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provision of national law, such as that at issue in the main proceedings, under which a pharmaceutical company which, pursuant to an agreement it is not obliged to enter into, makes payments to the state health insurance agency based on the revenue obtained from pharmaceutical products and which, therefore, does not retain the full amount of the consideration for those products is not entitled subsequently to reduce the taxable amount, solely because the payment method is not set out in advance in its commercial policy and the payments are not principally for promotional purposes?

2) If the answer to the first question is in the affirmative, should Article 273 of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax be interpreted as precluding a provision of national law, such as that at issue in the main proceedings, under which, in order to be able subsequently to reduce the taxable amount, an invoice made out to the person entitled to the refund providing proof of the transaction giving entitlement to that refund is required, even though the transaction that enables the subsequent reduction in the taxable amount is duly documented and can subsequently be verified, is based in part on truthful, publicly available information, and enables the tax to be collected correctly?

[...] [procedural consideration of domestic law]

Grounds

I. Factual background

In accordance with Article 195 of the az adózás rendjéről szóló 2017. évi CL. törvény (Law CL of 2017 on General Taxation Procedures, 'the new Law on General Taxation Procedures'), on 13 November 2018 the applicant, a pharmaceutical company, submitted a supplementary return in respect of its VAT return for the September 2018 tax period to the defendant tax office. In this supplementary return, the applicant reduced the amount of VAT it was required to pay for the tax period in question by HUF 354 687 000, citing the payments made under the special civil law agreements (known as funding volume agreements; 'the agreements') concluded by the applicant and the Nemzeti Egészségbiztosítási Alapkezelő (National Health Insurance Fund, 'NEAK'), as the state health insurance agency.

The agreements were entered into in respect of the medicinal products marketed by the applicant, JARDIANCE, JENTADUETO, PRADAX, SPIRIVA, TRAJENTA, STRIVERDI RESPIMAT, SPIOLTO RESPIMAT, SYNJARDY and OFEV, for the period from 1 October 2013 to 31 December 2017. Under the agreements, the applicant undertook to make payments to NEAK to reflect sales of those medicinal products that had social security funding, by deducting part of the revenue obtained from the sale of the products. The amount of the payment obligations was expressed in the form of a percentage of the gross social security funding for each packaged unit (each box) sold with funding (calculation per box);

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under certain agreements, it was set at 100% where the funding provided by social security for certain products exceeded a maximum amount (calculation based on annual maximum amounts). The payment obligation was settled either each calendar month or annually (in a single payment).

For outpatient healthcare, NEAK funds the price of prescription medicinal products that receive social security funding through what is known as the 'price subsidy scheme'. Under this scheme, payment of the price of the funded product takes place within the framework of a multilateral legal relationship, with responsibility for payment being shared between the patient and NEAK. The patient pays the pharmacy what is termed the subsidised price for the product he receives, which is the difference between the price of the product and the funding provided by social security. The marketing authorisation holder (in this case, the applicant) determines the price of the medicinal products funded by NEAK, which decides on approval of the price under a social security funding acceptance procedure, following a complex examination that incorporates health policy, professional and cost-effectiveness considerations, after which it sets the appropriate amount of funding.

The applicant sells the medicinal products direct to the wholesaler, the wholesaler sells them to the pharmacy, and the pharmacy sells them to the patients; in the latter case the price is reduced by the amount of the social security funding. Lastly, NEAK reimburses the pharmacy the amount of the funding. The consideration received by the pharmacy, which constitutes the VAT base, has two parts: the first is the payment made by the patient (the price reduced by the amount of the funding, known as the subsidised price), and the second is the payment from NEAK (the funding). The pharmacy has to pay the appropriate VAT on both amounts.

As far as the applicant is concerned, there is no legal requirement to enter into the agreements, but by doing so it ensures that the medicinal products it markets benefit from social security funding. At the same time, when it enters into the agreements, the applicant waives part of the consideration it receives from the wholesaler for the medicinal product (that is, part of the revenue it obtains), because the applicant pays part of that revenue to NEAK.

The agreements also benefit NEAK because, within the limits of its resources, they enable patients in need to have ongoing access to treatment with new and state-of-the art medicinal products using social security funding, while at the same time ensuring adherence to budget allocations by keeping expenditure on the medicinal products covered by the agreements within predetermined limits.

Although no invoice is issued for the payment made by the applicant to NEAK, there is documentary evidence of the agreements and of the payments made under them, which can subsequently be verified:

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– The basis for the payments is provided by the claim for payment issued to the applicant by NEAK, as the state health insurance agency.

– The bank record of the transfer is available.

– NEAK publishes the main details of the agreements on its website, in accordance with the provisions in the legislation.

