

Case C-20/22

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

10 January 2022

Referring court:

Conseil d'État (France)

Date of the decision to refer:

30 December 2021

Applicant:

Syndicat Les Entreprises du Médicament (LEEM)

Defendant:

Ministre des Solidarités et de la Santé

1. Subject matter and facts of the dispute:

- 1 The loi du 24 décembre 2019 de financement de la sécurité sociale pour 2020 (Law of 24 December 2019 on social security funding for 2020) inserted into the Code de la sécurité sociale (Social Security Code) Article L. 162-16-4-3, which gave the Ministers responsible for health and social security the authority to set, in given circumstances, for certain medicinal products or health products, a maximum price for sales to health establishments.
- 2 By application of 25 January 2021, the applicant seeks annulment of the decree implementing that article.

2. Provisions at issue:

EU law

Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

3 Article 4 provides:

‘1. In the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. Within 90 days of the start of this review, the competent authorities shall announce what increases or decreases in prices are being made, if any.

2. In exceptional cases, a person who is the holder of a marketing authorisation for a medicinal product may apply for a derogation from a price freeze if this is justified by particular reasons. [...]’.

French legislation

Social Security Code

4 Article L. 162-16-4-3, inserted by Law No 2019-1446 of 24 December 2019 on social security funding for 2020, provides:

‘I. The Ministers responsible for health and social security shall be entitled to set by decree, for certain medicinal products [...] or for certain health products [...], a maximum price for sales to health establishments, in one or more of the following situations:

1. Where there is a risk of unjustified expenditure, including in the light of a significant increase in the sale prices observed or in the light of the prices of comparable health products;

2. In the case of health products which, per unit or taking into account their total volume, foreseeably will be, or have been observed to be, particularly expensive for certain establishments.

II. The maximum price provided for in [paragraph] I shall be set, after the undertaking has been given the opportunity to comment:

[...]

III. The detailed rules for the implementation of this Article shall be defined by decree of the Conseil d'État [(Council of State, France)].'

Décret n° 2020-1437 du 24 novembre 2020 relatif aux modalités de fixation du prix maximal de vente aux établissements de santé d'un produit de santé (Decree No 2020-1437 of 24 November 2020 relating to the detailed rules for setting the maximum price for sales to health establishments of a health product)

3. Position of the applicant:

- 5 By means of a plea of illegality, the applicant maintains that the contested decree, and Article L. 162-16-4-3 of the Social Security Code, which it implements, infringe Article 4 of Directive 89/105. According to the applicant, the mechanism which Article L. 162-16-4-3 puts in place for capping the sale price of certain medicinal products constitutes a mechanism for a 'price freeze [...] on all medicinal products or on certain categories of medicinal products' within the meaning of Article 4 of Directive 89/105. It was therefore required to provide for an annual assessment of the macro-economic conditions justifying that the 'freeze be continued unchanged' and for the possibility for the party exploiting a proprietary medicinal product to benefit from a derogation 'in exceptional cases' and 'if this is justified by particular reasons'.

4. Assessment of the Council of State:

- 6 In the context of a reference by the Italian Council of State, which was ruling on legislation which offered the possibility, for the Minister responsible for health, to set an overall cap on pharmaceutical expenditure incurred as part of national health expenditure without a prior decision to freeze prices having formally been taken, the Court of Justice ruled in its judgment of 2 April 2009, *A. Menarini Industrie Farmaceutiche Riunite and Others* (C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07, EU:C:2009:217, paragraph 29), that 'the meaning of a "price freeze ... on all medicinal products or on certain categories of medicinal products" in Article 4(1) of Directive 89/105 encompasses all national measures controlling the prices of medicinal products even if those measures are not preceded by a freeze on those prices'. The Court of Justice based that interpretation on the general scheme of Directive 89/105 and its effectiveness in enabling the persons concerned to verify that the official listing of medicinal products corresponds to objective criteria and that there is no discrimination between national medicinal products and those from other Member States. The Court of Justice, however, also recalled, in paragraphs 35 and 36 of that judgment, that under the sixth recital of Directive 89/105, the requirements of that directive affect neither the Member States' policies for determining the prices of medicinal products nor national policies on price setting or the determination of social security schemes, except as far as it is necessary to attain transparency for the purposes of that directive, which has as its underlying principle the idea of

minimum interference in the organisation by Member States of their domestic social security policies.

- 7 The response to the plea in law alleging infringement of Article 4 of Directive 89/105 depends on the question of whether the concept of a ‘price freeze [...] on all medicinal products or on certain categories of medicinal products’ appearing in Article 4 of Directive 89/105 must be interpreted as applying to a measure whose purpose is to control the prices of medicinal products but which concerns only certain medicinal products, on an individual basis. In the present case, the mechanism which Article L. 162-16-4-3 puts in place for capping the price for sales to health establishments, whilst it seeks to control the prices of the medicinal products to which it is applied, relates only to certain medicinal products, on an individual basis, in the event of the fulfilment of one or more of the conditions which it sets down. It is not, therefore, intended to apply to all medicinal products or even to certain categories of them. Moreover, the assessment at least annually of the macro-economic conditions justifying that the freeze be continued unchanged, provided for by Article 4(1) of the directive, seems, in the present case, to be meaningless since, as already stated, the conditions set down by Article L. 162-16-4-3 of the Social Security Code for the measure for which it provides to be taken are not of a macro-economic nature but are based on the sale prices observed for the medicinal product concerned, considered alone or in the light of comparable medicinal products. Similarly, the possibility which, pursuant to Article 4(2) of the directive, must be offered to the holder of a marketing authorisation for a medicinal product to apply, in exceptional cases, for a derogation from a price freeze if this is justified by particular reasons seems pointless as regards a mechanism designed to take the form of individual decisions.
- 8 That question, which plays a decisive role in the resolution of the dispute, presents serious difficulties. It is necessary, consequently, to refer it to the Court of Justice.

5. Question referred for a preliminary ruling:

- 9 The proceedings brought by the syndicate Les Entreprises du médicament are stayed until the Court of Justice of the European Union has ruled on the question of whether

Article 4 of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems must be interpreted as meaning that the concept of a ‘price freeze [...] on all medicinal products or on certain categories of medicinal products’ applies to a measure whose purpose is to control the prices of medicinal products but which concerns only certain medicinal products, on an individual basis, and is not intended to apply to all medicinal products or even to certain categories of them, when the safeguards which that article attaches to the existence of such a price-freezing

measure as defined by that article appear, for such a measure, meaningless and pointless.

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