JUDGMENT OF THE COURT (Second Chamber)

4 May 2016 (*)

(Reference for a preliminary ruling — Approximation of laws — Directive 2014/40/EU — Articles 7, 18 and 24(2) and (3) — Articles 8(3), 9(3), 10(1)(a), (c) and (g), 13 and 14 — Manufacture, presentation and sale of tobacco products — Validity — Legal basis — Article 114 TFEU — Principle of proportionality — Principle of subsidiarity — Fundamental rights of the European Union — Freedom of expression — Charter of Fundamental Rights of the European Union — Article 11)

In Case C-547/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court) (United Kingdom), made by decision of 7 November 2014, received at the Court on 1 December 2014, in the proceedings

**The Queen,** on the application of:

**Philip Morris Brands SARL,**

**Philip Morris Ltd,**

**British American Tobacco UK Ltd**

v

**The Secretary of State for Health,**

Interested parties and interveners:

**Imperial Tobacco Ltd,**

**JT International SA,**

**Gallaher Ltd,**

**Tann UK Ltd,**

**Tannpapier GmbH,**

**V. Mane Fils,**

**Deutsche Benkert GmbH & Co. KG,**

**Benkert UK Ltd,**

**Joh. Wilh. von Eicken GmbH,**

THE COURT (Second Chamber),

composed of R. Silva de Lapuerta, President of the First Chamber, acting as President of the Second Chamber, J.L. da Cruz Vilaça, A. Arabadjiev (Rapporteur), C. Lycourgos and J.-C. Bonichot, Judges,

Advocate General: J. Kokott,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 1 October 2015,

after considering the observations submitted on behalf of:

– Philip Morris Brands SARL and Philip Morris Ltd, by M. Demetriou QC, K. Nairn QC, D. Piccinin and J. Egerton-Peters, Barristers,

– British American Tobacco UK Ltd, by N. Pleming QC, S. Ford and D. Scannell, Barristers, and L. Van Den Hende, advocaat, instructed by A. Lidbetter, Solicitor,

– Imperial Tobacco Ltd, by D. Rose QC, B. Kennelly and J. Pobjoy, Barristers, instructed by E. Sparrow and J. Gale, Solicitors,

– JT International SA and Gallaher Ltd, by J. MacLeod QC, D. Anderson QC, J. Flynn QC and V. Wakefield, Barrister, instructed by A. Morfey, T. Snelling and T. Baildam, Solicitors,

– Tann UK and Tannpapier GmbH, by T. Johnston, Barrister, instructed by S. Singleton, Solicitor,

– V. Mane Fils, by M. Chamberlain QC and Z. Al-Rikabi, Barrister, instructed by P. Wareham and J. Robinson, Solicitors,

– Deutsche Benkert GmbH & Co. KG and Benkert UK Ltd, by A. Henshaw QC and D. Jowell QC, instructed by M. Evans and F. Liberatore, Solicitors,

– Joh. Wilh. von Eicken GmbH, by A. Howard, Barrister, instructed by A.-M. Irwin and A. Rook, Solicitors,

– the United Kingdom Government, by V. Kaye and C. Brodie, acting as Agents, and by M. Hoskins QC, I. Rogers QC and S. Abram and E. Metcalfe, Barristers,

– Ireland, by J. Quaney and A. Joyce, acting as Agents, and by E. Barrington, Senior Counsel, J. Cooke, Senior Counsel, and E. Carolan, Barrister-at-Law,

– the French Government, by D. Colas and R. Coesme, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and P.G. Marrone, avvocato dello Stato,

– the Hungarian Government, by M.Z. Fehér, G. Koós and M. Bóra, acting as Agents,

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

– the Portuguese Government, by L. Inez Fernandes and A. Seiça Neves, acting as Agents,

– the European Parliament, by L. Visaggio, A. Tamás and M. Sammut, acting as Agents,

– the Council of the European Union, by J. Herrmann, O. Segnana and M. Simm, acting as Agents,

– the European Commission, by M. Van Hoof, J. Tomkin and C. Cattabriga, acting as Agents,

– the Kingdom of Norway, by K. Moen and K. Kloster, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 23 December 2015,

gives the following

**Judgment**

1 This request for a preliminary ruling concerns the interpretation and validity of a number of provisions of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1).

2 The request has been made in two sets of proceedings brought by (i) Philip Morris Brands SARL and Philip Morris Ltd ('PMI') and (ii) British American Tobacco UK Ltd ('BAT') against the Secretary of State for Health, concerning the legality of the 'intention and/or obligation' of the United Kingdom Government to implement Directive 2014/40.

**Legal context**

*World Health Organisation Framework Convention on Tobacco Control*

3 In the words of the preamble to the World Health Organisation Framework Convention on Tobacco Control ('the FCTC'), signed in Geneva on 21 May 2003, to which the European Union and its Member States are party, the Parties to that convention recognise that 'scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability' and that 'cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases'.

4 Article 7 of the FCTC, which is entitled 'Non-price measures to reduce the demand for tobacco', provides:

'… Each Party shall adopt and implement effective legislative, executive, administrative or other measures necessary to implement its obligations pursuant to Articles 8 to 13 and shall cooperate, as appropriate, with each other directly or through competent international bodies with a view to their implementation. The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of these Articles.'

5 Article 9 of the FCTC, which is entitled 'Regulation of the contents of tobacco products', provides:

'The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.'

6 Article 11 of the FCTC, which is entitled 'Packaging and labelling of tobacco products', provides:

'1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light” or “mild”; and

(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:

…

(iii) shall be large, clear, visible and legible,

(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,

(v) may be in the form of or include pictures or pictograms.’

7 Under Section 1.1 of the Partial Guidelines for Implementation of Articles 9 and 10 of the World Health Organisation Framework Convention on Tobacco Control (‘the Partial Guidelines for Implementation of Articles 9 and 10 of the FCTC’), the parties ‘are ... encouraged to implement measures beyond those recommended by these guidelines’.

8 Section 3.1.2 of those partial guidelines, which is headed ‘Ingredients (Regulation)’, describes the measures that the Contracting Parties could introduce to regulate ingredients, stating as follows:

‘3.1.2.1 Background

Regulating ingredients aimed at reducing tobacco product attractiveness can contribute to reducing the prevalence of tobacco use and dependence among new and continuing users. ...

3.1.2.2 Tobacco Products

(i) Ingredients used to increase palatability

The harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. Tobacco industry documents have shown that significant effort has been put into mitigating these unfavourable characteristics. Harshness can be reduced in a variety of ways including: adding various ingredients, eliminating substances with known irritant properties, balancing irritation alongside other significant sensory effects, or altering the chemical properties of tobacco product emissions by adding or removing specific substances.

…

Masking tobacco smoke harshness with flavours contributes to promoting and sustaining tobacco use. Examples of flavouring substances include benzaldehyde, maltol, menthol and vanillin.

Spices and herbs can also be used to improve the palatability of tobacco products. Examples include cinnamon, ginger and mint.

Recommendation

Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products.

…'

9 Under point 7 of the Guidelines for Implementation of Article 11 (Packaging and labelling of tobacco products) of the World Health Organisation Framework Convention on Tobacco Control (the 'Guidelines for Implementation of Article 11 of the FCTC'):

'Well-designed health warnings and messages are part of a range of effective measures to communicate health risks and to reduce tobacco use. Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text-only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. Larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people. Other elements that enhance effectiveness include locating health warnings and messages on principal display areas, and at the top of these principal display areas; the use of colour rather than just black and white; requiring that multiple health warnings and messages appear concurrently; and periodic revision of health warnings and messages.'

10 Point 12 of those guidelines, headed 'Size', states:

'Article 11.1(b)(iv) of the [FCTC] specifies that health warnings and messages on tobacco product packaging and labelling should be 50% or more, but no less than 30%, of the principal display areas. Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible. The text of health warnings and messages should be in bold print in an easily legible font size and in a specified style and colour(s) that enhance overall visibility and legibility.'

*Directive 2014/40*

11 Directive 2014/40 includes the following recitals:

'(7) Legislative action at Union level is ... necessary in order to implement the [FCTC] ..., the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.

…

(15) The lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. Some Member States have adopted legislation or entered into binding agreements

with the industry allowing or prohibiting certain ingredients. As a result, some ingredients are regulated in some Member States, but not in others. Member States also take differing approaches as regards additives in the filters of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles to the smooth functioning of the internal market are expected to increase in the coming years, taking into account the implementation of the FCTC and the relevant FCTC guidelines throughout the Union and in the light of experience gained in other jurisdictions outside the Union. The FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

(16) The likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than one of tobacco, which could facilitate initiation of tobacco consumption or affect consumption patterns. Measures introducing unjustified differences of treatment between different types of flavoured cigarettes should be avoided. However, products with characterising flavour with a higher sales volume should be phased out over an extended time period to allow consumers adequate time to switch to other products.

(17) The prohibition of tobacco products with characterising flavours does not preclude the use of individual additives outright, but it does oblige manufacturers to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. ...

…

(22) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the use of combined health warnings consisting of a picture and a text, information on cessation services and promotional elements in and on unit packets.

(23) Such disparities are liable to constitute a barrier to trade and to impede the smooth functioning of the internal market in tobacco products, and should, therefore, be eliminated. Also, it is possible that consumers in some Member States are better informed about the health risks of tobacco products than consumers in other Member States. Without further action at Union level, the existing disparities are likely to increase in the coming years.

(24) Adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. ...

(25) The labelling provisions should also be adapted to new scientific evidence. For example, the indication of the emission levels for tar, nicotine and carbon monoxide on unit packets of cigarettes has proven to be misleading as it leads consumers to believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings comprised of a text warning and a corresponding colour photograph are more effective than warnings consisting only of text. As a consequence, combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the surface of unit packets. Minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness.

…

(27) Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words “low-tar”, “light”, “ultra-light”, “mild”, “natural”, “organic”, “without additives”, “without flavours” or “slim”, or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. ...