– The price that provides the basis for the social security funding for medicinal products and the details of the funding are held on an official public register managed by NEAK.

– The pharmacy receives the balancing payment in the form of the social security funding from NEAK under a price subsidy agreement between the pharmacy and NEAK. The method for the balancing funding is set out in the legislation, in the price subsidy agreement and in the general terms of contract, which means that the balancing payment is based on valid prescriptions or working documents that have been duly completed with the relevant details.

– Traceability and monitoring of sales of the medicinal products in question can be ensured through the public information on the sale of medicinal products published by NEAK on its website and the applicant's own sales data.

In the light of all the above, the defendant tax office rejected the supplementary return submitted by the applicant; that is, it did not allow the subsequent reduction in the taxable amount. Following an appeal by the applicant, the defendant upheld the original decision. According to the defendant, Article 77 of the Law on VAT contains all the grounds for a reduction in the taxable amount listed in Article 90(1) of the VAT Directive, and therefore it cannot be concluded that there is any discrepancy between EU law, because in transposing the directive into national law there is no requirement for the wording of the provisions in national law to be exactly the same as those in the directive. The directive simply establishes certain regulatory objectives, leaving the national legislature free to decide how to achieve them. It argued that the judgment of the Court of Justice of 20 December 2017 in *Boehringer Ingelheim Pharma* (C-462/16) was based on different facts and therefore does not apply in the present case. In its opinion, having regard to their content, the payments to NEAK do not satisfy the requirements in Article 77(4) of the Law on VAT (that they must be determined by the commercial policy or be made for promotional purposes). By contrast, the purpose of the requirements in Article 78(3) and (4) of the Law on VAT is to ensure the correct collection of tax and to prevent tax evasion.

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II.1. Hungarian law

***Az adózás rendjéről szóló 2017. évi CL. törvény* (new Law on General Taxation Procedures)**

Article 195:

'Where the taxpayer has submitted a supplementary return claiming only that the legal provision on which the liability for tax is based is unconstitutional or contrary to a legal act of the European Union of general application which is directly applicable, or that a municipal decree is contrary to another legal provision, the tax authorities shall give a decision on the supplementary return within 15 days of the filing date of that return without carrying out any checks, provided that the Constitutional Court, the Kúria (Supreme Court) or the Court of Justice of the European Union had not yet given a ruling on that issue at the time of filing the supplementary return or that return does not comply with the terms of the published ruling.'

***Az általános forgalmi adóról szóló 2007. évi CXXVII. törvény* (Law CXXVII of 2007 on Value Added Tax, 'Law on VAT')**

Article 65:

'In respect of the supply of goods or services, unless otherwise specified in the present law, the taxable amount shall consist of the consideration, expressed in money terms, obtained or to be obtained by the supplier from the purchaser of the goods, the recipient of the services or a third party, including any form of subsidy directly linked to the price of the supply of goods or services.'

Article 77:

'1. In respect of the supply of goods or services or the intra-Community acquisition of goods, amendment or termination of the contract — including cases where the contract is invalid or there is no contract — shall be grounds for a subsequent reduction in the taxable amount corresponding to the amount of any payment on account or consideration that has been or is to be refunded.

[…]

4. If, after he has supplied the goods or services, the taxable person refunds a sum of money for promotional purposes in accordance with the conditions set out in his commercial policy, to a person (irrespective of whether that person is a taxable or a non-taxable person) who did not purchase the goods or services giving rise to the entitlement to the refund directly from the said taxable person, the taxable person making the refund may subsequently reduce the taxable amount in respect of the supply of goods or services for which the refund is given

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(transaction giving entitlement to a reduction in the taxable amount), provided that:

a) the supply of goods or services that was made directly to the person entitled to the refund (transaction giving entitlement to a refund) is a taxable transaction carried out within national territory, and

b) the amount to be refunded is less than the sum arrived at by multiplying the number of the transactions giving entitlement to a refund by the lower unit price, including tax, of the goods or services supplied under the promotional campaign in question, with respect to all transactions giving entitlement to a reduction in the taxable amount.

5. For the purposes of applying paragraph 4, the amount refunded shall be deemed to include the amount of the tax.'

Article 78:

'3. In order for Article 77(4) to apply, the taxable person providing the refund must have:

a) a copy of the invoice made out to the person entitled to the refund which provides proof of the transaction giving entitlement to the refund and which demonstrates unequivocally that the transaction in question is a taxable transaction carried out within national territory, and

b) proof of the money transfer or payment in cash which demonstrates unequivocally that the taxable person has refunded the sum specified in his commercial policy to the person entitled to receive it.

