Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

23 April 2020 *

(References for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Articles 62 and 69 — Particulars on the labelling and package leaflet of homeopathic medicinal products — Exhaustive list of the particulars or possibility to add information that is useful to the patient and is compatible with the summary of product characteristics –Dosage schedules for homeopathic medicinal products)

In Joined Cases C-101/19 and C-102/19,

REQUESTS for a preliminary ruling under Article 267 TFEU from the Bundesverwaltungsgericht (Federal Administrative Court, Germany), by decisions of 6 November 2018, received at the Court on 11 February 2019, in the proceedings

Deutsche Homöopathie-Union DHU Arzneimittel GmbH & Co. KG

v

Bundesrepublik Deutschland,

THE COURT (Eighth Chamber),

composed of L.S. Rossi, President of the Chamber, J. Malenovský (Rapporteur) and F. Biltgen, Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Deutsche Homöopathie-Union DHU Arzneimittel GmbH & Co. KG, by A. Pannenbecker, Rechtsanwalt,

– the Bundesrepublik Deutschland, by K. Hechinger, acting as Agent,

– the Greek Government, by V. Karra, S. Charitaki and S. Papaioannou, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and F. De Luca, avvocato dello Stato,

– the Polish Government, by B. Majczyna, acting as Agent,

* Language of the case: German.

– the European Commission, by A.C. Becker and A. Sipos, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of Articles 62 and 69 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) ('Directive 2001/83').

2 The requests have been made in two proceedings between Deutsche Homöopathie-Union DHU Arzneimittel GmbH & Co. KG ('DHU') and the Bundesrepublik Deutschland (Federal Republic of Germany) concerning the refusal to register homeopathic medicinal products the package leaflets of which include dosage schedules.

Legal context

EU law

3 Recitals 2, 5, 17, 21, 23, 25 and 40 of Directive 2001/83 are worded as follows:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

…

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

…

(17) It is necessary to adopt specific provisions for immunological medicinal products, homeopathic medicinal products, radiopharmaceuticals, and medicinal products based on human blood or human plasma.

…

(21) Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient.

…

(23) It is desirable in the first instance to provide users of these homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety.

…

(25) The usual rules governing the authorisation to market medicinal products should be applied to homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect. In particular, those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission.

…

(40) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'

4 Under Article 1 of Directive 2001/83:

'For the purposes of this directive, the following terms shall bear the following meanings:

…

5. Homeopathic medicinal product:

Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic medicinal product may also contain a number of principles.

…

25. Labelling:

Information on the immediate or outer packaging.

26. Package leaflet:

A leaflet containing information for the user which accompanies the medicinal product.

…'

5 Article 8(3) of that directive provides:

'The application [for a marketing authorisation] shall be accompanied by the following particulars and documents, submitted in accordance with Annex I:

…

(e) Therapeutic indications, contra-indications and adverse reactions.

(f) Posology, pharmaceutical form, method and route of administration and expected shelf life.

…’

6 Under Article 11 of that directive:

‘The summary of the product characteristics shall contain, in the order indicated below, the following information:

…

4. clinical particulars:

…

4.2. posology and method of administration for adults and, where necessary for children,

…’

7 Article 14(1) and (2) of that directive is worded as follows:

‘1. Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

– they are administered orally or externally,

– no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto,

– there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor’s prescription.

…

2. The criteria and rules of procedure provided for in Article 4(4), Article 17(1) and Articles 22 to 26, 112, 116 and 125 shall apply by analogy to the special, simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.’

8 Pursuant to Article 16(1) of Directive 2001/83:

‘Homeopathic medicinal products other than those referred to in Article 14(1) shall be authorised and labelled in accordance with Articles 8, 10, 10a, 10b, 10c and 11.’

9 Under Article 58 of that directive:

‘The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.’

10 Article 59(1) of that directive states:

‘The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

…

(d) the necessary and usual instructions for proper use, and in particular:
(i) the dosage,
(ii) the method and, if necessary, route of administration;

…’

11 In accordance with Article 62 of that directive:

‘The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature.’