(28) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimensions of the health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including the shape and opening mechanism. ... Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the concerned products.

…

(33) Cross-border distance sales of tobacco products could facilitate access to tobacco products that do not comply with this Directive. There is also an increased risk that young people would get access to tobacco products. Consequently, there is a risk that tobacco control legislation would be undermined. Member States should, therefore, be allowed to prohibit cross-border distance sales. Where cross-border distance sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are appropriate to ensure the effectiveness of this Directive. ...

…

(48) Moreover, this Directive does not harmonise the rules on smoke-free environments ... Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so.

…

(53) Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the FEU [Treaty], with WTO obligations and do not affect the full application of this Directive.

(54) Moreover, in order to take into account possible future market developments, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating

to the specific situation in the Member State concerned and provided the provisions are justified by the need to protect public health, taking into account the high level of protection achieved through this Directive. Member States should notify such stricter national provisions to the Commission.

(55) A Member State should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the FEU [Treaty] and do not jeopardise the full application of this Directive. ...

…

(60) Since the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the EU [Treaty]. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.'

12 Article 1 of Directive 2014/40, entitled 'Subject matter', provides:

'The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;

(c) the prohibition on the placing on the market of tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the obligation to submit a notification of novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;

in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the [FCTC].'

13 In accordance with points 24 and 25 of Article 2 of Directive 2014/40, entitled 'Definitions', 'flavouring' means 'an additive that imparts smell and/or taste', whilst 'characterising flavour' means 'a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product'.

14 Article 7 of that directive, entitled 'Regulation of ingredients', provides as follows:

‘1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

…

7. Member States shall prohibit the placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine.

…

14. In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.’

15 Chapter II, entitled ‘Labelling and packaging’, of Title II of Directive 2014/40 contains, inter alia, rules concerning (i) the health warnings that must appear on the labelling and unit packets, (ii) the presentation of tobacco products, (iii) the appearance and content of unit packets, (iv) the traceability of those products and (v) the security features which the products must carry.

16 In particular, Article 8 of that directive, entitled ‘General provisions’, provides, in paragraph 3:

‘Member States shall ensure that the health warnings on a unit packet and any outside packaging are irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall remain intact when opening the unit packet other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.’

17 Under Article 9 of Directive 2014/40, which is entitled ‘General warnings and information messages on tobacco products for smoking’:

‘1. Each unit packet and any outside packaging of tobacco products for smoking shall carry one of the following general warnings:

“Smoking kills — quit now”

or

“Smoking kills”

Member States shall determine which of the general warnings referred to in the first subparagraph is to be used.

2. Each unit packet and any outside packaging of tobacco products for smoking shall carry the following information message:

“Tobacco smoke contains over 70 substances known to cause cancer.”

3. For cigarette packets and roll-your-own tobacco in cuboid packets the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings shall have a width of not less than 20 mm.

For packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into two when the packet is open, the general warning and the information message shall appear in their entirety on the larger parts of those split surfaces. The general warning shall also appear on the inside of the top surface that is visible when the packet is open.

The lateral surfaces of this type of packet shall have a height of not less than 16 mm.

For roll-your-own tobacco marketed in pouches the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings. For roll-your-own tobacco in cylindrical packets the general warning shall appear on the outside surface of the lid and the information message on the inside surface of the lid.

Both the general warning and the information message shall cover 50% of the surfaces on which they are printed.

…’

18 Article 10 of the directive, entitled ‘Combined health warnings for tobacco products for smoking’, provides

‘1. Each unit packet and any outside packaging of tobacco products for smoking shall carry combined health warnings. The combined health warnings shall:

(a) contain one of the text warnings listed in Annex I and a corresponding colour photograph specified in the picture library in Annex II;

…

(c) cover 65% of both the external front and back surface of the unit packet and any outside packaging. Cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65% of their respective half of the curved surface;

…

(g) in the case of unit packets of cigarettes, respect the following dimensions:

(i) height: not less than 44 mm;

(ii) width: not less than 52 mm.

…’

19 Article 13 of Directive 2014/40, ‘Product presentation’, provides:

‘1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:

(a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

(b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;

(c) refers to taste, smell, any flavourings or other additives or the absence thereof;

(d) resembles a food or a cosmetic product;

(e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.’

20 Under Article 14 of the directive, entitled ‘Appearance and content of unit packets’:

‘1. Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.

2. A unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.’

21 Article 18 of Directive 2014/40, entitled ‘Cross-border distance sales of tobacco products’, is worded as follows:

‘1. Member States may prohibit cross-border distance sales of tobacco products to consumers. Member States shall cooperate to prevent such sales. Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited. Member States which do not prohibit such sales shall require retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State, where the retail outlet is established, and in the Member State, where the actual or potential consumers are located. ...

…

3. The Member States of destination of tobacco products sold via cross-border distance sales may require that the supplying retail outlet nominates a natural person to be responsible for verifying —

before the tobacco products reach the consumer — that they comply with the national provisions adopted pursuant to this Directive in the Member State of destination, if such verification is necessary in order to ensure compliance and facilitate enforcement.

…'

22 Article 24 of that directive, entitled 'Free movement', provides:

'1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.

3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.'

23 Article 28 of Directive 2014/40, entitled 'Report', specifies, in paragraph 2(a), that the Commission, in its report on the application of the directive, is to indicate, amongst other things, 'the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments'.

24 The directive must, under Article 29 thereof, be transposed into the national legal orders of the Member States by 20 May 2016 and the relevant provisions must enter into force from that date.

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

25 PMI and BAT brought claims before the referring court seeking judicial review of the 'intention and/or obligation' of the United Kingdom Government to implement Directive 2014/40 in national law.

26 They argue that the directive is invalid, in whole or in part, on the ground that it infringes Articles 114 TFEU, 290 TFEU and 291 TFEU, the principles of proportionality and subsidiarity and Article 11 of the Charter of Fundamental Rights of the European Union ('the Charter').

27 The referring court considers that the arguments advanced by the claimants in the main proceedings are 'reasonably arguable'.

28 In those circumstances, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is [Directive 2014/40] invalid in whole or in part because Article 114 TFEU does not provide an adequate legal basis? In particular:

(a) In relation to Article 24(2) of [Directive 2014/40]:

(i) on its proper interpretation, to what extent does it permit Member States to adopt more stringent rules in relation to matters relating to the "standardisation" of the packaging of tobacco products; and,

(ii) in light of that interpretation, is Article 24(2) invalid because Article 114 TFEU does not provide an adequate legal basis?

(b) Is Article 24(3) [of Directive 2014/40], which allows Member States to prohibit a category of tobacco or related products in specified circumstances, invalid because Article 114 TFEU does not provide an adequate legal basis?

(c) Are the following provisions invalid because Article 114 TFEU does not provide an adequate legal basis:

(i) the provisions of Chapter II of Title II [of Directive 2014/40], which relate to packaging and labelling;

(ii) Article 7 [of Directive 2014/40], in so far as it prohibits menthol cigarettes and tobacco products with a characterising flavour;

(iii) Article 18 [of Directive 2014/40], which allows Member States to prohibit cross-border distance sales of tobacco products; and,

(iv) Articles 3(4) and 4(5) [of Directive 2014/40], which delegate powers to the Commission in relation to emission levels?

(2) In relation to Article 13 [of Directive 2014/40]:

(a) on its true interpretation, does it prohibit true and non-misleading statements about tobacco products on the product packaging; and,

(b) if so, is it invalid because it violates the principle of proportionality and/or Article 11 of the [Charter]?

(3) Are any or all of the following provisions of [Directive 2014/40] invalid because they infringe the principle of proportionality:

(a) Article 7(1) and (7), in so far as [it] prohibit[s] the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components;

(b) Articles 8(3), 9(3), 10(1)(g) and 14, in so far as they impose various pack standardisation requirements; and,

(c) Article 10(1)(a) and (c), in so far as [it] require[s] health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging?

(4) Are any or all of the following provisions of [Directive 2014/40] invalid because they infringe Article 290 TFEU:

(a) Article 3(2) and (4) concerning maximum emission levels;

(b) Article 4(5) relating to measurement methods for emissions;

(c) Article 7(5), (11) and (12) concerning the regulation of ingredients;

(d) Articles 9(5), 10(1)(f), 10(3), 11(6), 12(3) and 20(12) concerning health warnings;

(e) Article 20(11) concerning the prohibition of electronic cigarettes and/or refill containers; and/or,

(f) Article 15(12) concerning data storage contracts?

(5) Are Articles 3(4) and 4(5) [of Directive 2014/40] invalid because they breach the principle of legal certainty and/or impermissibly delegate powers to external bodies that are not subject to the procedural safeguards required by EU law?

(6) Are any or all of the following provisions of [Directive 2014/40] invalid because they infringe Article 291 TFEU:

(a) Article 6(1) concerning reporting obligations;

(b) Article 7(2) [to] (4) and (10) concerning implementing acts relating to the prohibition of tobacco products in certain circumstances; and/or,

(c) Articles 9(6) and 10(4) concerning health warnings?

(7) Is [Directive 2014/40] and in particular Articles 7, 8(3), 9(3), 10(l)(g), 13 and 14 invalid for failure to comply with the principle of subsidiarity?'

**Consideration of the questions referred**

*Admissibility*

29 The European Parliament, the Council of the European Union and the Commission, as well as the French Government, maintain that the request for a preliminary ruling is inadmissible in whole or in part.

Admissibility of the request for a preliminary ruling in its entirety

30 It is argued that the request for a preliminary ruling is inadmissible in its entirety on the ground (i) that there is no genuine dispute between the parties and (ii) that the claims for judicial review challenging the 'intention and/or obligation' of the United Kingdom Government to implement a directive are a means of circumventing the system of remedies established by the FEU Treaty.

31 In that regard, it should be recalled that it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation or the validity of a rule of EU law, the Court is in principle bound to give a ruling (judgment in *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraph 24).

