

Anonymised version

Translation

C-715/23 – 1

Case C-715/23

Request for a preliminary ruling

Date lodged:

23 November 2023

Referring court:

Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (Slovenia)

Date of the decision to refer:

23 November 2023

Appellant:

Farmacija, d.o.o.

Respondent:

Občina Benedikt

[...]

REQUEST FOR A PRELIMINARY RULING

Parties to the main proceedings

- 1 Applicant: **Farmacija**, [...], **Lubiana – Polje** ('the applicant for review') is calling for legal protection against the **Občina Benedikt** (Municipality of Benedikt), [...], **Benedikt** ('the Municipality of Benedikt') in connection with the exercise of pharmaceutical activity in that municipality. Because the conduct of the Municipality of Benedikt, which is the subject of dispute between the parties, also affects the position of **MN**, [...], **Maribor**, which exercises pharmaceutical

activities in that municipality, this entity must also be considered a party in the main proceedings.

Referring body

- 2 The Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal, Slovenia),¹ ('the Državna revizijska komisija'), is a referral body in the Republic of Slovenia that – pursuant to the Zakon o pravnem varstvu v postopkih javnega naročanja (Law on legal protection in public procurement procedures, 'the ZPVPJN')² – is a special, independent and autonomous national body tasked with determining whether public contracts have been awarded legally at all stages of the award procedure (Article 60(1) of the ZPVPJN).
- 3 In the Republic of Slovenia, legal protection against breaches of the procedure for awarding public contracts and against breaches of the procedure for awarding concessions, governed by the Zakon o nekaterih koncesijskih pogodbah (Law on certain concession contracts, 'the ZNKP'),³ is provided through the following procedures:
 - a preliminary review procedure before the contracting authority,
 - a review procedure before the Državna revizijska komisija, and
 - court proceedings at first instance before the Okrožno sodišče (District Court, Slovenia) designated as having exclusive jurisdiction by the law governing the judicial system.

Legal protection before the Okrožno sodišče (District Court) is limited to the assessment of liability to pay compensation for the damage that has arisen and to recognition of actions to obtain a declaration that the corresponding contracts are invalid.

- 4 If the contracting authority rejects the application for review on procedural grounds in the course of a preliminary review proceeding, the applicant for review may appeal. In such a case, as part of the appeal procedure, the Državna revizijska komisija assesses the legality of the conduct of the contracting authority in terms of the rejection of the application for review.
- 5 The Court of Justice of the European Union has already recognised that the Državna revizijska komisija has the status of a 'national court or tribunal' within the meaning of Article 267 TFEU in its judgments of 8 June 2017, *Medisanus*

¹ [...]

² [...]

³ [...]

(C-296/15, EU:C:2017:431), 10 September 2020, *Tax-Fin-Lex* (C-367/19, EU:C:2020:685), and 10 November 2022, *Sharengo* (C-486/21, EU:C:2022:868).

- 6 The circumstances justifying the conclusion that the Državna revizijska komisija has been recognised as having the status of ‘national court or tribunal’ within the meaning of Article 267 TFEU have not changed since the above-mentioned judgments of the Court of Justice.⁴

Subject matter of the main proceedings

- 7 On 11 March 2022, the Municipality of Benedikt granted MN authorisation for an indefinite period to run a branch pharmacy located in Benedikt, without (prior) publication of a concession notice.
- 8 The applicant filed an application for review with the Municipality of Benedikt, complaining that, by issuing the above-mentioned authorisation, the Municipality had granted a concession for the exercise of pharmaceutical activity without having carried out the corresponding procedure, and had therefore breached Directive 2014/23.
- 9 The Municipality of Benedikt rejected the application for review, without examining it on the merits, considering that the applicant for review did not enjoy legal protection in the preliminary review procedure and in the review procedure. In that sense, in the view of the Municipality of Benedikt, the granting of authorisation to operate a branch pharmacy does not, in essence, constitute the award of a services concession, which would be governed by the ZNKP.⁵
- 10 The applicant lodged an appeal against this decision of the Municipality of Benedikt, which was referred by the Municipality of Benedikt to the Državna revizijska komisija. The applicant for review reiterates that, by granting the authorisation, the Municipality of Benedikt awarded a services concession without conducting the relevant procedure, claiming, in essence, that a concession for the exercise of pharmaceutical activity falls within the scope of the ZNKP or within the scope of Directive 2014/23.
- 11 The Državna revizijska komisija’s decision in the proceedings in question turns on whether the granting of authorisation for the purpose of exercising pharmaceutical activity falls within the scope of Directive 2014/23.
- 12 In the opinion of the Državna revizijska komisija, the Municipality of Benedikt awarded a concession for the exercise of pharmaceutical activity when it granted authorisation for the operation of a branch pharmacy. Indeed, pharmaceutical activity can also be carried out in a branch pharmacy. Although national

⁴ [...]