12 Article 68 of Directive 2001/83 provides:

‘Without prejudice to the provisions of Article 69, homeopathic medicinal products shall be labelled in accordance with the provisions of this title and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.’

13 Under Article 69 of that directive:

‘1. In addition to the clear mention of the words “homeopathic medicinal product”, the labelling and, where appropriate, the package insert for the medicinal products referred to in Article 14(1) shall bear the following, and no other, information:

– the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(5); if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name,

– name and address of the registration holder and, where appropriate, of the manufacturer,

– method of administration and, if necessary, route,

– expiry date, in clear terms (month, year),

– pharmaceutical form,

– contents of the sales presentation,

– special storage precautions, if any,

– a special warning, if necessary for the medicinal product,

– manufacturer’s batch number,

– registration number,

– "homeopathic medicinal product without approved therapeutic indications",

– a warning advising the user to consult a doctor if the symptoms persist.

2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:

– the price of the medicinal product,

– the conditions for refunds by social security bodies.'

German law

14 In accordance with the first sentence of Paragraph 38(1) of the Gesetz über den Verkehr mit Arzneimitteln (Law relating to trade in medicinal products), in the version published on 12 December 2005 (BGBl. I, p. 3394), as last amended by the Law of 18 July 2017 (BGBl. I, p. 2757) ('the AMG'), medicinal products (finished products) which are medicinal products within the meaning of Paragraph 2(1) or Paragraph 2(2), point 1, of the AMG can be placed on the market as homeopathic medicinal products only if they have been entered in a register of homeopathic medicinal products kept by the competent higher federal authority.

15 Under the first sentence of Paragraph 38(2), read in conjunction with Paragraph 22(1), point 10, of the AMG, the application for registration must include, inter alia, particulars concerning the dosage. As follows from Paragraph 39(2), point 1, of the AMG, the competent higher federal authority must refuse registration, inter alia, where the documents submitted are incomplete, or, pursuant to Paragraph 39(2), point 4, of the AMG, where there is reason to suspect that a medicinal product, if used as intended, will have harmful effects to an extent beyond that found to be acceptable by medical science.

16 Under the first sentence of Paragraph 11(3) of the AMG, read in conjunction with Paragraph 10(4) thereof, particulars relating to the dosage are not part of those which must be included in the package leaflet. By contrast, according to Paragraph 10(4), first sentence, point 7, the mandatory information includes warnings, including information other than that provided for by EU law, in so far as it is necessary for safe use.

17 In accordance with the first sentence of Paragraph 11(3) of the AMG, read in conjunction with the seventh sentence of Paragraph 11(1) thereof, voluntary information is permissible in so far as it relates to the use of the medicinal product, is useful from the point of view of the health education of patients and is not inconsistent with the information provided for in Paragraph 11a of the AMG (specialist information).

The disputes in the main proceedings and the questions referred for a preliminary ruling

18 On 8 and 12 June 2009, DHU made applications for registration to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products, Germany; 'the Institute') concerning two homeopathic medicinal products in the form of a cream to be applied to the skin, namely 'Calcium fluoratum Lotio Biochemisches Funktionsmittel Nr. 1' (Case C-101/19) and 'Silicea Lotio Biochemisches Funktionsmittel Nr. 11' (Case C-102/19).

19 The package leaflets of those medicinal products provided, in similar terms, dosage schedules as follows:

'Unless otherwise indicated, the usual route of administration is the following: the [name of the medicinal product] must be applied 1 to 2 times a day. Apply the cream in a thin layer and massage gently until absorbed. Homeopathic medicinal products must not be used over longer periods without medical advice.'

20 By decisions of 23 December 2011, the Institute granted the requested registrations; however, it did so on the condition that DHU remove the dosage schedules from the package leaflets.