32 It follows that questions concerning EU law enjoy a presumption of relevance. The Court may refuse to give a ruling on a question referred by a national court only where it is quite obvious that the interpretation, or the determination of validity, of a rule of EU law that is sought bears no relation to the facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment in *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraph 25).

33 As regards, first, the genuine nature of the dispute in the main proceedings, it should be noted that the claims for judicial review of the 'intention and/or obligation' of the United Kingdom Government to implement Directive 2014/40, which the claimants in the main proceedings have brought before the referring court, have been held admissible by the latter, even though, when those claims were brought, the period prescribed for implementation of the directive had not yet expired and no national implementation measures had been adopted. There is, moreover, disagreement between the claimants in the main proceedings and the Secretary of State for Health as to whether or not the abovementioned claims are well founded. Given that the referring court has been asked to resolve that disagreement, it is not obvious that the dispute in the main proceedings is not genuine (see, by analogy, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraphs 36 and 38).

34 As regards, secondly, the argument that the claim for judicial review of the 'intention and/or obligation' of the United Kingdom Government to implement a directive is a means of circumventing the system of remedies established by the FEU Treaty, the Court has already held admissible several requests for preliminary rulings concerning the validity of secondary legislation made in judicial review claims, in particular in the cases that resulted in the judgments in*British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741); *Intertanko and Others* (C-308/06, EU:C:2008:312); and *Afton Chemical* (C-343/09, EU:C:2010:419).

35 Moreover, the opportunity open to individuals to plead the invalidity of an EU act of general application before national courts is not conditional upon that act actually having been the subject of implementing measures adopted pursuant to national law. In that respect, it is sufficient if the national court is called upon to hear a genuine dispute in which the question of the validity of such an act is raised indirectly. That condition is fulfilled in the case of the main proceedings, as is apparent from paragraph 33 of this judgment (see, by analogy, judgments in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 40, and *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraph 29).

36 Accordingly, the request for a preliminary ruling cannot be declared inadmissible in its entirety.

Admissibility of certain of the questions referred

37 The admissibility of certain of the questions referred must be examined in the light, first, of the argument that Question 1(a), (b) and (c)(iii), which concerns the interpretation and validity of Articles 18 and 24(2) and (3) of Directive 2014/40, is hypothetical and unrelated to the purpose of the main proceedings.

38 Articles 18 and 24(2) and (3) of the directive are addressed to the Member States, permitting them, in essence, to maintain or introduce in their domestic legal orders certain prohibitions or further requirements. Whilst it is true that those provisions thus grant the Member States an option, rather than laying down an obligation to act, the fact remains that those provisions may be taken into account when national measures implementing Directive 2014/40 are adopted. Indeed, the nature, content and extent of those measures may vary depending on the interpretation and validity of Articles 18 and 24(2) and (3) of the directive.

39 The fact that the order for reference contains no indication of whether the United Kingdom intends to make use of those provisions when it implements Directive 2014/40 in its domestic legal order does not mean that questions relating to their interpretation and validity are purely hypothetical. Indeed, the decision to make use of those provisions could depend upon the outcome of the main proceedings, which concern precisely the intention and/or obligation of the United Kingdom to implement the directive.

40 Accordingly, it is not obvious that the interpretation and determination of the validity of those provisions are unrelated to the purpose of the main proceedings or that the problems raised are hypothetical.

41 Points (a), (b) and (c)(iii) of Question 1 are thus admissible.

42 As regards, secondly, the admissibility of Question 1, point (c)(iv), and Questions 4 to 6, it must be noted that those questions concern the validity of Article 3(2) and (4), Article 4(5), Article 6(1), Article 7(2) to (5) and (10) to (12), Article 9(5) and (6), Article 10(1)(f), (3) and (4), Article 11(6), Article 12(3), Article 15(12) and Article 20(11) and (12) of Directive 2014/40. Those provisions empower the Commission to adopt various delegated and implementing acts.

43 Clearly, none of those provisions are addressed to the Member States. The provisions do not therefore relate to the implementation of that directive in the domestic legal systems of the Member States.

44 Moreover, it has not been argued that the invalidity of one or more of those provisions would entail the invalidity of other provisions of the directive that do entail implementation by the Member State.

45 That being so, it is obvious that Question 1, point (c)(iv), and Questions 4 to 6 bear no relation to the purpose of the main proceedings, which concern the intention and/or obligation of the United Kingdom to implement Directive 2014/40.

46 Accordingly, Question 1, point (c)(iv), and Questions 4 to 6 must be declared inadmissible.

47 With regard, thirdly, to the admissibility of Question 7, which concerns the validity of Articles 7, 8(3), 9(3), 10(1)(g), 13 and 14 of Directive 2014/40, it should be borne in mind that it follows from the spirit of cooperation which must prevail in the operation of the preliminary reference procedure that it

is essential that the national court sets out in its order for reference the precise reasons why it considers a reply to its questions concerning the interpretation or validity of certain provisions of EU law to be necessary to enable it to give judgment (see to that effect, inter alia, judgments in *Bertini and Others*, 98/85, 162/85 and 258/85, EU:C:1986:246, paragraph 6; *ABNA and Others*, C-453/03, C-11/04, C-12/04 and C-194/04, EU:C:2005:741, paragraph 46; and *IATA and ELFAA*, C-344/04, EU:C:2006:10, paragraph 31).

48 It is therefore important that the national court should set out, in particular, the precise reasons which led it to question the validity of certain provisions of EU law and set out the grounds of invalidity which, consequently, appear to it capable of being upheld (see to that effect, inter alia, judgment in *Greenpeace France and Others*, C-6/99, EU:C:2000:148, paragraph 55, and order in *Adiamix*, C-368/12, EU:C:2013:257, paragraph 22). Such a requirement also arises under Article 94(c) of the Rules of Procedure of the Court.

49 Furthermore, according to settled case-law of the Court, the information provided in orders for reference not only enables the Court to give useful answers but also serves to ensure that the governments of the Member States and other interested persons are given an opportunity to submit observations in accordance with Article 23 of the Statute of the Court of Justice of the European Union. It is for the Court to ensure that that opportunity is safeguarded, given that, under Article 23, only the orders for reference are notified to the interested parties, accompanied by a translation in the official language of each Member State, but excluding any case file that may be sent to the Court by the national court (see, inter alia, judgments in *Holdijk and Others*, 141/81 to 143/81, EU:C:1982:122, paragraph 6; *Lehtonen and Castors Braine*, C-176/96, EU:C:2000:201, paragraph 23; and order in *Adiamix*, C-368/12, EU:C:2013:257, paragraph 24).

50 It follows from the foregoing, first, that in a reference for a preliminary ruling, the Court will examine the validity of an EU act or certain provisions thereof in the light of the grounds of invalidity set out in the order for reference. Secondly, if there is no mention of the precise reasons which led the referring court to question the validity of that act or of those provisions, the questions relating to the validity thereof will be inadmissible.

51 In the present case, the referring court does not explain the reasons why it decided, in the context of Question 7, to raise a question with the Court concerning the validity of Articles 8(3), 9(3), 10(1)(g), 13 and 14 of Directive 2014/40. All the elements in the order for reference which pertain to that question relate exclusively to Article 7 of the directive.

52 In those conditions, Question 7 is admissible only in so far as it concerns Article 7 of Directive 2014/40.

53 Having regard to all the foregoing considerations, the Court must declare inadmissible Question 1, point (c)(iv), Questions 4 to 6 and Question 7 in so far as it concerns Articles 8(3), 9(3), 10(1)(g), 13 and 14 of Directive 2014/40.

*Question 1*

54 By Question 1 the referring court asks, in essence, whether Directive 2014/40 is invalid in whole or in part by reason of the fact that Article 114 TFEU does not provide an adequate legal basis. In

particular, that court has some doubts about the validity of Articles 7, 18 and 24(2) and (3) of the directive and that of the provisions of Chapter II of Title II thereof.

55 The Court notes that, notwithstanding the wording of Question 1, the order for reference does not give any precise ground of invalidity as regards Directive 2014/40 as a whole. The reasoning in the order for reference relates exclusively to the validity of each of the provisions set out in the previous paragraph of this judgment, taken in isolation.

56 In those circumstances, the Court, in answering Question 1, will examine the grounds of invalidity raised against each of those provisions. If, on conclusion of that examination, one of those provisions were to be declared invalid, it would be necessary to consider whether that invalidity affects the validity of Directive 2014/40 as a whole.

57 Article 114(1) TFEU establishes that the Parliament and the Council are to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

58 In that regard, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 114 TFEU, it is otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market (see, to that effect, judgments in *Germany* v *Parliament and Council*, C-376/98, EU:C:2000:544, paragraphs 84 and 95; *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraphs 59 and 60;*Arnold André*, C-434/02, EU:C:2004:800, paragraph 30; *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 29; *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 37; and *Vodafone and Others*, C-58/08, EU:C:2010:321, paragraph 32).

59 It is also settled case-law that, although recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade as a result of divergences in national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them (judgments in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 61; *Arnold André*, C-434/02, EU:C:2004:800, paragraph 31; *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 30; *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 38; and *Vodafone and Others*, C-58/08, EU:C:2010:321, paragraph 33).

60 The Court has also held that, provided that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, the EU legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made (judgments in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 62; *Arnold André*, C-434/02, EU:C:2004:800, paragraph 32;*Swedish Match*, C-210/03, EU:C:2004:802, paragraph 31; and *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 39).

61 The point should also be made that the first subparagraph of Article 168(1) TFEU provides that a high level of human health protection is to be ensured in the definition and implementation of all EU policies and activities, and that Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed (judgments in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 62; *Arnold André*, C-434/02,

EU:C:2004:800, paragraph 33; *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 32; and *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 40).