⁵ The ZNKP transposed Directive 2014/23 into Slovenian law.

legislation provides for the granting of authorisation for the operation of a branch pharmacy, this does not constitute an authorisation within the meaning of recital 14 of Directive 2014/23, namely an authorisation by which the Member State or a public authority thereof establishes the conditions for the exercise of an economic activity that is granted on request of the economic operator (and not on the initiative of the contracting authority), where the economic operator meets certain predetermined requirements.⁶

- 13 The Municipality of Benedikt meets the criteria enabling it to be considered a contracting authority within the meaning of Article 6 of Directive 2014/23. Because the authorisation for exercise of pharmaceutical activity in the Benedikt area is granted for an indefinite period of time, the Državna revizijska komisija believes that the estimated value of the pharmaceutical service exceeds the threshold laid down in Article 8 of Directive 2014/23.⁷
- 14 However, the Državna revizijska komisija has doubts as to whether services relating to pharmaceutical activity constitute, in substance, services falling within the scope of Directive 2014/23.

Relevant legal provisions

European Union law

- 15 Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts

As laid down in Article 1 of Directive 2014/23:

This Directive establishes rules on the procedures for procurement by contracting authorities and contracting entities by means of a concession, whose value is estimated to be not less than the threshold laid down in Article 8.

Under Article 4 of Directive 2014/23:

1. This Directive does not affect the freedom of Member States to define, in conformity with Union law, what they consider to be services of general economic interest, how those services should be organised and financed, in compliance with the State aid rules, and what specific obligations they should be subject to. Equally, this Directive does not affect the way in which the Member States organise their social security systems.

⁶ The number of pharmacy outlets in a given area is limited, as a municipality may only establish a new pharmacy (branch) where the legal conditions for its opening (number of inhabitants in the catchment area, distance between the existing pharmacy and the new branch) are met.

⁷ The Državna revizijska komisija does not have any data on the estimated value, as the Municipality of Benedikt considers that neither the ZNKP nor Directive 2014/23 is applicable to the present case and therefore considers that it is not required to calculate the estimated value.

2. Non-economic services of general interest shall fall outside the scope of this Directive.

Article 19 of Directive 2014/23 states as follows:

Concessions for social and other specific services listed in Annex IV falling within the scope of this Directive shall be subject only to the obligations arising from Article 31(3) and Articles 32, 46 and 47.

National law

- 16 Zakon o nekaterih koncesijskih dejavnostih (Law on certain concession [contracts], ‘the ZNKP’)

Article 2 of the ZNKP states as follows:

The following terms are used in this Law:

18. ‘non-economic services of general interest’: non-economic services that, by law, are provided as services of general interest and are not offered on the market for remuneration, which are therefore subject to specific public service obligations.

Article 10 of the ZNKP states as follows:

The provisions of this law and the provisions of special laws apply to concessions governed by this law and special laws, where they are not contrary to this law.

Article 11(1) of the ZNKP provides:

This law shall not apply to:

1. concessions for non-economic services of general interest.

Article 15 of the ZNKP establishes as follows:

Concessions for social services and other specific services listed in Annex IV to Directive 2014/23/EU shall be subject to the provisions of this law governing the obligation to prepare preparatory acts, the obligation to publish notices referred to in Articles 35 and 40 of this law, and legal protection in concessionaire selection procedures under this law.

- 17 Zakon o zdravstveni dejavnosti (Law on healthcare, ‘the ZZDej’)⁸

Article 1 of the ZZDej states as follows:

⁸ [...]

Healthcare is provided at primary, secondary and tertiary level.

Primary healthcare covers basic healthcare and pharmaceutical activity.

Article 3 of the ZZDej states as follows:

Healthcare providers are domestic and foreign natural and legal persons that have obtained authorisation from the Ministry of Health to provide healthcare.

