

Case C-248/23**Request for a preliminary ruling****Date lodged:**

18 April 2023

Referring court:

Fővárosi Törvényszék (Hungary)

Date of the decision to refer:

30 March 2023

Applicant:

Novo Nordisk AS

Defendant:

Nemzeti Adó- és Vámhivatal Fellebbviteli Igazgatósága

Fővárosi Törvényszék (Budapest High Court, Hungary)

[...]

In the administrative-law tax proceedings brought as a result of the action lodged by Novo Nordisk AS ([...] Bagsvaerd, Denmark) [...], the applicant, against the Nemzeti Adó- és Vámhivatal Fellebbviteli Igazgatósága (Appeals Directorate of the National Tax and Customs Authority) ([...] Budapest, Hungary) [...], the defendant, the Budapest High Court has issued the following

ORDER:

Pursuant to Article 267 of the Treaty on the Functioning of the European Union, the referring court [...] refers the following question to the Court of Justice of the European Union for a preliminary ruling:

Must 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 the national legislation at issue in the main proceedings, under which a pharmaceutical company which makes payments *ex lege* to the State health insurance agency based on the revenue obtained from publicly funded

pharmaceutical products is not entitled subsequently to reduce the taxable amount, by reason of the fact that the payments are made *ex lege*, that payments made under a funding volume agreement and investments made by the company in research and development in the health sector may be deducted from the base amount for the payment obligation, and that the amount payable is collected by the State tax authority, which immediately transfers it to the State health insurance agency?

[...] [Matters of national procedural law]

GROUNDNS

I. Facts

- 1 In Hungary, the retail sale of medicinal products is carried out through pharmacies, except in hospitals. Pharmacies are supplied by wholesale distributors and those distributors are, in turn, supplied by distributors of pharmaceutical products.
- 2 Medicinal products may be subsidised by the Nemzeti Egészségbiztosítási Alapkezelő (National Health Insurance Fund Management Agency, Hungary; ‘the NEAK’) through the ‘purchase price subsidy’ scheme. Under that scheme, the NEAK subsidises the purchase price of medicinal products which are sold on prescription and funded by the social security system in the context of outpatient care. Payment of the price of the subsidised medicinal product is then shared between the NEAK and the patient. The patient pays the pharmacy an amount, known as the ‘subsidised price’, which is the difference between the price of the medicinal product and the subsidy paid by the NEAK. The NEAK subsequently reimburses the amount of the subsidy to the pharmacy. The price of the medicinal products received by the pharmacy, which is the taxable amount for value added tax (‘VAT’), thus comprises two parts: the subsidy paid by the NEAK and the ‘subsidised price’ paid by the patient. The pharmacy is therefore required to pay VAT on both the amount paid by the patient and the sum paid by the NEAK.
- 3 Following a review in which various factors are taken into account, the NEAK decides whether to include a medicinal product on the list of subsidised medicinal products and then determines the amount of the subsidy depending on the price set by the distributor.
- 4 Novo Nordisk AS is a company registered in Denmark which manufactures and markets medicinal products. In the course of its business, it sells the medicinal products it manufactures in Hungary.
- 5 Novo Nordisk AS, together with Novo Nordisk Hungária Kft., belongs to a group of companies which, in its own name and on behalf of Novo Nordisk AS, entered into agreements with the NEAK on the portfolio of subsidised projects and on funding volume. Under the funding volume agreements (as regards the project

portfolio and the packaging price), Novo Nordisk AS made payments to the NEAK to reflect sales of the medicinal products subsidised by the social security system ('the payment obligation under the funding volume agreements') and, to that end, used a portion of the revenue obtained from the sale of those medicinal products.