62 It follows from the foregoing that when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products such as to bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the European Union, Article 114 TFEU authorises the EU legislature to intervene by adopting appropriate measures, in compliance with Article 114(3) TFEU and with the legal principles mentioned in the FEU Treaty or identified in the case-law, in particular the principle of proportionality (judgments in *Arnold André*, C-434/02, EU:C:2004:800, paragraph 34; *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 33; and *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 41).

63 It is also to be observed that, by using the words 'measures for the approximation' in Article 114 TFEU, the authors of the Treaty intended to confer on the EU legislature a discretion, depending on the general context and the specific circumstances of the matter to be harmonised, as regards the method of approximation most appropriate for achieving the desired result, in particular in fields with complex technical features (judgments in *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 42, and *United Kingdom* v *Parliament and Council*, C-270/12, EU:C:2014:18, paragraph 102). It was thus open to the EU legislature, in the exercise of that discretion, to proceed towards harmonisation only in stages and to require only the gradual abolition of unilateral measures adopted by the Member States (judgment in *Rewe-Zentral*, 37/83, EU:C:1984:89, paragraph 20).

64 Depending on the circumstances, the measures referred to in Article 114(1) TFEU may consist in requiring all the Member States to authorise the marketing of the product or products concerned, subjecting such an obligation of authorisation to certain conditions, or even provisionally or definitively prohibiting the marketing of a product or products (judgments in *Arnold André*, C-434/02, EU:C:2004:800, paragraph 35; *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 34; and *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 43).

65 The question whether the conditions for recourse to Article 114 TFEU as a legal basis for the provisions of Directive 2014/40 covered by Question 1 were met must be determined in the light of those principles.

Question 1(a)

66 By Question 1(a) the referring court asks, in essence, whether Article 24(2) of Directive 2014/40 must be interpreted as permitting Member States to adopt rules in relation to the standardisation of the packaging of tobacco products which are more stringent than those provided for by the directive and whether, in light of that interpretation, Article 24(2) is invalid because Article 114 TFEU does not provide an adequate legal basis for it.

67 Under Article 24(1) of Directive 2014/40, Member States may not, for considerations relating to aspects regulated by the directive, and subject to paragraphs 2 and 3 of Article 24, prohibit or restrict the placing on the market of tobacco or related products which comply with the directive. According to Article 24(2), Directive 2014/40 is not to affect the right of a Member State to maintain or introduce,

under certain conditions, ‘further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products’.

68 The claimants in the main proceedings, Ireland, the United Kingdom Government and the Norwegian Government submit that Article 24(2) of Directive 2014/40 permits the Member States to maintain or introduce further requirements in relation to all matters relating to the packaging of tobacco products, regardless of whether or not such matters are regulated by the directive. On the other hand, the Portuguese Government, the Parliament, the Council and the Commission take the view that that power can extend only to the aspects of packaging which have not been harmonised by the directive.

69 It must be observed in this regard that Article 24(2) of Directive 2014/40 may in fact lend itself to several interpretations, and consequently the precise extent of the power granted to the Member States is not entirely unambiguous. First, the directive does not contain a definition of the expressions ‘further requirements’ and ‘standardisation’, which are used in Article 24(2). Secondly, Article 24(2) does not indicate whether or not that power extends to aspects of the packaging of tobacco products which have been harmonised by Directive 2014/40.

70 The Court has consistently held that, if the wording of secondary law is open to more than one interpretation, preference should be given to the interpretation which renders the provision consistent with the Treaty rather than to the interpretation which leads to its being incompatible with the Treaty (see, inter alia, judgment in *Ordre des barreaux francophones et germanophone and Others*, C-305/05, EU:C:2007:383, paragraph 28).

71 If Article 24(2) of Directive 2014/40 were interpreted as permitting Member States to maintain or introduce further requirements in relation to all aspects of the packaging of tobacco products, including those which have been harmonised by the directive, that would amount, in essence, to undermining the harmonisation effected by the directive with regard to the packaging of those products. Indeed, the consequence of such an interpretation would be to permit Member States to replace the requirements relating to packaging which have been harmonised by the directive with other requirements, introduced at national level, and to do so in breach of the rules laid down in Article 114(4) to (10) TFEU relating to the retention and introduction of national provisions derogating from a harmonisation measure.

72 Such an interpretation would render Article 24(2) of Directive 2014/40 incompatible with Article 114 TFEU.

73 However, Article 24(2) of Directive 2014/40 may also be interpreted as meaning that it permits Member States to maintain or introduce further requirements only in relation to aspects of the standardisation of the packaging of tobacco products which have not been harmonised by the directive. Whilst it is true that the wording of Article 24(2) does not contain a specific statement to that effect, the fact remains that such an interpretation is consonant with the objective and general scheme of the directive.

74 It is clear from Article 1(b) of Directive 2014/40 that the objective of the directive is to approximate the laws, regulations and administrative provisions of the Member States concerning ‘certain’ aspects of the labelling and packaging of tobacco products. It follows that the directive is not intended to harmonise all aspects of the labelling and packaging of those products.

75 That conclusion is borne out by Article 28(2)(a) of Directive 2014/40, which provides that, when the Commission prepares the report referred to in Article 28(1) of the directive, it is to pay special attention to, amongst other things, the 'experience gained with respect to the design of package surfaces not governed by [the] directive'.

76 Recital 53 of Directive 2014/40 states in this connection that, in light of the different degrees of harmonisation achieved by the directive, the Member States should retain the power to impose further requirements relating, for example, to the colours of the packaging of tobacco products or to provide for the further standardisation of that packaging. There is nothing in the directive which provides for, or prohibits, such standardisation and nor is there a provision that regulates the colours of the packaging of tobacco products, without prejudice to the requirements set out in Article 13 of the directive.

77 Furthermore, it follows from the general scheme of Directive 2014/40 that the latter does not bring about full harmonisation in relation to the manufacture, presentation and sale of tobacco products and related products. That is borne out by, inter alia, recitals 47 and 48 of the directive, which refer to a number of aspects that are not governed by it. Similarly, recital 55 of the directive states that Member States should remain free to maintain or introduce national laws applying to all products placed on their national markets 'for aspects not regulated by [the] directive'.

78 Consideration must therefore thus be given to whether the interpretation of Article 24(2) of Directive 2014/40 proposed in paragraph 73 of this judgment renders that provision compatible with Article 114 TFEU.

79 Admittedly, by permitting Member States to maintain or introduce further requirements relating to aspects of packaging that have not been harmonised by Directive 2014/40, Article 24(2) does not guarantee that products whose packaging complies with the requirements of the directive may move freely on the internal market.

80 However, that is the inevitable consequence of the method of harmonisation chosen by the EU legislature in the present case. As has been recalled in paragraph 63 of this judgment, the EU legislature has a discretion, in particular with regard to the possibility of proceeding towards harmonisation only in stages and requiring only the gradual abolition of unilateral measures adopted by the Member States.

81 As the Advocate General has observed in point 119 of her Opinion, a measure for partial harmonisation in relation to the labelling and packaging of tobacco products, such as the harmonisation achieved by Directive 2014/40, undeniably offers advantages for the functioning of the internal market, since, whilst it does not eliminate all obstacles to trade, it does eliminate some.

82 In contrast to the directive at issue in the case that gave rise to the judgment in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544), paragraph 1 of Article 24 of Directive 2014/40 read in conjunction with paragraph 2 thereof, as it has been interpreted in paragraph 73 of this judgment, forbids the Member States from preventing, on grounds relating to the aspects of packaging harmonised by that directive, the import, sale or consumption of tobacco products which comply with the requirements laid down by the directive. Those provisions thus play a part in achieving the objective of improving the conditions for the functioning of the internal market and are therefore compatible with Article 114 TFEU (see, by analogy, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 74).

83 It follows that an interpretation of Article 24(2) of Directive 2014/40 to the effect that it permits the Member States to maintain or introduce further requirements solely in relation to aspects of the packaging of tobacco products that are not harmonised by the directive renders Article 24(2) consistent with Article 114 TFEU. Therefore, applying the case-law cited in paragraph 70 of this judgment, the Court accepts that interpretation.

84 In the light of the foregoing considerations, the answer to Question 1(a) is as follows:

– Article 24(2) of Directive 2014/40 must be interpreted as permitting Member States to maintain or introduce further requirements in relation to aspects of the packaging of tobacco products which are not harmonised by that directive;

– consideration of that question has disclosed no factor of such a kind as to affect the validity of that provision.

Question 1(b)

85 By Question 1(b), the referring court asks whether Article 24(3) of Directive 2014/40 is invalid because Article 114 TFEU does not constitute an adequate legal basis for that provision.

86 Article 24(3) of Directive 2014/40 provides, inter alia, that a Member State may prohibit a 'certain category' of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through that directive.

87 It is true that by permitting the Member States to prohibit a certain category of tobacco or related products even though they comply with the requirements of Directive 2014/40, Article 24(3) of the directive is capable of impeding the free movement of those products.

88 However, Directive 2014/40 is not intended to interfere with the policies of the Member States concerning the lawfulness of tobacco products as such.

89 Indeed, recital 48 of Directive 2014/40 makes clear that the directive 'does not harmonise the rules on smoke-free environments'. Such rules could extend from a prohibition on smoking in certain places to a prohibition on the placing on the market of an entire category of tobacco products.

90 It follows that Article 24(3) of Directive 2014/40 concerns an aspect which is not covered by the harmonisation measures in the directive and which is not, therefore, to be subject to the rules laid down in Article 114(4) to (10) TFEU relating to the introduction of national measures derogating from a harmonisation measure.

91 Article 24(3) of Directive 2014/40, read in conjunction with paragraph 1 of that article, thus seeks to delineate the scope of the directive by clarifying that tobacco and related products which comply with the requirements laid down by the directive may move freely on the internal market, provided that those products belong to a category of tobacco products or related products which is, as such, lawful in the Member State in which they are marketed.