The public health service includes health services that are guaranteed to be provided on a continuous and regular basis, in the public interest, by the State and local authorities and which, on the basis of the principle of solidarity and in accordance with the rules governing healthcare and health insurance, are guaranteed as rights deriving from compulsory health insurance and are funded, in whole or in part, through public resources, drawn primarily from compulsory health insurance. The health services referred to in the preceding sentence, as non-economic services of general interest, must be provided by non-profit healthcare providers in such a way that the surplus of revenue over expenditure is allocated to the provision and development of healthcare.⁹

Article 20(1) of the ZZDej establishes the following:

Pharmaceutical activity is carried out in accordance with a special law. This law applies to matters not regulated by a special law.

18 Zakon o lekarniški dejavnosti (Law on pharmaceutical activity, ‘the ZLD-1’)¹⁰

Article 1 of the ZLD-1 states that:

This law regulates the purpose, content and conditions for carrying out pharmaceutical activity, the organisation, conditions and procedures for issuing and implementing concessions, professionals in the pharmaceutical sector and their professional associations, online pharmaceutical activity and supervision.

Article 2 of the ZLD-1 establishes that:

The purpose of pharmaceutical activities is to ensure an efficient and high-quality supply of medicines and other products to support medical treatment and health protection, and to provide advice to patients and health professionals on their safe, correct and effective use.

In addition to the purpose described in the preceding paragraph, pharmaceutical activity also ensures that pharmaceutical treatment can be provided for the

⁹ Article 3(2), second sentence, of the ZZDej was annulled by the Ustavno sodišče Republike Slovenije (Constitutional Court of the Republic of Slovenia) in so far as it regulates the surplus of revenue over expenditure for operators of pharmaceutical activity under concession.

¹⁰ [...]

purpose of maintaining health and obtaining the clinical, humanitarian and economic results expected from a therapy.

Article 5 of the ZLD-1 states as follows:

Pharmaceutical activity is a public health service that guarantees the continuous and regular supply of medicines to the population and health professionals and the pharmaceutical treatment of patients.

Pharmaceutical activity takes place at the primary, secondary and tertiary levels of healthcare.

The network of pharmaceutical activities under this law is guaranteed at primary level by the municipality or several neighbouring municipalities jointly, and at secondary and tertiary levels by the State.

Article 6(1) of the ZLD-1 states as follows:

Pharmaceutical activity includes:

- the supply of prescription and non-prescription medicines for human and veterinary use,
- the supply of food for special medical purposes,
- the pharmaceutical treatment of patients,
- the advisory activities of pharmacists,
- pharmaceutical intervention,
- telepharmacy services,
- the preparation of magistral drugs for human and veterinary use,
- the preparation of products to support therapies and health maintenance,
- the production of galenical drugs for human and veterinary use,
- radiopharmaceutical activities,
- quality control of raw materials for the preparation and production of magistral and galenical drugs,
- quality control of galenical drugs,
- monitoring of data and reporting of adverse reactions or suspected adverse reactions,

- the take-back of unused or residual medicines in accordance with the regulations governing the management of medicinal waste,
- other activities related to the supply of medicines and other products, ensuring their correct, rational and safe use.

Article 7 of the ZLD-1 states as follows:

In addition to the activities referred to in the previous article, pharmacies may also carry out the following activities:

- the supply of other products to support therapy and health maintenance,
- the production of galenical products,
- the preparation of homeopathic magistral drugs,
- the supply of veterinary products,
- the supply of biocides and chemicals,
- the performance of self-diagnosis measurements and tests,
- prevention and health education activities,
- pedagogical and educational activities,
- scientific research activities,
- other activities and services in the field of health promotion and protection,
- the delivery of medicines and other products to the homes of patients, to health professionals and to other natural or legal persons,
- other pharmaceutical-related services.

Article 8(1) of the ZLD-1 states as follows:

Pharmaceutical activity at primary level is exercised:

- in a pharmacy,
- in a branch pharmacy, or
- at a doctor's dispensary.

Article 15(1) of the ZLD-1 states as follows:

Pharmaceutical activity is funded through public and private resources. The public resources referred to in the previous sentence include, in particular:

- payments for services provided in the context of pharmaceutical activity on the basis of contracts concluded with health insurance bodies,
- payments from budget appropriations,
- the founding institution's resources.

Article 27(1) of the ZLD-1 states as follows:

A public pharmacy body at primary level is established within its territory by a municipality or jointly by several neighbouring municipalities, after consultation with the competent professional body and with the agreement of the Ministry.