- 6 In addition to that contractual obligation, pursuant to Articles 36(1) and 40/A(1) of the biztonságos és gazdaságos gyógyszer- és gyógyászatisegédeszköz-ellátás, valamint a gyógyszerforgalmazás általános szabályairól szóló 2006. évi XCVIII. törvény (Law No XCVIII of 2006 laying down general provisions on the reliable and economically viable supply of medicinal products and medical equipment and on the marketing of medicinal products; 'the Law on the marketing of medicinal products'), Novo Nordisk AS made payments of 20% and 10% in relation to the social security subsidy for medicinal products benefitting from any kind of public funding sold by that company through pharmacies ('the *ex lege* payment obligation').
- 7 In discharging the *ex lege* payment obligation after the sale of the products, Novo Nordisk AS waives part of the consideration it receives from the wholesaler, that is to say, part of its turnover. Whether or not the *ex lege* payment obligation applies and the overall amount payable thereunder depends on the quantity of medicinal products sold and the amount of the social security subsidy.
- 8 In essence, under the *ex lege* payment obligation, Novo Nordisk AS reimburses the NEAK, which funds the medicinal products, a fixed percentage set in advance in respect of each medicinal product with a subsidised purchase price.
- 9 The *ex lege* payment obligation is discharged by means of a payment, pursuant to a tax return, into the account of the State tax authority, which immediately transfers the amount paid to the account of the National Health Insurance Fund.
- 10 On 16 July 2021, Novo Nordisk AS, in its capacity as distributor of pharmaceutical products, filed a corrected VAT return with the first-tier tax authority of the defendant for the tax period covering January 2016, in accordance with Article 195 of the az adózás rendjéről szóló 2017. évi CL. törvény (Law No CL of 2017 on general taxation procedures; 'the Law on general taxation procedures'). By means of the corrected tax return, the applicant reduced the amount of VAT payable for that tax period by HUF 7 832 000, citing the payments it had made under both the funding volume agreements [...] entered into with the NEAK, as State health insurance agency, and Articles 36(1) and 40/A(1) of the Law on the marketing of medicinal products.
- 11 The first-tier tax authority rejected the applicant's corrected tax return and refused the subsequent reduction in the taxable amount. As a result of the administrative action brought by the applicant before the defendant, the latter allowed the reduction in the taxable amount as regards the sums paid pursuant to the payment

obligation under the funding volume agreements, referring in that respect to the judgment of the Court of Justice of the European Union in Case C-717/19.

- 12 However, the defendant refused the reduction in the taxable amount as regards the *ex lege* payment obligation. It stated that this is a statutory payment obligation which is not a price reduction but a special tax. In the defendant's view, the law frames the payment obligation not as a price reduction but as a tax. That payment obligation stems not from the funding volume agreements but directly from statutory provisions. It is not a price reduction because it is not given by the distributor of pharmaceutical products to the final consumer and because the payments are primarily mechanisms to achieve budgetary and health objectives. Legal literature also regards those payments as special taxes. *Ex lege* payment obligations are governed by the az adóigazgatási rendtartásról szóló 2017. évi CLI. törvény (Law No CLI of 2017 on tax administration) [...] and by the Law on general taxation procedures. The sums paid in that respect must be credited to the tax authority and, under Article 6(2)(a) of the Law on general taxation procedures, they are treated as taxes. According to the tax authority, that payment obligation is a tax on medicinal products, a levy payable under a mandatory statutory provision which cannot be regarded as a price reduction.

II.1. Hungarian law

Az adózás rendjéről szóló 2017. évi CL. törvény (Law No CL of 2017 on general taxation procedures) (new Law on general taxation procedures)

Article 195 Where a taxpayer has filed a corrected return claiming only that the legal provision on which the liability to tax is based is unconstitutional or contrary to a legal act of the European Union that is of general application and directly applicable, or that a municipal decree is contrary to another legal provision, the tax authorities shall give a decision on the corrected return within 15 days of the filing date thereof, without carrying out any checks, provided that, at the time of filing the corrected return, the Constitutional Court, the Kúria [(Supreme Court, Hungary)] or the Court of Justice of the European Union has not yet given a ruling on that issue or the corrected return does not comply with the terms of the published ruling.

Az általános forgalmi adóról szóló 2007. évi CXXVII. törvény (Law No CXXVII of 2007 on value added tax)

Article 65 In respect of the supply of goods or services, the taxable amount, unless otherwise specified in the present law, 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 subsidies 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 in whole or in part.

[...]

