JUDGMENT OF THE COURT (Second Chamber)
4 May 2016 (*)
(Reference for a preliminary ruling — Approximation of laws — Directive 2014/40/EU — Article 20 — Electronic cigarettes and refill containers — Validity — Principle of equal treatment — Principles of proportionality and legal certainty — Principle of subsidiarity — Charter of Fundamental Rights of the European Union — Articles 16 and 17)

In Case C-477/14,
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 9 October 2014, received at the Court on 27 October 2014, in the proceedings
Pillbox 38 (UK) Ltd

v

The Secretary of State for Health,

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: V. Tourrès, Administrator,
having regard to the written procedure and further to the hearing on 1 October 2015,
after considering the observations submitted on behalf of:
Pillbox 38 (UK) Ltd, by K. Beal QC, instructed by P. Rowley, Solicitor,
the United Kingdom Government, by V. Kaye, acting as Agent, and by M. Hoskins QC and I. Rogers QC, and S. Abram and E. Metcalfe, Barristers,
the Spanish Government, by A. Gavela Llopis, acting as Agent,
the French Government, by D. Colas and R. Coesme, acting as Agents,
the European Parliament, by L. Visaggio and J. Rodrigues and by I. McDowell, acting as Agents,
the Council of the European Union, by M. Simm and by J. Herrmann and A. Norberg, acting as Agents,
the European Commission, by C. Cattabriga and J. Tomkin, acting as Agents,
after hearing the Opinion of the Advocate General at the sitting on 23 December 2015,
gives the following

Judgment

This request for a preliminary ruling concerns the validity of Article 20 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).

The request has been made in proceedings between Pillbox 38 (UK) Ltd, trading as 'Totally Wicked' ('Pillbox'), and 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

By Council Decision 2004/513/EC of 2 June 2004 (OJ 2004 L 213, p. 8), the World Health Organisation Framework Convention on Tobacco Control, signed at Geneva on 21 May 2003 ('the FCTC'), was approved on behalf of the European Community.

Directive 2014/40

Recitals 7, 33, 36, 38 to 41, 43 to 45, 47 and 48 of Directive 2014/40 state:

Legislative action at Union level is also necessary in order to implement the [FCTC] ..., the provisions of which are binding on the Union and its Member States. …

…

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. …

…

Electronic cigarettes and refill containers should be regulated by this Directive, unless they are — due to their presentation or function — subject to [Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)] or to [Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1)]. Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

…

Nicotine-containing liquid should only be allowed to be placed on the market under this Directive, where the nicotine concentration does not exceed 20 mg/ml. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set.

Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market under this Directive. Delivery of nicotine doses at consistent levels under normal conditions of use is necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses.

Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child- and tamperproof, including by means of child-proof labelling, fastenings and opening mechanisms.

In view of the fact that nicotine is a toxic substance and considering the potential health and safety risks, including to persons for whom the product is not intended, nicotine-containing liquid should only be placed on the market in electronic cigarettes or in refill containers that meet certain safety and quality requirements. It is important to ensure that electronic cigarettes do not break or leak during use and refill.

…

Disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. Without further action at Union level, those disparities are likely to increase over the coming years, also taking into account the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national provisions on advertising and sponsorship of those products having cross-border effects, taking as a base a high level of protection of human health. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalise the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers.

In order to perform their regulatory tasks, the Commission and Member States need comprehensive information on market developments as regards electronic cigarettes and refill containers. To this end manufacturers and importers of these products should be subject to reporting obligations on sales volumes, preference of various consumer groups and mode of sales. It should be ensured that this information is made available to the general public, taking the need to protect trade secrets duly into account.

In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors operate an appropriate system for monitoring and recording suspected adverse effects and inform the competent authorities about such effects so that appropriate action can be taken. It is warranted to provide for a safeguard clause that would allow Member States to take action to address serious risks to public health.

…

This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non-smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance with [Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ 1998 L 204, p. 37)].

Moreover, this Directive does not harmonise the rules on smoke-free environments, or on domestic sales arrangements or domestic advertising, or brand stretching, nor does it introduce an age limit for electronic cigarettes or refill containers. …'

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:

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].'

In accordance with points 4, 16 and 17 of Article 2 of that directive, entitled 'Definitions', the following definitions apply:

"tobacco products" means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

…

"electronic cigarette" means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

"refill container" means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette.'

Under the heading 'Regulation of ingredients', Article 7 of that directive provides, in paragraph 6:

'Member States shall prohibit the placing on the market of tobacco products containing the following additives:

vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

additives having colouring properties for emissions;

for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

additives that have [carcinogenic, mutagenic or reprotoxic] properties in unburnt form.'

Entitled 'Electronic cigarettes', Article 20 of Directive 2014/40 reads as follows:

'1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with this Directive and with all other relevant Union legislation.

This Directive does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive [2001/83] or to the requirements set out in Directive [93/42].

2. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;

a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;

toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;

information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;

a description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;

a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Where Member States consider that the information submitted is incomplete, they shall be entitled to request the completion of the information concerned.

Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted to them.

3. Member States shall ensure that:

nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;

the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;

the nicotine-containing liquid does not contain additives listed in Article 7(6);

only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture;

except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;

electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;

electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

4. Member States shall ensure that:

unit packets of electronic cigarettes and refill containers include a leaflet with information on:

instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

contra-indications;

arnings for specific risk groups;

possible adverse effects;

addictiveness and toxicity; and

contact details of the manufacturer or importer and a legal or natural contact person within the Union;

unit packets and any outside packaging of electronic cigarettes and refill containers:

include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

without prejudice to point (i) of this point, do not include elements or features referred to in Article 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and

rry one of the following health warnings:

"This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers."

or

"This product contains nicotine which is a highly addictive substance."