Article 39(1) of the ZLD-1 states as follows:

For the exercise of pharmaceutical activity at primary level, a concession may be granted, under the conditions laid down in this law, to a natural person who is the owner of the pharmaceutical business or to a legal person in which the owner of the pharmaceutical business – who is also the manager or the governing body of that legal person – holds more than 50% of the share capital ('the concessionaire').

Description of the pharmaceutical activity at issue in the main proceedings

- 19 In the Republic of Slovenia, pharmaceutical activity is regulated by law in order to ensure that all services involving the supply of medicines to users are performed by persons adequately qualified for that purpose, so as to avoid the risk of harming the health of the users of those services. The fundamental objective of carrying out pharmaceutical activity is therefore not the making of a profit, but, rather, the pursuit of an individual profit-making purpose is subordinate to the exercise of the right to healthcare and, within the community, to the satisfaction of public needs in the interest of public health. The above applies irrespective of who is exercising the pharmaceutical activity.
- 20 In the Republic of Slovenia, pharmaceutical activity is part of the health service and is carried out as a public health service, through which the continuous and regular supply of medicines to the population and health professionals and the pharmaceutical treatment of patients is guaranteed. The purpose of these activities is to ensure an efficient and high-quality supply of medicines and other products to support medical treatment and health protection, and to provide advice to patients and health professionals on their safe, correct and effective use. An essential element of pharmaceutical activity is the supply of prescription and non-prescription medicines for human and veterinary use (retail trade in medicines), and the supply of foods for special medical purposes, where supply of a medicine means the delivery of the medicine to the user along with the provision of appropriate instructions for use and advice on correct and safe use. The retail trade in medicines for human use, accompanied by appropriate professional advice, is

only carried out in pharmacies and specialised outlets, but to a very limited extent in the latter.¹¹

- 21 The network of pharmaceutical activities at primary level is managed by the municipalities, which are autonomous local authorities. Municipalities exercise their competence to establish a network of pharmaceutical activities through the (co-)establishment of a public pharmaceutical body, and thus by granting a concession for the exercise of pharmaceutical activity to a natural or legal person. Pharmaceutical activity takes place in pharmacies, branch pharmacies or doctor's dispensaries.
- 22 Legal persons (not established by a municipality) may therefore only exercise pharmaceutical activity if a concession is granted. This position is held by natural or legal persons (not established by a municipality) in the territory of the municipality that granted the concession, or in the territory of neighbouring municipalities, if these have jointly granted a concession. It is therefore only through the granting of a concession that natural or legal persons (not established by a municipality) are given the possibility of exercising pharmaceutical activity.
- 23 Pharmaceutical activity is funded through public and private resources. Public resources – namely funds generated through compulsory health insurance – are used to fund the supply of prescription medicines, which includes both the prescription medicine itself¹² and the pharmaceutical service associated with that supply, as well as the provision of appropriate instructions and advice on the correct and safe use of the medicine. The pharmaceutical service charge for the supply of a prescription medicine (weighted by score) is the same for all prescription medicines and for all pharmaceutical service providers. Public resources are also used to fund stand-by and on-call services.
- 24 Non-prescription medicines are paid for entirely from private or user resources. In this context, some non-prescription medicines have a maximum price, while others have a price determined according to free market rules.

¹¹ Namely only with the specific authorisation of the Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices) and only for medicinal products and medical devices not subject to medical prescription, which are intended only to alleviate the mildest symptoms and the use of which may involve only a low level of risk. In such cases, that Agency may also impose restrictions on the dosage of medicinal products, the size of the corresponding packs and the number of units sold [Article 126 of the Zakon o zdravilih (Law on medicinal products)].

¹² Medicines that can be prescribed under health insurance are classified in lists (so-called positive or intermediate lists). Inclusion on the list also depends on the proportion of the price of the listed medicine that is covered by compulsory health insurance. The remainder is covered by supplementary health insurance or is borne by the user himself or herself if no supplementary health insurance has been taken out in the form of voluntary health insurance.