4. If, after he or she has supplied the goods or services, the taxable person, in accordance with the conditions set out in his or her commercial policy, refunds a sum of money for promotional purposes to a person (irrespective of whether or not that person is a taxable person) who did not purchase the goods or services giving rise to the entitlement to the refund directly from that 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 (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.

A biztonságos és gazdaságos gyógyszer- és gyógyászatisegédeszköz-ellátás, valamint a gyógyszerforgalmazás általános szabályairól szóló 2006. évi XCVIII. törvény (Law No XCVIII of 2006 laying down general provisions on the reliable and economically viable supply of medicinal products and medical equipment and on the marketing of medicinal products) (Law on the marketing of medicinal products)

Article 36 1. The holder of the marketing authorisation for a medicinal product or, where the holder does not carry on any distribution activities in Hungary, the distributor appointed by agreement concluded between them and approved by the State tax authority, and the person who has submitted an application for a social security subsidy for a preparation and, if that person does not distribute the preparation, the distributor (for the purposes of this Chapter, together, ‘the holder of the marketing authorisation for the medicinal product’), shall be subject, as regards medicinal products and preparations (for the purposes

of this Chapter, together, ‘medicinal products’) sold in pharmacies and benefitting from any kind of public funding, with the exception of the medicinal products referred to in Article 38(1) and the preparations referred to in the legislation on infant formula and follow-on formula, to the obligation to pay 20% of a part of the social security subsidy, based on the sales data according to medical prescriptions for the reference month, in proportion to the production price or the import price (together, ‘the production price’) (production price/consumer price). The holder of the marketing authorisation for the medicinal product shall be subject, as regards the preparations referred to in the legislation on infant formula and follow-on formula sold in pharmacies and benefitting from any kind of public funding, to the obligation to pay 10% of a part of the social security subsidy, based on the sales data according to medical prescriptions for the reference month, in proportion to the production price (production price/consumer price). The payment obligation shall be calculated for each product and for each type of subsidy. ‘Social security subsidy’ means the gross subsidy, including value added tax. ‘Consumer price’ means the gross consumer price. ‘Production price’ means the net production price, excluding value added tax.

Article 37 1. The health insurance agency responsible for managing the National Health Insurance Fund shall forward to the person liable for payment or shall publish on its website, no later than the tenth day of the second calendar month following the reference month, the subsidy and sales data needed to discharge the payment obligations laid down in Article 36(1) and (2).

2. In accordance with the payment obligations laid down in Article 36(1) and (2), the holder of the marketing authorisation for the medicinal product and the holder of the wholesale distribution authorisation for the medicinal product shall, no later than the twentieth day of the third calendar month following the reference month, file a return with the State tax authority using the form made available by that authority and, at the same time, shall make payment into the account opened for that *specific purpose* by the tax authority with the Treasury.

Article 40 The State tax authority:

(a) shall transfer the amount received pursuant to Article 36(1), (2), (4) and (4a) to the account of the National Health Insurance Fund opened with the Treasury, as indicated in special rules;

(b) shall carry out that transfer immediately after payment is made.

Article 40/A 1. In addition to the payment obligation laid down in Article 36(1), the holder of the marketing authorisation for a medicinal product or, where the holder does not carry on any distribution activities in Hungary, the distributor appointed by agreement concluded between them and approved by the State tax authority (for the purposes of this article, together, ‘the holder of the marketing authorisation for the medicinal product’), shall be subject, as regards medicinal products sold in pharmacies and benefitting from any kind of public

funding for at least six years, the price of which, taken as the basis for that funding, exceeds HUF 1 000, to the obligation to pay 10% of a part of the social security subsidy, based on the sales data according to medical prescriptions for the reference month, in proportion to the production price or the import price (together, 'the production price') (production price/consumer price), provided that there is no other product which is also publicly funded and whose active pharmaceutical ingredient and route of administration are identical to those of the product in question, but which is sold under a different trade mark by a different marketing authorisation holder. The payment obligation shall be calculated for each product and for each type of subsidy.

4. The payment obligation laid down in paragraph 1 shall be governed by the Law on tax administration and the Law on general taxation procedures, subject to the differences established in this law.