4. The proof of payment referred to in paragraph 3(b) shall contain the following information:

a) The name and address of the person entitled to the refund and, where the person in question is a taxable person, his tax identification number.

b) Information on the right to a deduction in respect of the transaction in question, based on the declaration by the person entitled to the refund.'

***A kötelező egészségbiztosítás ellátásairól szóló 1997. évi LXXXIII. törvény* (Law LXXXIII of 1997 on the services provided by the compulsory health insurance system)**

Article 30/A:

'The health insurance agency may enter into agreements with the marketing authorisation holders referred to in Article 36(1) of Law XCVIII of 2006 on the marketing of medicinal products, with operators who market medical supplies,

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and with health service providers, in respect of the prices, quantities and quality requirements for any products and health services that may be marketed at subsidised prices, or in respect of any other matters the parties consider essential.'

***A biztonságos és gazdaságos gyógyszer- és gyógyászatisegédeszköz-ellátás, valamint a gyógyszerforgalmazás általános szabályairól szóló 2006. évi XCVIII. törvény* (Law XCVIII of 2006 on general provisions concerning the reliable and economically viable supply of medicinal products and medical supplies and on the marketing of medicinal products, 'Law on the marketing of medicinal products')**

Article 17:

'4. Advertising is not permitted for medicinal products and foodstuffs that are available only on prescription from a pharmacy or that have been approved for social security funding, or for medical supplies funded by the social security system.'

Article 26:

'2. In order to adhere to the budgetary framework, the health insurance agency may enter into the funding volume agreements referred to in paragraph 5 in respect of medicinal products which already receive funding or have recently been approved for funding or in respect of certain categories or types of such products, and in respect of medicinal products funded on grounds of fairness.

[…]

5. The payment obligation stipulated in the funding volume agreements may be determined:

a) in proportion to the price subsidy paid per subsidised unit sold;

b) on the basis of the difference between the total subsidy paid for one or more products during the period referred to in the agreement and the maximum amount fixed in the agreement;

[...] [irrelevant provisions]

e) it may also be determined in accordance with the dosage instructions for the medicinal product in question, based on the difference between the prescribed dose and the reference dose fixed in the agreement in accordance with cost-effectiveness considerations.

6. The provisions in paragraph 5 may also be applied concurrently in respect of a preparation.'

Article 28:

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‘1. For the purposes of funding medicinal products that have been approved for social security funding, the health insurance agency may use the following funding methods:

[…]

c) Funding volume agreements.

[…]’

<u>A törzskönyvezett gyógyszerek és a különleges táplálkozási igényt kielégítő tápszerek társadalombiztosítási támogatásba való befogadásának szempontjairól és a befogadás vagy a támogatás megváltoztatásáról [szóló] 32/2004. (IV 26.) ESzCsM rendelet</u> (Ministry of Health Regulations No 32/2004 of 26 April 2004 on the criteria for the acceptance for social security funding of registered medicinal products and foodstuffs for specific nutritional uses and on changes to acceptance or funding)

Article 11:

‘1. In the case of the funding volume agreements referred to in Article 26 of the Law on the marketing of medicinal products, the amount of the volume of funding shall be determined having regard to the recommendation made by a professional healthcare association as to the number of patients who may be treated, taking into account the prevalence or incidence of the disease.’

II.2. EU law

<u>Council Directive 2006/112/EC on the common system of value added tax</u> (‘VAT Directive’)

Article 73

‘In respect of the supply of goods or services, other than as referred to in Articles 74 to 77, the taxable amount shall include everything which constitutes consideration obtained or to be obtained by the supplier, in return for the supply, from the customer or a third party, including any form of subsidy directly linked to the price of the supply.’

Article 90

‘1. In the case of cancellation, refusal or total or partial non-payment, or where the price is reduced after the supply takes place, the taxable amount shall be reduced accordingly under conditions which shall be determined by the Member States.

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2. In the case of total or partial non-payment, Member States may derogate from paragraph 1.'

Article 273

'Member States may impose other obligations which they deem necessary to ensure the correct collection of VAT and to prevent evasion, subject to the requirement of equal treatment as between domestic transactions and transactions carried out between Member States by taxable persons and provided that such obligations do not, in trade between Member States, give rise to formalities connected with the crossing of frontiers.

The option under the first paragraph may not be relied upon in order to impose additional invoicing obligations over and above those laid down in Chapter 3.'

III. Reasons for the request for a preliminary ruling

The first question referred

In its judgment of 20 December 2017 in *Boehringer Ingelheim Pharma* (C-462/16), the Court of Justice held that Article 90(1) of the VAT Directive must be interpreted as meaning that the discount granted, in accordance with national law, by a pharmaceutical company to a private health insurance company results, for the purposes of that article, in a reduction of the taxable amount in favour of that pharmaceutical company, when it supplies medicinal products via wholesalers to pharmacies which make supplies to persons covered by private health insurance that reimburses the purchase price of the medicinal products to persons it insures.