Grounds for seeking a preliminary ruling

- 25 The Državna revizijska komisija is seeking to determine whether pharmaceutical activity, such as that at issue in the main proceedings, where the essential element is the supply to users of prescription and non-prescription medicines for human use, along with advice on the correct and safe use of such products, can be regarded as a non-economic service of general interest falling outside the scope of Directive 2014/23.
- 26 Directive 2014/23 does not explicitly define the terms ‘non-economic services of general interest’ and ‘services of general economic interest’. In terms of settled case-law, it follows from the need for a uniform application of EU law and the principle of equality that the terms of a provision of EU law, which make no express reference to the law of the Member States for the purpose of determining its meaning and scope, must normally be given an autonomous and uniform interpretation throughout the European Union, which must take into account the context of the provision and the objective pursued by the legislation in question.
- 27 It follows from recital 6 of Directive 2014/23 that Member States are free to decide to organise the provision of services either as services of general economic interest or as non-economic services of general interest or as a mixture thereof. It is clear from the case-law of the Court of Justice¹³ that EU law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the organisation of health services such as pharmacies, and account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved.
- 28 The national legislature has expressly established that healthcare is a non-economic service of general interest. Since pharmaceutical activity is part of healthcare, the legislature has thus established that pharmaceutical activity is also a non-economic service of general interest.
- 29 Although, according to the Državna revizijska komisija, pharmaceutical activity is a socially relevant activity, since its purpose is to ensure public health and its primary objective is not to make a profit, it is nevertheless apparent from case-law that services normally provided for remuneration constitute economic activities, since the essential characteristic of remuneration resides in the fact that it

¹³ Judgments of the Court of Justice of 19 May 2009, *Commission v Italy* (C-531/06, EU:C:2009:315) and 19 May 2009, *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316).

constitutes financial consideration for the service in question, without however having to be paid for by the recipient of that service.¹⁴

- 30 The Državna revizijska komisija therefore doubts that a pharmaceutical service, such as that at issue in the main proceedings, can be classified as a non-economic service of general interest, since providers of pharmaceutical services are remunerated for the provision of such services from the resources of the compulsory health insurance system and from the resources of users. Under national legislation,¹⁵ in the case of the supply of a prescription medicine, the pharmaceutical service providers receive reimbursement of the purchase price of the medicine from the resources of compulsory health insurance, and also receive a predetermined sum for the handling of the prescription, the delivery of the medicine and advice on its use. In the case of the supply of a non-prescription medicine, users pay the price in full.
- 31 Where services relating to the operation of a pharmaceutical business, such as the one at issue in the main proceedings, where the object is primarily the supply of prescription and non-prescription medicines for human use along with advice on their correct and safe use, cannot be regarded as non-economic services of general interest and where, as a result, the provision of such services falls within the scope of Directive 2014/23, the Državna revizijska komisija raises the further question as to whether the provision of such services can be regarded as social services or other specific services referred to in Annex IV to that directive.
- 32 The services mentioned could be included under the CPV code 85149000 (Pharmaceutical services), but it is not possible to deduce from Regulation (EC) No 2195/2002 on the Common Procurement Vocabulary (CPV) which services are to be included under this CPV code. Equally, the explanatory notes on CPV codes,¹⁶ which do not constitute a formal source of law, do not make it possible to determine which services are included under the CPV code 85149000 (Pharmaceutical services).

Decision and content of the request for a preliminary ruling

- 33 Since the Državna revizijska komisija requires a ruling on the interpretation of European Union law in order for a decision to be adopted, the Državna revizijska komisija hereby submits the following two questions to the Court of Justice for a preliminary ruling under the third paragraph of Article 267 TFEU, with the proviso that the answer to the second question is necessary only if the answer to the first question is negative:

¹⁴ Judgment of 14 [July] 2022, *Asociación Estatal de Entidades de Servicios de Atención a Domicilio (ASADE)*, C-436/20, EU:C:2022:559.

¹⁵ Articles 23 and 63 of the *Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju* (Law on healthcare and health insurance).

¹⁶ [...]

1. **Can a service relating to the exercise of a pharmaceutical activity, the main purpose of which is to supply users with prescription and non-prescription medicines for human use, along with advice to users on the correct and safe use of those medicines, be classified as a ‘non-economic service of general interest’ within the meaning of Article 4(2) of Directive 2014/23/EC?**

2. **Can a service relating to the exercise of a pharmaceutical activity, the main purpose of which is to supply users with prescription and non-prescription medicines for human use, along with advice to users on the correct and safe use of those medicines, be classified in the same way as social and other specific services within the meaning of Article 19 of Directive 2014/23?**

[...]

WORKING DOCUMENT