92 It should be made clear in this regard that the EU legislature may properly decide to include, in a legislative measure adopted on the basis of Article 114 TFEU, provisions intended to set out the issues which are not the subject of the harmonising measures adopted, particularly since Article 24(3) of

Directive 2014/40 lays down conditions and a mechanism intended to guard against arbitrary discrimination or disguised restrictions on trade between the Member States, in the interest of the smooth functioning of the internal market which underpins Article 114 TFEU.

93 The Court must also reject the argument based on the alleged inconsistency between Article 24(3) of Directive 2014/40 and Article 7 thereof, which is said to result from the fact that, on the one hand, the objective of the prohibition on characterising flavours laid down in Article 7 is to abolish disparities between the rules of the Member States, while, on the other, Article 24(3) facilitates the emergence of such disparities.

94 That argument is, in fact, based on a misunderstanding of the relationship between Article 7 and Article 24(3) of Directive 2014/40. Those provisions, without being in any way contradictory, are complementary. In prohibiting tobacco products with a characterising flavour, Article 7 of the directive seeks to eliminate disparities existing in that respect between the rules of the Member States, in order, in particular, to ensure the free movement of tobacco products in general. Under Article 24(1) of Directive 2014/40, those products, where they comply with, inter alia, Article 7, enjoy freedom of movement on the internal market as long as the category of tobacco products to which they belong is not — as follows from Article 24(3) of the directive — prohibited, as such, in the Member State in which they are marketed.

95 Having regard to the foregoing, consideration of Question 1(b) has disclosed no factor of such a kind as to affect the validity of Article 24(3) of Directive 2014/40.

Question 1(c)

96 By Question 1(c), the referring court asks whether the provisions of Chapter II of Title II of Directive 2014/40, and Articles 7 and 18 thereof, are invalid because Article 114 TFEU does not constitute an adequate legal basis for those provisions.

– Question 1(c)(i)

97 The grounds of invalidity raised in the order for reference with regard to the provisions of Chapter II (entitled ‘Labelling and packaging’) of Title II of Directive 2014/40 concern, in the first place, the alleged absence of any actual or likely divergences between national rules concerning the labelling and packaging of tobacco products which are liable to hinder the free movement of those products. Existing differences are said to be driven, not by such divergences in rules, but rather by the manufacturers’ commercial strategy of tailoring the packaging and labelling of their products to consumer preferences, which vary from one Member State to another.

98 It must be noted in this regard that it is apparent from recitals 22, 23 and 28 of Directive 2014/40 and from the impact assessment of 19 December 2012, drawn up by the Commission and accompanying the Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (SWD(2012) 452 final, Part 1, p. 30 et seq.), that there were, when Directive 2014/40 was adopted, significant disparities between national rules on the labelling and packaging of tobacco products. Whilst, inter alia, some Member States prescribed combined health warnings consisting in a picture and text, others required text warnings only. In

addition, there were disparities at national level in the size of cigarette packets, the minimum number of cigarettes per unit packet and the advertising allowed on those units.

99 Moreover, as is stated in recitals 23 and 24 of Directive 2014/40, in the absence of further action at EU level, those disparities were likely to increase in the years to come, in view in particular of the need to adapt the rules on labelling to relevant international developments, such as the developments mentioned in the FCTC guidelines on the packaging and labelling of tobacco products.

100 Given that the market for tobacco products is one in which trade between Member States represents a relatively large part, national rules laying down the requirements to be met by those products, in particular requirements relating to their designation, composition or labelling, are in themselves liable, in the absence of harmonisation at EU level, to constitute obstacles to the free movement of goods (see, to that effect, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 64).

101 In accordance with the case-law cited in paragraph 62 of this judgment, when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products, which bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the European Union, Article 114 TFEU authorises the EU legislature to take action.

102 In the second place, the validity of the provisions of Chapter II of Title II of Directive 2014/40 is challenged on the ground that those provisions do not contribute to the elimination of obstacles to the free movement of tobacco products, since some of them require, in any event, that the manufacturers produce different packaging for each Member State. That is the case, in particular, of rules concerning tax stamps, which are different for each Member State, and of rules relating to health warnings, which must appear in the official language(s) of the Member State in which the product is marketed.

103 Whilst it is true that some provisions of Chapter II of Title II of Directive 2014/40 require that certain elements of the labelling and packaging of tobacco products are adapted to take account of, amongst other things, the official language(s) or the tax legislation of the Member State of marketing, the fact remains that the directive harmonises other elements of the labelling and packaging of those products, such as the shape of the unit packets, the minimum number of cigarettes per unit packet and the size and combined nature of health warnings. As the Advocate General has observed in point 98 of her Opinion, those measures thus contribute to the removal of obstacles to trade, since they allow the undertakings concerned to reduce costs through economies of scale.

104 As regards, in the third place, the argument that the provisions of Chapter II of Title II of Directive 2014/40 are liable to introduce distortions of competition by reducing the ability of the manufacturers to differentiate their products, the Court finds that it relates to observance of the principle of proportionality, with which Question 3(b) and (c) is concerned.

105 It follows from the foregoing that consideration of Question 1(c)(i) has disclosed no factor of such a kind as to affect the validity of the provisions of Chapter II of Title II of Directive 2014/40.

– Question 1(c)(ii)

106 According to the order for reference, the validity of Article 7 of Directive 2014/40, which prohibits the placing on the market of tobacco products with a characterising flavour, is challenged on the ground, first, that there are no actual or likely divergences between Member States' rules as regards, in particular, the use of menthol which are such as to create obstacles to trade.

107 That argument concerns specifically the use of menthol as a characterising flavour rather than the use of all the flavours covered by that prohibition. The argument is based on the premiss that Article 114 TFEU requires the EU legislature to establish the existence of actual or likely divergences between the rules of the Member States relating to the placing on the market of tobacco products containing menthol in particular.

108 It must, however, be noted in this regard that the EU legislature decided to adopt uniform rules for all tobacco products containing a characterising flavour. It thus took the view, as can be seen from recital 16 of Directive 2014/40, that those products could facilitate initiation of tobacco consumption or affect consumption patterns.

109 In addition, the EU legislature took into account, as recital 15 of the directive confirms, the Partial Guidelines for Implementation of Articles 9 and 10 of the FCTC, which call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

110 It must be stated in this connection that those partial guidelines likewise do not draw any distinction between the various flavourings that may be added to tobacco products. On the contrary, Section 3.1.2.2 of the partial guidelines recommends that Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products. In this regard, reference is explicitly made in that section to menthol as a flavour which masks tobacco smoke harshness and contributes to promoting and sustaining tobacco use.

111 Whilst it is correct that the FCTC guidelines do not have binding force, they are intended, in accordance with Articles 7 and 9 of the FCTC, to assist the Contracting Parties in implementing the binding provisions of that convention.

112 Furthermore, those guidelines are based on the best available scientific evidence and the experience of the Parties to the FCTC, as can be seen from Section 1.1 of the guidelines, and have been adopted by consensus, including by the European Union and its Member States, as is stated in recital 7 of Directive 2014/40.

113 Accordingly, the recommendations thus drawn up are intended to have a decisive influence on the content of the rules adopted in the area under consideration, as is confirmed by the EU legislature's express decision to take those recommendations into account when adopting Directive 2014/40, mention of which is made in recitals 7 and 15 of the directive.

114 It follows that tobacco products containing a characterising flavour, whether that is menthol or another flavouring, have certain similar, objective characteristics and similar effects as regards initiating tobacco consumption and sustaining tobacco use.

115 That being so, the EU legislature could properly make all characterising flavours subject to the same set of legal rules.

116 Accordingly, for Article 114 TFEU to be capable of constituting an adequate legal basis for Article 7 of Directive 2014/40, it is sufficient to establish that divergences exist between the national rules concerning tobacco products containing a characterising flavour, as a whole, which are such as to present obstacles to the free movement of those products, or that it is likely that such divergences will emerge in the future.

117 As regards, in the second place, the argument that the prohibition laid down in Article 7 of Directive 2014/40 does not have as its object facilitation of the smooth functioning of the internal market, it should be noted that, as is apparent from both recital 15 of the directive and the impact assessment referred to in paragraph 98 of this judgment (Part 1, p. 34, and Part 4, p. 6 et seq.), there were, when the directive was adopted, significant discrepancies between the regulatory systems of the Member States, given that some of them had established different lists of permitted or prohibited flavourings, whilst others had not adopted any specific rules on the matter.

118 In addition, it seems likely that, in the absence of any measures at EU level, disparate sets of rules applying to tobacco products containing a characterising flavour, including menthol, would have been implemented at national level.

119 Indeed, as has been stated in paragraph 110 of this judgment, the Partial Guidelines for Implementation of Articles 9 and 10 of the FCTC recommend that the Parties to that framework convention 'regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products', including menthol.

120 As a result of the broad discretion thus afforded to the Contracting Parties by those partial guidelines, it is foreseeable, with a sufficient degree of probability, that in the absence of measures at EU level, the relevant national rules could develop in divergent ways, including with regard to the use of menthol.

121 Article 7 of Directive 2014/40, in prohibiting the placing on the market of tobacco products with a characterising flavour, guards precisely against such divergences in the rules of the Member States.

122 According to the case-law cited in paragraph 59 of this judgment, recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade as a result of divergences in national laws, when the emergence of such obstacles is likely and the harmonisation measure adopted is designed to prevent them.

123 Furthermore, as has already been stated in paragraph 100 of this judgment, the market for tobacco products is one in which trade between Member States represents a relatively large part and, therefore, national rules laying down the requirements to be met by those products, in particular requirements relating to their composition, are in themselves liable, in the absence of harmonisation at EU level, to constitute obstacles to the free movement of goods.

124 It should also be recalled that, according to the case-law cited in paragraph 64 of this judgment, the measures that may be adopted on the basis of Article 114 TFEU can consist, inter alia, in prohibiting, provisionally or definitively, the marketing of a product or products.