21 The actions brought by DHU against those decisions were dismissed by the administrative court at first instance and subsequently by the administrative court on appeal, the latter ruling, inter alia, that:

– the dosage schedules do not form part of either the mandatory information to be supplied for the medicinal product or the essential characteristics thereof;

– those schedules cannot be subject to registration simply because DHU is required to supply information concerning the dosage during the registration procedure, and

– the applicable rules do not provide for inclusion of the dosage in the information on registered homeopathic medicinal products and, in any event, the dosage is not useful information for the purposes of the health education of the patient.

22 Having been granted leave to lodge an appeal on a point of law due to the fundamental importance of the legal question raised in the present case, DHU lodged an appeal on a point of law before the referring court.

23 In those circumstances, the Bundesverwaltungsgericht (Federal Administrative Court, Germany) decided to stay the proceedings and to refer the following questions, which are worded identically in Case C-101/19 and Case C-102/19, to the Court of Justice for a preliminary ruling:

'(1) Does Article 69 of Directive [2001/83] make exhaustive provision with respect to the permissible content of package leaflets for the medicinal products referred to in Article 14(1) [of that directive] or may other information within the meaning of Article 62 of [that directive] be included?

(2) May dosage schedules for the medicinal products referred to in Article 14(1) of Directive [2001/83] constitute information which is useful to the patient within the meaning of Article 62 of [that directive]?'

Consideration of the questions referred

24 By its two questions, which it is appropriate to examine together, the referring court asks, in essence, whether Directive 2001/83 must be interpreted as precluding the package leaflet referred to in Article 69 thereof from including information other than that listed in that provision, in particular dosage schedules for homeopathic medicinal products covered by that provision.

25 In the first place, it must be noted that Article 69(1) of Directive 2001/83 concerns only the category of homeopathic medicinal products defined in Article 1, point 5, of that directive as any medicinal product prepared from substances called 'homeopathic stocks' in accordance with a homeopathic

manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States and which can, under that provision, contain a number of principles.

26 However, it is apparent from Articles 13 to 16 of Directive 2001/83, which form part of Chapter 2 of that directive, entitled 'Specific provisions applicable to homeopathic medicinal products', in turn contained in Title III of that directive, entitled 'Placing on the market', that that directive distinguishes between homeopathic medicinal products which require an authorisation in order to be placed on the market and those subject to a special, simplified registration procedure.

27 It follows from Article 16(1) of Directive 2001/83, read in the light of recital 25 thereof, that homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks are subject to the usual rules governing the authorisation to market medicinal products.

28 Under Article 14(1) of that directive, which expressly refers to Article 69 thereof, only homeopathic medicinal products which satisfy three cumulative conditions may be subject to a special, simplified registration procedure, namely that they are administered orally or externally, that no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto, and that there is a sufficient degree of dilution to guarantee its safety (see, to that effect, judgment of 12 May 2005, *Meta Fackler*, C-444/03, EU:C:2005:288, paragraph 16).

29 In the second place, Article 69(1) of Directive 2001/83 falls under Title V, entitled 'Labelling and package leaflet'.

30 In accordance with Article 1, point 25, of that directive, the term 'labelling' must be understood as referring to 'information on the immediate or outer packaging'. As regards the term 'package leaflet', Article 1, point 26, of that directive defines it as being 'a leaflet containing information for the user which accompanies the medicinal product'.

31 As regards the latter concept, it is important to note, first, that Article 58 of Directive 2001/83 states that the inclusion in the packaging of all medicinal products of a package leaflet is to be obligatory unless all the information required by Articles 59 and 62 of that directive is directly conveyed on the outer packaging or on the immediate packaging.

32 Next, Article 59(1) of that directive lays down the indications, information and instructions that the package leaflet must contain, which include 'the necessary and usual instructions for proper use'. These include the dosage of the medicinal product.

33 Finally, Article 62 of that directive provides that the package leaflet may also include, on a voluntary basis, other information, in particular information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of an element of a promotional nature.

34 In the third place, as regards, more specifically, the labelling of homeopathic medicinal products, Article 68 of Directive 2001/83 contains the rule according to which, without prejudice to the provisions of Article 69 of that directive, such medicinal products are to be identified by a reference on their labels, in clear and legible form, to their homeopathic nature and must be labelled in accordance with the provisions of Title V of that directive.