The Hungarian funding system is similar to the German funding arrangements for private health insurance, with the difference that, in Hungary, the payments made to NEAK, as the public health insurance agency, are not based on a mandatory law but on a civil law agreement which the parties enter into voluntarily. The applicant is not obliged to enter into a contract of this type with NEAK, but the consequence of the agreement is the same as in Case C-462/16. Specifically, that consequence is that the applicant could only dispose of a sum corresponding to the price of the sale of those medicinal products to pharmacies, reduced by that discount, (judgment of 20 December 2017, *Boehringer Ingelheim Pharma*, paragraph 35). However, the Court of Justice did not address the question of whether it is still possible to make a subsequent reduction in the taxable amount where the discount is not granted under a mandatory provision of law but is instead voluntary, as in the present case.

According to the defendant, the sums paid to NEAK cannot be classed as a subsequent refund for promotional purposes. Given that the advertising of medicinal products funded by social security is prohibited under Article 17(4) of Law XCVIII of 2006 on the marketing of medicinal products, sales promotions for prescription-only medicinal products covered by the agreements are not

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permitted. Moreover, the requirement that the sums in question should be determined by the taxable person 'in accordance with the conditions set out in his commercial policy' is not satisfied either, as the amounts of the payments made under the agreements are not determined by the applicant but by a professional healthcare association under Article 11(1) of the Ministry of Health Regulations No 32/2004 of 26 April 2004.

Under Article 90(1) of the VAT Directive, the taxable amount is to be reduced by the appropriate amount under conditions to be determined by the Member States. While the Member State appears to be free to establish the conditions for the subsequent reduction of the taxable amount, in *Boehringer Ingelheim Pharma* the Court of Justice did not address the question of the extent to which, where conditions are imposed on the subsequent reduction of the taxable amount, a restriction is proportionate to the regulatory objective. The question is justified because, in order to reach a decision on the case, it is necessary to determine whether the Hungarian legislation breaches the principle of fiscal neutrality and whether it constitutes a disproportionate restriction, having regard to the objective pursued by the legislation. Indeed, the Hungarian legislation deprives all pharmaceutical companies that have concluded agreements similar to those at issue in the main proceedings of the possibility of subsequently reducing the taxable amount.

In the opinion of this court in the present case, NEAK should be deemed to be the final consumer of the supply provided by a pharmaceutical company, meaning that the amount received by the tax authorities may not in any circumstances exceed the amount paid by the final consumer (judgment of 24 October 1996, *Elida Gibbs*, C-317/94, paragraph 24). Consequently, given that the taxable person retains part of the consideration because of the discount granted by the applicant to NEAK, in effect there has been a reduction in the price after the supply took place in accordance with the provisions of Article 90(1) of the VAT Directive. In these circumstances, the applicant was not able freely to dispose of the full amount of the price received on the sale of its products to pharmacies or to wholesalers (judgment of 20 December 2017, *Boehringer Ingelheim Pharma*, paragraphs 41 to 43).

The second question referred

In order to be able subsequently to reduce the taxable amount, the Hungarian legislation requires a copy of the invoice made out to the person entitled to the refund as proof of the transaction giving entitlement to the said refund, together with proof of a money transfer or cash payment.

In the present case, no invoice was issued in respect of the applicant to NEAK; all that is available is a claim for payment sent to the applicant by NEAK and the bank receipt providing proof of the transfer payment. According to the method stipulated in the agreement, NEAK calculates the amount stated in the claim for payment on the basis of information on the volume of medicinal products sold and

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prescriptions for the relevant period. Therefore, although there is no invoice, the transaction is duly documented, since details of the agreements and of the volume of medicinal products sold are publicly available, and the funding is settled on the basis of official public registers. It is also important to note that NEAK is a state health insurance agency, and therefore it can unquestionably be taken for granted that the details it includes in the claim for payment are correct.

Article 273 of the VAT Directive allows Member States to impose additional obligations to ensure the correct collection of VAT and to prevent tax evasion. This court considers that the restrictions must be proportionate to the objective pursued. In the case at issue here, the possibility of tax evasion has not been raised and has not been invoked by the defendant, while the correct collection of VAT can be ensured, even if there is no invoice, based on the information referred to in the previous paragraph and taking into account the involvement of the public body.

In *Boehringer Ingelheim Pharma* the Court of Justice did not examine what the formal requirements are and what documents are necessary in order to enable a subsequent reduction in the taxable amount, and therefore the question referred is justified.

[...] [procedural consideration of domestic law]

Budapest, 16 September 2019.

[…]

[signatures]

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