125 It follows that removing divergences between the national rules concerning the composition of tobacco products, or preventing those rules from developing in divergent ways, including by means of

an EU-wide prohibition of certain additives, is intended to facilitate the smooth functioning of the internal market for the products concerned.

126 Having regard to the foregoing, consideration of Question 1(c)(ii) has disclosed no factor of such a kind as to affect the validity of Article 7 of Directive 2014/40.

– Question 1(c)(iii)

127 According to the order for reference, the validity of Article 18 of Directive 2014/40 is challenged on the ground that the provision does not contribute to improving the functioning of the internal market but, instead, facilitates the emergence of disparities between national rules, with the result that Article 114 TFEU does not provide an adequate legal basis for Article 18 of the directive.

128 Article 18 of Directive 2014/40 provides, on the one hand, that Member States may prohibit cross-border distance sales of tobacco products to consumers and, on the other, imposes a series of common rules on Member States which permit that method of sale.

129 The rationale behind Article 18 is apparent from recital 33 of Directive 2014/40, according to which cross-border distance sales of tobacco products, first, could facilitate access to tobacco products that do not comply with the directive and, second, entail an increased risk of young people getting access to those products.

130 That provision thus seeks to ensure that the rules on conformity laid down by Directive 2014/40 are not circumvented, whilst taking as a basis a high level of human health protection, especially for young people.

131 The Court has already had occasion to point out that an EU measure adopted on the basis of Article 114 TFEU may incorporate provisions whose purpose is to ensure that requirements aimed at improving the conditions for the functioning of the internal market are not circumvented (see, to that effect, judgments in*Germany* v *Parliament and Council*, C-376/98, EU:C:2000:544, paragraph 100, and *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 82).

132 As to the objection that Article 18 of Directive 2014/40 would result in the emergence of disparities between the relevant national rules because some Member States might decide to prohibit cross-border distance sales, whilst others might continue to allow them, the Court observes that the rules relating to cross-border distance sales of tobacco products had not been the subject of harmonising measures at EU level prior to the adoption of that directive. Consequently, Member States were already applying different rules in respect of this type of sale, as is shown by the impact assessment referred to in paragraphs 98 and 117 of this judgment (Part 4, p. 8). The argument that Article 18 of the directive will give rise to such disparities therefore cannot be accepted.

133 Furthermore, as has been stated in paragraph 128 of this judgment, Article 18 also sets forth a series of common rules that apply to all the Member States which do not prohibit those sales, thereby approximating their laws, regulations or administrative provisions in the matter, within the meaning of Article 114 TFEU.

134 It should be recalled in this regard that, in accordance with the case-law cited in paragraph 63 of this judgment, Article 114 TFEU confers a discretion on the EU legislature, in particular with regard to

the possibility of proceeding towards harmonisation only in stages and requiring only the gradual abolition of unilateral measures adopted by the Member States.

135 Accordingly, within the bounds of that discretion, the legislature could properly harmonise certain aspects of cross-border sales of tobacco products, whilst leaving other aspects of such sales to be determined by Member States.

136 It follows from the foregoing that consideration of Question 1(c)(iii) has disclosed no factor of such a kind as to affect the validity of Article 18 of Directive 2014/40.

*Question 2*

137 By Question 2 the referring court asks, in essence, whether Article 13(1) of Directive 2014/40 must be interpreted as prohibiting the display on the labelling of unit packets and on the outside packaging, as well as on the tobacco product itself, of certain information, although that information is factually accurate, and, if that is the case, whether Article 13(1) is invalid because it infringes Article 11 of the Charter and the principle of proportionality.

The interpretation of Article 13(1) of Directive 2014/40

138 Article 13(1) of Directive 2014/40 prohibits, in essence, the inclusion on the labelling of unit packets and on the outside packaging, as well on the tobacco product itself, of any element or feature that is such as to promote a tobacco product or encourage its consumption.

139 It is important to point out in this regard that such promotion or encouragement may result from certain information or claims, even when these are factually accurate.

140 For example, under Article 13(1)(a) of Directive 2014/40 'labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product'. That provision thus clearly attributes no importance to the question of whether or not this type of information is factually accurate. That indifference is due to the fact, explained in recital 25 of the directive, that indications of this type may be misleading in that they lead consumers to believe that certain cigarettes are less harmful than others.

141 Likewise, the prohibitions of any element or feature (i) suggesting that a particular tobacco product is less harmful than others (Article 13(1)(b) of Directive 2014/40), or (ii) referring to taste, smell, any flavourings or other additive (Article 13(1)(c) of the directive), or (iii) suggesting that a certain tobacco product has improved biodegradability or other environmental advantages (Article 13(1)(e) of the directive), also apply irrespective of whether the claims in question are factually accurate.

142 As is stated in recital 27 of Directive 2014/40, certain words or expressions, such as 'low-tar', 'light', 'ultra-light', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', and other elements or features could mislead consumers, in particular young people, by suggesting that the products concerned are less harmful or that they have beneficial effects.

143 That interpretation is consistent with the objective pursued by Directive 2014/40, which is, in accordance with Article 1 thereof, to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

144 A high level of protection of that kind requires that consumers of tobacco products, who are a particularly vulnerable class of consumers because of the addictive effects of nicotine, should not be encouraged to consume those products by means of, albeit factually accurate, information, which they may interpret as meaning that the risks associated with their habits are reduced or that the products have certain benefits.

145 Consequently, Article 13(1) of Directive 2014/40 must be interpreted as prohibiting the display, on the labelling of unit packets and on the outside packaging, as well as on the tobacco product itself, of any information covered by that provision, even if the information concerned is factually accurate.

The validity of Article 13(1) of Directive 2014/40

146 The referring court asks the Court to examine the validity of Article 13(1) of Directive 2014/40 in the light of Article 11 of the Charter and the principle of proportionality.

147 Article 11 of the Charter affirms the freedom of expression and information. That freedom is also protected under Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, which applies, in particular, as is clear from the case-law of the European Court of Human Rights, to the dissemination by a business of commercial information, including in the form of advertising. Given that the freedom of expression and information laid down in Article 11 of the Charter has — as is clear from Article 52(3) thereof and the Explanations Relating to the Charter as regards Article 11 — the same meaning and scope as the freedom guaranteed by the Convention, it must be held that that freedom covers the use by a business, on the packaging and labelling of tobacco products, of indications such as those covered by Article 13(1) of Directive 2014/40 (judgment in*Neptune Distribution*, C-157/14, EU:C:2015:823, paragraphs 64 and 65).

148 The prohibition on including on the labelling of unit packets and on outside packaging, as well as on the tobacco product itself, the elements and features referred to in Article 13(1) of Directive 2014/40 constitutes, it is true, an interference with a business's freedom of expression and information.

149 In accordance with Article 52(1) of the Charter, any limitation on the exercise of the rights and freedoms laid down by the Charter must be provided for by law and respect the essence of those rights and freedoms and, in compliance with the principle of proportionality, is permissible only if it is necessary and actually meets objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

150 In that regard, the Court finds, first, that the interference identified in paragraph 148 of this judgment must be regarded as being provided for by law given that it results from a provision adopted by the EU legislature.

151 Secondly, the essence of a business's freedom of expression and information is not affected by Article 13(1) of Directive 2014/40 inasmuch as that provision, far from prohibiting the communication of all information about the product, merely controls, in a very clearly defined area, the labelling of those products by prohibiting only the inclusion of certain elements and features (see, by analogy, judgments in *Deutsches Weintor*, C-544/10, EU:C:2012:526, paragraph 57, and*Neptune Distribution*, C-157/14, EU:C:2015:823, paragraph 71).

152 Thirdly, the interference with the freedom of expression and information that has been found to exist meets an objective of general interest recognised by the European Union, namely, the protection of health. Given that it is undisputed that tobacco consumption and exposure to tobacco smoke are causes of death, disease and disability, the prohibition laid down in Article 13(1) of Directive 2014/40 contributes to the achievement of that objective in that it is intended to prevent the promotion of tobacco products and incitements to use them.

153 Fourthly, as regards the proportionality of the interference found, it is important to point out that the second sentence of Article 35 of the Charter and Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU require that a high level of human health protection be ensured in the definition and implementation of all the Union's policies and activities.

154 In those circumstances, the determination of the validity of Article 13(1) of Directive 2014/40 must be carried out in accordance with the need to reconcile the requirements of the protection of those various fundamental rights and legitimate general interest objectives, protected by the EU legal order, and striking a fair balance between them (see, to that effect, judgment in *Neptune Distribution*, C-157/14, EU:C:2015:823, paragraph 75).

155 It should be stated in that regard that the discretion enjoyed by the EU legislature, in determining the balance to be struck, varies for each of the goals justifying restrictions on that freedom and depends on the nature of the activities in question. In the present case, the claimants in the main proceedings rely, in essence, under Article 11 of the Charter, on the freedom to disseminate information in pursuit of their commercial interests.

156 It must, however, be stated that human health protection — in an area characterised by the proven harmfulness of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic — outweighs the interests put forward by the claimants in the main proceedings.

157 Indeed, as is apparent from the second sentence of Article 35 of the Charter and Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU, a high level of human health protection must be ensured in the definition and implementation of all the European Union's policies and activities.

158 The Court finds, in the light of the foregoing, (i) that the prohibition laid down in Article 13(1) of Directive 2014/40 is such as to protect consumers against the risks associated with tobacco use, as follows from paragraph 152 of this judgment, and (ii) that that prohibition does not go beyond what is necessary in order to achieve the objective pursued.

159 On this point, the Court cannot accept the argument that the prohibition concerned is not necessary because consumer protection is already adequately ensured by the mandatory health warnings mentioning the risks associated with tobacco use. In fact, awareness of those risks may, on the contrary, be diminished by information that might suggest that the product concerned is less harmful or is beneficial in some respects.