5. The State tax authority shall inform the health insurance agency of the approval of the agreement between the holder of the marketing authorisation and the distributor, referred to in paragraph 1, within eight days of the date of approval.

6. The health insurance agency responsible for managing the National Health Insurance Fund shall forward to the person liable for payment or shall publish on its website, no later than the tenth day of the second calendar month following the reference month, the subsidy and sales data needed to discharge the payment obligation laid down in paragraph 1.

7. In accordance with the payment obligation laid down in paragraph 1, the holder of the marketing authorisation for the medicinal product shall, no later than the twentieth day of the third calendar month following the reference month, file a return with the State tax authority using the form made available by that authority and, at the same time, shall make payment into the account opened for that *specific purpose* by the tax authority with the Treasury.

8. The health insurance agency responsible for managing the National Health Insurance Fund shall provide, at the same time as the data forwarding service referred to in paragraph 6, an electronic data forwarding service for the benefit of the State tax authority concerning the data needed to monitor the persons liable for payment.

9. The State tax authority shall transfer the amount received pursuant to paragraph 1 to the account of the National Health Insurance Fund opened with the Treasury, as indicated in special rules, and shall carry out that transfer immediately after payment is made.

II.2. European Union law

Council Directive 2006/112/EC on the common system of value added tax ('the 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 subsidies 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.

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. Grounds for the request for a preliminary ruling

- 13 In its judgment of 20 December 2017 in Case C-462/16 (*Boehringer Ingelheim Pharma*), the Court held that Article 90(1) of the VAT Directive must be interpreted as meaning that the discount granted, under 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, where 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.

- 14 In its judgment in Case C-717/19 (*Boehringer Ingelheim*), the Court held that that provision precludes a national law that provides that a pharmaceutical company may not reduce its taxable amount for VAT by the portion of its revenue obtained from the sale of medicinal products subsidised by the State health insurance agency which it reimburses to that organisation under a contract entered into by the State health insurance agency and that company, because the amounts paid in that regard were not set out in advance by that company in its commercial policy and because those payments were not made for promotional purposes.
- 15 Distributors of pharmaceutical products help fund the Hungarian medicinal product subsidy system in two ways. First, they make payments to the NEAK, as the State health insurance agency, under civil law contracts entered into by the parties voluntarily. The applicant is not obliged to conclude such contracts with the NEAK, but, if it does not do so for a given pharmaceutical product, that product will not receive public funding. The Court ruled on those payments in its judgment in Case C-717/19.
- 16 Second, under Articles 36(1) and 40/A(1) of the Law on the marketing of medicinal products, distributors of pharmaceutical products are subject, as regards publicly funded medicinal products, to an additional payment obligation of 10% and 20% in proportion to the production price. That payment obligation is characterised by the fact that, although the State tax authority collects the payments and oversees discharge of the obligation, it immediately transfers the sums collected to the NEAK. It is also characterised by the fact that payments made to the NEAK under a funding volume agreement have an impact on the quantum of the *ex lege* payment obligation and, in addition, deductions from that payment obligation may be made in respect of other items. Discounts aside, the consequence of actually discharging the payment obligation is that the taxable person who distributes pharmaceutical products does not receive a portion of the consideration. The preamble to the bill which initially introduced the *ex lege* payment obligation stated that *'it is usual commercial practice for a purchaser to obtain a discount based on the purchase volume. Since the largest purchaser of medicinal products is the social security system, the insurance agency must be the beneficiary of the reduction related to sales of the subsidised medicinal products, which must also be laid down by law'*.
- 17 The defendant contends that the *ex lege* payment obligation is not a price reduction because, first, it is not a reduction in the price which, based on the quantity of products previously purchased, is granted until discharge and, second, it is not granted to the final consumer, so that there is no direct link between the consideration for the sale made by the person liable for payment, the payment and the consideration paid by the final consumer. The *ex lege* payment obligation is binding and not reciprocal, is intended to meet budgetary projections for the medicinal product subsidy and has no effect on the subsidised price paid by the patient. The tax authority not only acts as collector of the tax, but also has oversight powers, and the applicant does not reimburse the NEAK, but discharges a payment obligation in favour of the Treasury. Chapter IV of the Law on the