35 In those circumstances, it must be considered that the rule in Article 68 of Directive 2001/83 is a general rule from which the provisions of Article 69 of that directive derogate as special rules.

36 With respect to those special provisions, Article 69(1) of Directive 2001/83 provides that the labelling and, where appropriate, the package insert for the medicinal products referred to in Article 14(1) of that directive is to bear various information listed in the provision, and no other information.

37 It is clear from the wording of Article 69(1) of Directive 2001/83 that, first, only the homeopathic medicinal products referred to in Article 14(1) of that directive, which therefore satisfy the conditions referred to in paragraph 28 of the present judgment, are subject to the derogation from Article 68 of that directive.

38 Next, in the light of the expression 'where appropriate' used in Article 69(1) of Directive 2001/83, read in conjunction with Article 58 of that directive, the package leaflet of the medicinal product concerned is not mandatory unless the information referred to in Article 69(1) is not directly conveyed on the outer packaging or on the immediate packaging.

39 Finally, it is apparent from the expression 'shall bear the following, and no other, information', also used in Article 69(1) of Directive 2001/83, first, that where the package leaflet is mandatory, all the information listed in that provision must necessarily be included in that package leaflet, and, second, that no other information may be added, with the exception of the information listed exhaustively in Article 69(2) of that directive, where the Member State concerned requires that additional information to be shown.

40 It must be noted that dosage schedules are not included in the information listed in Article 69(1) and (2) of Directive 2001/83.

41 In those circumstances, dosage schedules cannot be included, in addition to the information listed in Article 69(1) and (2) of Directive 2001/83, either directly or indirectly, under Article 62 of that directive, which allows for certain voluntary information to be added, in the package leaflet of homeopathic medicinal products within the meaning of Article 14(1) of that directive.

42 That interpretation is not called into question by the fact that the Polish-language version of Article 69(1) of Directive 2001/83 omits the reference to 'no other information'.

43 The need for uniform application and, therefore, for uniform interpretation of an EU measure precludes one version of the text being considered in isolation, but requires that the measure be interpreted by reference to the general scheme and purpose of the rules of which it forms part (see, to that effect, judgments of 17 March 2016, *Kødbranchens Fællesråd*, C-112/15, EU:C:2016:185, paragraph 36, and of 20 December 2017, *Polkomtel*, C-277/16, EU:C:2017:989, paragraph 59).

44 Furthermore, beyond the various criteria for the interpretation of Article 69(1) of Directive 2001/83 set out in the preceding paragraphs of the present judgment, the conclusion in paragraph 41 thereof is corroborated by the interest of safeguarding public health, which is, as stated in recital 2 of that directive, the essential aim of any rules governing the production, distribution and use of medicinal products.

45 In accordance with Article 8(3)(e) and (f) of that directive, the particulars relating to the posology and the therapeutic indications are necessary for medicinal products that require a marketing authorisation, in contrast to the homeopathic medicinal products referred to in Article 69(1) of that directive, which are subject only to a special, simplified registration procedure.

46 As regards the latter medicinal products, allowing the package leaflet to include dosage schedules in addition to the information listed in Article 69 of Directive 2001/83 would have the effect of rendering the distinction between homeopathic medicinal products and those requiring a marketing authorisation unclear, uncertain and inconsistent and could ultimately deceive users as to the characteristics of the medicinal product concerned.

47 In the light of the foregoing considerations, the answer to the questions referred is that Directive 2001/83 must be interpreted as precluding the package leaflet referred to in Article 69 thereof from including information other than that listed in that provision, in particular dosage schedules for homeopathic medicinal products covered by that provision.

Costs

48 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Eighth Chamber) hereby rules:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as modified by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as precluding the package leaflet referred to in Article 69 thereof from including information other than that listed in that provision, in particular dosage schedules for homeopathic medicinal products covered by that provision.

[Signatures]