160 Nor can the Court accept the argument that the objective pursued could be achieved by other, less restrictive measures, such as regulating the use of the elements and features referred to in Article 13 of Directive 2014/40, instead of prohibiting them, or adding certain supplementary health

warnings. Such measures would not be as effective for ensuring the protection of consumers' health, since the elements and features referred to in Article 13 are, by their very nature, likely to encourage smoking (see, to that effect, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 140). It cannot be accepted that those elements and features may be included for the purpose of giving consumers clear and precise information, inasmuch as they are intended more to exploit the vulnerability of consumers of tobacco products who, because of their nicotine dependence, are particularly receptive to any element suggesting there may be some kind of benefit linked to tobacco consumption, in order to vindicate or reduce the risks associated with their habits.

161 In those circumstances, it must be held that, in prohibiting the placing, on the labelling of unit packets and on the outside packaging, as well as on the tobacco product itself, of the elements and features referred to in Article 13(1) of Directive 2014/40, even when they include factually accurate information, the EU legislature did not fail to strike a fair balance between the requirements of the protection of the freedom of expression and information and those of human health protection.

162 Accordingly, Article 13(1) of Directive 2014/40 does not infringe either Article 11 of the Charter or the principle of proportionality.

163 Having regard to the foregoing, consideration of Question 2 has disclosed no factor of such a kind as to affect the validity of Article 13(1) of Directive 2014/40.

*Question 3*

164 By Question 3, the referring court asks whether Articles 7(1) and (7), 8(3), 9(3), 10(1)(a), (c) and (g) and 14 of Directive 2014/40 are invalid because they infringe the principle of proportionality.

165 According to settled case-law, that principle requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is necessary in order to achieve those objectives; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, to that effect, judgments in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 122; *ERG and Others*, C-379/08 and C-380/08, EU:C:2010:127, paragraph 86; and *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraphs 67 and 91).

166 With regard to judicial review of the conditions referred to in the previous paragraph of this judgment, the EU legislature must be allowed broad discretion in an area such as that involved in the main proceedings, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. Consequently, the legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institutions are seeking to pursue (see, to that effect, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 123).

167 The question whether the provisions of Directive 2014/40 to which Question 3 refers infringe the principle of proportionality must be determined in the light of those principles.

Question 3(a)

168 Question 3(a) concerns the validity of Article 7(1) and (7) of Directive 2014/40 in the light of the principle of proportionality. Those provisions prohibit the placing on the market of tobacco products with a characterising flavour or containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity.

169 According to the order for reference, the validity of those provisions is challenged on the ground that the prohibition on the use of menthol is neither appropriate nor necessary to achieve the directive's objective and that the impact of the prohibition is disproportionate.

170 As regards, in the first place, the suitability of the prohibition on the placing on the market of tobacco products containing menthol, it is argued, in essence, that the prohibition is not appropriate for achieving the objective of protecting human health, especially as regards young people, because menthol is not attractive to them and its use consequently does not facilitate initiation of tobacco consumption.

171 It should be recalled in this regard that the objective of Directive 2014/40 is, according to Article 1 thereof, twofold in that it seeks to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

172 On this point, it must be stated that, as follows from paragraph 125 of this judgment, the prohibition on the placing on the market of tobacco products with a characterising flavour is capable of facilitating the smooth functioning of the internal market for tobacco and related products.

173 That prohibition is also appropriate for ensuring a high level of human health protection, especially for young people. Indeed, it is not disputed that certain flavourings are particularly attractive to young people and that they facilitate initiation of tobacco consumption.

174 As regards the argument that young people are not attracted to menthol and that the use thereof does not facilitate that initiation, it has already been stated in paragraph 115 of this judgment that the EU legislature could properly make all characterising flavours subject to the same set of legal rules. Accordingly, the appropriateness of the prohibition in question for the purpose of achieving the object of human health protection cannot be called into question solely in respect of a particular flavouring.

175 The point should also be made that, according to the Partial Guidelines for Implementation of Articles 9 and 10 of the FCTC — which should, on account of the findings made in paragraph 112 of this judgment — be recognised as being of particularly high evidential value, menthol, amongst other flavours, contributes to promoting and sustaining tobacco use and, because of its palatability, renders tobacco products more attractive to consumers.

176 Furthermore, Directive 2014/40 is aimed at ensuring a high level of health protection for consumers as a whole and consequently its ability to achieve that aim cannot be assessed solely in relation to a single category of consumers.

177 Accordingly, the prohibition laid down in Article 7 of Directive 2014/40 cannot be regarded as manifestly inappropriate for achieving the objective of facilitating the smooth functioning of the internal

market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

178 With regard, in the second place, to whether that prohibition is necessary, it should be borne in mind, first, that, as has already been stated in paragraph 110 of this judgment, the Partial Guidelines for Implementation of Articles 9 and 10 of the FCTC recommend that the Parties to the FCTC, inter alia, prohibit ingredients that may be used to increase palatability in tobacco products. In addition, in accordance with Section 1.1 of those partial guidelines, the Parties to the FCTC are encouraged to implement measures beyond those recommended by the guidelines.

179 It was thus lawful for the EU legislature — taking account of those recommendations and in the exercise of its broad discretion — to impose a prohibition on all characterising flavours.

180 Secondly, as regards the less restrictive measures advocated by some of the parties to the main proceedings, they do not appear to be equally suitable for achieving the objective pursued.

181 Raising — solely in respect of tobacco products with a characterising flavour — the age limit from which their consumption is permitted is unlikely to reduce the attractiveness of those products and thus prevent persons above that age from starting smoking. In addition, any prohibition on sale resulting from an increase in that age limit can, in any event, be easily circumvented when the products concerned are marketed.

182 The organisation of targeted information campaigns on the danger of tobacco products with characterising flavours is not, as such, likely to remove divergences between national rules relating to the placing on the market of such products and thus improve the conditions for the functioning of the internal market.

183 So far as the adoption of lists of prohibited or permitted flavourings is concerned, such a measure could result in the introduction of unjustified differences of treatment between the various types of tobacco products with a characterising flavour. Moreover, such lists may quickly become out of date because of continuing developments in the manufacturers' commercial strategies and are readily susceptible to circumvention.

184 The Court therefore finds that the prohibition on the placing on the market of tobacco products with a characterising flavour does not go manifestly beyond what is necessary to achieve the objective sought.

185 As regards, in the third place, the allegedly disproportionate effects of the prohibition on the use of menthol as a characterising flavour because of the negative economic and social consequences that such a prohibition entails, it should be borne in mind that even though, as in the present case, the EU legislature has a broad legislative power, it must base its choice on objective criteria and examine whether objectives pursued by the measure chosen are such as to justify even substantial negative economic consequences for certain operators (see, to that effect, judgment in *Luxembourg* v *Parliament and Council*, C-176/09, EU:C:2011:290, paragraph 63 and the case-law cited).

186 Indeed, under Article 5 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality, annexed to the EU Treaty and to the FEU Treaty, draft legislative acts must take account

of the need for any burden falling upon economic operators to be minimised and commensurate with the objective to be achieved.

187 In the present case, the EU legislature made sure that the negative economic and social consequences of the prohibition on the placing on the market of tobacco products with a characterising flavour were limited.

188 Thus, first, in order to give both the tobacco industry and consumers time to adapt, Article 7(14) of Directive 2014/40 provides that, in the case of tobacco products with a characterising flavour whose EU-wide sales volumes represent 3% or more in a particular product category, the prohibition on the placing of those products on the EU market is to apply only from 20 May 2020.

189 Second, it can be seen from the impact assessment referred to in paragraphs 98, 117 and 132 of this judgment (Part 1, p. 114, and Part 6, p. 2), which is not disputed on this point, that the prohibition in question is expected to result in a decrease in cigarette consumption in the European Union of 0.5% to 0.8% over a five-year period.

190 Those elements show that the EU legislature weighed up, on the one hand, the economic consequences of that prohibition and, on the other, the requirement to ensure, in accordance with the second sentence of Article 35 of the Charter and Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU, a high level of human health protection with regard to a product which is characterised by properties that are carcinogenic, mutagenic and toxic to reproduction. The impact of the prohibition laid down in Article 7 of Directive 2014/40 thus does not appear manifestly disproportionate.

191 Having regard to the foregoing, consideration of Question 3(a) has disclosed no factor of such a kind as to affect the validity of Article 7(1) and (7) of Directive 2014/40.

Question 3(b)

192 The provisions at which Question 3(b) is directed include various rules concerning the labelling and packaging of tobacco products which relate, in essence, to the integrity of health warnings after the packet has been opened (Article 8(3) of Directive 2014/40), to the position and minimum dimensions of the general health warning and the information message (Article 9(3) of the directive), to the minimum dimensions of combined health warnings (Article 10(1)(g) of the directive) and to the shape of unit packets of cigarettes and the minimum number of cigarettes per unit packet (Article 14 of the directive).

193 It appears from the order for reference that the validity of this set of provisions is challenged, in extremely summary and general terms, on the ground, first, that the provisions are neither appropriate nor necessary to achieve the objective of public health protection. It is argued that, instead of the requirements imposed, which are considered to be very intrusive, there are less restrictive measures, such as, for example, a requirement that health warnings must be fully visible and not be distorted by packet shapes. Secondly, it is argued that the disputed requirements will prevent the differentiation of tobacco products and will cause distortions of competition. Thirdly, the requirement laid down in Article 14(1) of Directive 2014/40, pursuant to which a unit packet of cigarettes is to include at least 20 cigarettes, cannot be justified on grounds of public health protection.

194 Most of those objections call in question the proportionality of those requirements solely in relation to the objective of ensuring a high level of human health protection, while disregarding the

objective of facilitating the smooth functioning of the internal market, thus failing to pay due regard to the fact that Directive 2014/40 and, in particular, the provisions covered by Question 3(b) pursue both those objectives.

195 As has been stated in paragraphs 97 to 105 of this judgment, Chapter II of Title II of Directive 2014/40, to which the provisions covered by Question 3(b) belong, contributes to improving the conditions for the functioning of the internal market for tobacco products by removing disparities on this point between the rules of the Member States.