marketing of medicinal products governs the payment obligation under the funding volume agreements, which is classified as a price reduction, whereas the *ex lege* payment obligation is governed by Chapter V of that law and cannot therefore be classified as a price reduction. The *ex lege* payment obligation is a tax, since it is possible to deduct from its base amount, first, pursuant to Article 38(4) of the Law on the marketing of medicinal products, payments made for the reference period under funding volume agreements, net of VAT, and, second, pursuant to Article 36(10) of that law, research and development investments, which would not be possible if the *ex lege* payment obligation was not a tax. In accordance with Article 78(a) of the VAT Directive, the taxable amount is to include taxes, and, since the payment obligation framed in mandatory terms in Articles 36(1) and 40/A(1) of the Law on the marketing of medicinal products is a special tax, it cannot be classified as a price reduction enabling the taxable amount to be reduced.

- 18 The referring court considers that it is not possible to resolve the dispute between the parties on the basis of Hungarian law and the practice of the tax authority established by that law without looking at it in relation to EU law, the fundamental principles of the VAT Directive and the law to be applied by the national court, and without examining whether Hungarian law and the practice of the tax authority established by that law comply with the requirements stemming from the neutrality of VAT provided for by EU law, given that a pharmaceutical company which makes payments *ex lege* to the State health insurance agency based on the revenue obtained from publicly funded pharmaceutical products is not entitled subsequently to reduce the taxable amount, by reason of the fact that the payments are made *ex lege*, that payments made under a funding volume agreement and investments made by the company in research and development in the health sector may be deducted from the base amount for the payment obligation, and that the amount payable is collected by the State tax authority, which immediately transfers it to the State health insurance agency.
- 19 The referring court is of the view that, in the present case, the NEAK should be regarded as the final consumer of the supplies of goods made by the applicant, since the fact that, in the main proceedings, the direct beneficiary of the supplies of the medicinal products in question is not the State health insurance agency which subsequently reimburses the amount of the subsidy to the pharmacy, but the insured persons themselves who pay the subsidised price to the pharmacy, does not break the direct link between the supply of goods made and the consideration received (judgment of 6 October 2021, *Boehringer Ingelheim*, C-717/19, paragraph 45), such that the amount payable to the tax authority may not exceed that paid by the final consumer (judgments of 24 October 1996, *Elida Gibbs*, C-317/94, paragraph 24, and of 6 October 2021, *Boehringer Ingelheim*, C-717/19, paragraph [46]). As regards the classification as a price reduction, all that matters is that the taxable person has not received all or part of the consideration for his or her goods (judgment of 6 October 2021, *Boehringer Ingelheim*, C-717/19, paragraph 51).

- 20 Under Article 90(1) of the VAT Directive, the taxable amount is to be reduced accordingly under conditions to be determined by the Member States. Given that, in the context of the factual background outlined above, there was no examination of a payment obligation established *ex lege* under which the sums due were payable to the tax authority but were ultimately transferred to the State health insurance agency, the Court has not had occasion to consider whether the *ex lege* payment obligation at issue in the present case, under which the tax authority collects the sums due and also oversees the filing of returns in respect of that obligation as well as payment, and which national legislation classifies as a tax on medicinal products with the sums due being transferred immediately by the tax authority to the NEAK, may be regarded as the grant of a discount proportionate to the payments made by the distributor of pharmaceutical products under a funding volume agreement.

In those circumstances, the referring court seeks to ascertain whether the principle of fiscal neutrality is infringed by the fact that pharmaceutical companies are not entitled subsequently to reduce the taxable amount when having to discharge a payment obligation under which the direct recipient of the sums payable is the State tax authority but the indirect recipient of those sums is the NEAK, which ultimately bears the purchase price of the medicinal products, such that payment helps fund the medicinal product subsidy.

IV. Other procedural issues

[...] [Matters of national procedural law]

Budapest, 30 March 2023.

[...] [signatures]