196 The same is true of the minimum number of cigarettes per packet, prescribed in Article 14(1) of Directive 2014/40, and specifically mentioned in the order for reference. The main aim of that requirement is to remove differences between the rules of the Member States, as recital 28 of the directive confirms.

197 The requirements in question also help to achieve the objective of ensuring a high level of human health protection. As the Advocate General has stated in points 191 and 192 of her Opinion, innovative, novel or unusual shapes may help to maintain or enhance the attraction of the product and encourage its use. Similarly, certain packet shapes may obstruct the visibility of health warnings and, as a consequence, reduce their efficacy, as is stated in recitals 25 and 28 of Directive 2014/40. As regards the requirement that a unit packet must contain at least 20 cigarettes, it can be explained by the fact that smaller sales units are more of an inducement to start smoking because the consumer is inclined to think that they are cheaper, less of a constraint and psychologically more acceptable.

198 As to the less restrictive measure mentioned in paragraph 193 of this judgment, it is sufficient to observe that it is not aimed at removing differences between the Member States' rules on the labelling and packaging of tobacco products and it is therefore not appropriate for the purpose of achieving the objective of improving the functioning of the internal market.

199 Although those requirements may, by their very nature, to some extent increase the similarity between tobacco products, the fact remains that they concern only certain aspects of the labelling and packaging of those products and therefore still allow for adequate opportunities for product differentiation.

200 In view of the foregoing considerations, it cannot be accepted that the requirements laid down in Articles 8(3), 9(3), 10(1)(g) and 14 of Directive 2014/40 are manifestly inappropriate or manifestly go beyond what is necessary to attain the objective of improving the conditions for the functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

201 Accordingly, the Court finds that consideration of Question 3(b) has disclosed no factor of such a kind as to affect the validity of those provisions.

Question 3(c)

202 Article 10(1)(a) and (c) of Directive 2014/40, with which Question 3(c) is concerned, provides, in substance, that each unit packet and the outside packaging must carry combined health warnings taking the form of one of the messages listed in Annex I to the directive and a corresponding colour

photograph as set out in Annex II thereto. The combined health warning must cover 65% of the external front and back surface of each unit packet.

203 The validity of those provisions is challenged, in essence, on account of the size of the area reserved for those warnings. Thus, it is alleged (i) that an area of that extent is neither appropriate nor necessary to achieve the objective of public health protection, (ii) that the figure of 65% is arbitrary and cannot be justified by the FCTC recommendations and (iii) that its impact is manifestly disproportionate.

204 As regards (i) the appropriateness of large combined health warnings, the Guidelines for Implementation of Article 11 of the FCTC explain, in point 7, that, in comparison with small, text-only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. Such warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people.

205 The affixing of large combined health warnings thus does not appear manifestly inappropriate for achieving the objective sought.

206 As regards (ii) the allegedly arbitrary nature of the size of the area which Article 10(1)(a) and (c) of Directive 2014/40 reserves for the combined health warnings, the Court notes that, in accordance with Article 11(1)(b)(iv) of the FCTC, these warning should cover '50% or more' of the principal display areas of the unit packets, but not less than 30%.

207 On this point, the Guidelines for Implementation of Article 11 of the FCTC recommend, in point 12, that the Contracting Parties consider using health warnings and messages that cover 'more than 50%' of the principal display areas and aim to cover 'as much of the principal display areas as possible', since according to existing evidence, 'the effectiveness of health warnings and messages increases with their size'.

208 Against that background the EU legislature cannot be accused of having acted arbitrarily in selecting a figure of 65% for the area reserved for combined health warnings pursuant to Article 10(1)(a) and (c) of Directive 2014/40. Indeed, that selection is based on criteria deriving from the FCTC recommendations and, in making it, the EU legislature acted within the bounds of its broad discretion, to which reference is made in paragraph 166 of this judgment.

209 Concerning (iii) the necessity of the measure in question and its allegedly disproportionate impact on the ability of manufacturers to communicate information about the product concerned to consumers, it should be pointed out, first, that the area reserved for those warnings allows for a sufficient space for that type of information on the unit packets.

210 Secondly, the restrictions thereby imposed must be weighed up against the requirement to ensure a high level of human health protection in an area characterised by the toxicity of the product concerned and its addictive effects.

211 Having regard to the foregoing considerations, it does not appear that, in adopting Article 10(1)(a) and (c) of Directive 2014/40, the EU legislature manifestly went beyond the limits of what is appropriate and necessary to attain the objective of improving the conditions for the functioning of the internal

market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

212 Accordingly, the Court finds that consideration of Question 3(c) has disclosed no factor of such a kind as to affect the validity of Article 10(1)(a) and (c) of Directive 2014/40.

*Question 7*

213 In view of the finding made in paragraph 52 of this judgment, Question 7 should be addressed only in so far as it concerns the validity of Article 7 of Directive 2014/40 in the light of the principle of subsidiarity.

214 The Court notes in this regard that the order for reference does not mention any ground of invalidity based on that principle and concerning Directive 2014/40 as a whole. Only the validity of Article 7 of the directive is challenged in so far as that article prohibits the placing on the EU market of tobacco products containing menthol as a characterising flavour. It is claimed that the EU legislature merely asserted, using a standard formula, that the principle of subsidiarity was complied with, without showing that the internal market benefits deriving from that prohibition are sufficient to justify action on the part of the European Union. It is argued that public health protection could have been sufficiently achieved at the level of Member States.

215 The principle of subsidiarity is set out in Article 5(3) TEU, under which the European Union, in areas which do not fall within its exclusive competence, is to act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved at EU level. Furthermore, Article 5 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality, annexed to the EU Treaty and to the FEU Treaty, lays down guidelines for the purpose of determining whether those conditions are met (judgment in *Estonia* v *Parliament and Council*, C-508/13, EU:C:2015:403, paragraph 44).

216 An initial review of compliance with the principle of subsidiarity is undertaken, at a political level, by national parliaments in accordance with the procedures laid down for that purpose by Protocol (No 2).

217 Subsequently, responsibility for that review lies with the EU judicature, which must verify both compliance with the substantive conditions set out in Article 5(3) TEU and compliance with the procedural safeguards provided for by that protocol.

218 As regards, in the first place, the judicial review of compliance with the substantive conditions laid down in Article 5(3) TEU, the Court must determine whether the EU legislature was entitled to consider, on the basis of a detailed statement, that the objective of the proposed action could be better achieved at EU level.

219 Since the present case concerns an area — the improvement of the functioning of the internal market — which is not among those in respect of which the European Union has exclusive competence, it must be determined whether the objective of Directive 2014/40 could be better achieved at EU level (see, to that effect, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraphs 179 and 180).

220 In this regard, as has been mentioned in paragraph 143 of this judgment, Directive 2014/40 has two objectives in that it seeks to facilitate the smooth functioning of the internal market for tobacco and related products, while ensuring a high level of protection of human health, especially for young people.

221 Even if the second of those objectives might be better achieved at the level of Member States, the fact remains that pursuing it at that level would be liable to entrench, if not create, situations in which some Member States permit the placing on the market of tobacco products containing certain characterising flavours, whilst others prohibit it, thus running completely counter to the first objective of Directive 2014/40, namely the improvement of the functioning of the internal market for tobacco and related products.

222 The interdependence of the two objectives pursued by the directive means that the EU legislature could legitimately take the view that it had to establish a set of rules for the placing on the EU market of tobacco products with characterising flavours and that, because of that interdependence, those two objectives could best be achieved at EU level (see, by analogy, judgment in *Vodafone and Others*, C-58/08, EU:C:2010:321, paragraph 78, and *Estonia* v *Parliament and Council*, C-508/13, EU:C:2015:403, paragraph 48).

223 Moreover, as has been stated in paragraph 115 of this judgment, the EU legislature could properly make all characterising flavours subject to the same set of legal rules.

224 Consequently, the Court must reject the arguments seeking to establish that the objective of human health protection could have been better achieved at national level as regards specifically the prohibition on the placing on the market of tobacco products with characterising flavours.

225 As regards, in the second place, compliance with formal requirements and, in particular, the statement of reasons for Directive 2014/40 in the light of the principle of subsidiarity, it should be borne in mind that, according to the Court's case-law, observance of the obligation to state reasons must be evaluated not only by reference to the wording of the contested act, but also by reference to its context and the circumstances of the individual case (see, to that effect, judgment in *Estonia* v *Parliament and Council*, C-508/13, EU:C:2015:403, paragraph 61).

226 In the present case, it is undisputed that the Commission's proposal for a directive and its impact assessment include sufficient information showing clearly and unequivocally the advantages of taking action at EU level rather than at Member State level.

227 Accordingly, it is established to the requisite legal standard that that information enabled both the EU legislature and national parliaments to determine whether the proposal complied with the principle of subsidiarity, whilst also enabling individuals to understand the reasons relating to that principle and the Court to exercise its power of review.

228 Having regard to the foregoing, consideration of Question 7 has disclosed no factor of such a kind as to affect the validity of Article 7 of Directive 2014/40.

**Costs**

229 Since these proceedings are, for the parties to the main proceedings, a step in the action 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 (Second Chamber) hereby rules:

**1. Article 24(2) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC must be interpreted as permitting Member States to maintain or introduce further requirements in relation to aspects of the packaging of tobacco products which are not harmonised by that directive.**

**2. Article 13(1) of Directive 2014/40 must be interpreted as prohibiting the display, on the labelling of unit packets and on the outside packaging, as well as on the tobacco product itself, of any information covered by that provision, even if the information concerned is factually accurate.**

**3. Consideration of the questions referred for a preliminary ruling by the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court) has disclosed no factor of such a kind as to affect the validity of Articles 7, 18 and 24(2) and (3) of Directive 2014/40 or that of the provisions of Chapter II of Title II of that directive.**

[Signatures]