Member States shall determine which of these health warnings is to be used;

health warnings comply with the requirements specified in Article 12(2).

5. Member States shall ensure that:

commercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market;

commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;

any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited;

any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

audiovisual commercial communications to which [Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ 2010 L 95, p. 1)] applies, are prohibited for electronic cigarettes and refill containers.

6. Article 18 of this Directive shall apply to cross-border distance sales of electronic cigarettes and refill containers.

7. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:

comprehensive data on sales volumes, by brand name and type of the product;

information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;

e mode of sale of the products; and

executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately conventional tobacco consumption among young people and non-smokers.

…

13. The Commission shall, by means of an implementing act, lay down a common format for the notification provided for in paragraph 2 and technical standards for the refill mechanism provided for in paragraph 3(g).

…'

Directive 2014/40 must, under Article 29 thereof, be transposed into the legal orders of the Member States by 20 May 2016 at the latest and the relevant provisions must enter into force from that date.

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

Pillbox brought a claim 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.

It claims that Article 20 of that directive is invalid on the ground that it infringes the principles of proportionality, legal certainty, equal treatment, free competition and subsidiarity, as well as Articles 16 and 17 of the Charter of Fundamental Rights of the European Union ('the Charter').

The referring court considers that the arguments advanced by Pillbox in support of its claim are 'reasonably arguable'.

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 question to the Court of Justice for a preliminary ruling:

'Is Article 20 of Directive 2014/40 invalid, either in whole or in a relevant part, for one or more of the following reasons:

it imposes either as a whole or in a relevant part a series of obligations on electronic cigarette manufacturers and/or retailers which infringe the principle of proportionality, read in conjunction with the principle of legal certainty?

for equivalent or similar reasons, it fails to comply with the principle of equality and/or unlawfully distorts competition?

it fails to comply with the principle of subsidiarity?

it infringes the rights of electronic cigarette manufacturers or retailers under Articles 16 and 17 of the Charter?'

Consideration of the question referred

Admissibility

The European Parliament, the Commission and the French Government submit that the request for a preliminary ruling is inadmissible on the ground (i) that there is no genuine dispute between the parties, (ii) that the claim for judicial review challenging 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 and (iii) that the question referred is hypothetical owing to the fact that the referring court does not set out the relevant factual and legal material or the reasons that led it to raise the question of the validity of Article 20 of Directive 2014/40.

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).

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).

As regards, first, the genuine nature of the dispute in the main proceedings, it should be noted that the claim for judicial review of the 'intention and/or obligation' of the United Kingdom Government to implement Directive 2014/40, which Pillbox has brought before the referring court, has 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 Pillbox and the Secretary of State for Health as to whether or not the abovementioned claim is 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).

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).

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 17 of the present 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).

Accordingly, it does not appear that a claim such as that in the main proceedings seeks to circumvent the system of remedies established by the FEU Treaty.

As regards, thirdly, the allegedly hypothetical nature of the question referred owing to the fact that the referring court does not set out the relevant factual and legal material or the reasons that led it to raise the question of the validity of Article 20 of Directive 2014/40, it should be observed, first, that the mere fact that the referring court failed to state whether the electronic cigarettes marketed by Pillbox fell within the scope of Article 20 of that directive does not make the question referred hypothetical.

It is apparent from the order for reference that Pillbox manufactures and distributes, within the internal market, electronic cigarettes under the brand name 'Totally Wicked' as well as refill containers and related products. In accordance with Article 1(f) of Directive 2014/40, the objective of that directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the placing on the market and the labelling of electronic cigarettes and refill containers. In addition, the validity of some compliance rules imposed on those products pursuant to Article 20 of that directive, including the rule relating to the maximum content of nicotine which may be contained in the liquid of those products, is precisely the subject of the question referred.

In those circumstances, the question referred is not manifestly hypothetical.

As regards, moreover, the obligation on the referring court to set out the reasons that led it to raise the question of the validity of Article 20 of Directive 2014/40, it does indeed follow 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).

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.

Furthermore, according to the 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).

It follows that, in a reference for a preliminary ruling, the Court will examine the validity of an EU act or certain provisions thereof only in the light of the grounds of invalidity set out in the order for reference.

In the present case, the referring court reproduced some of the arguments put forward by Pillbox, stating that those arguments are 'reasonably arguable'.

It follows that the referring court considers that the grounds of invalidity, relied on by Pillbox and set out in the

order for reference, may, in its view, be upheld.

Moreover, those indications enabled the Parliament, the Commission and the French Government to state their views effectively on the question submitted to the Court.

It follows from the foregoing that the question referred is admissible.

Substance

By its question, the referring court asks, in essence, whether Article 20 of Directive 2014/40 is invalid on the ground that it infringes the principles of proportionality, legal certainty, equal treatment, free competition and subsidiarity and also Articles 16 and 17 of the Charter.

The validity of Article 20 of Directive 2014/40 in the light of the principles of equal treatment and free competition

It is appropriate to examine, in the first place, the question referred in so far as it concerns the validity of Article 20 of Directive 2014/40 in the light of the principles of equal treatment and free competition.

It is apparent from the order for reference that the failure to observe those principles is alleged to stem, in essence, from the fact that Article 20 of Directive 2014/40 reserves for electronic cigarettes less favourable treatment than that to which tobacco products are subject, even though electronic cigarettes are less harmful than tobacco products.

The Court has consistently held that the principle of equal treatment requires that comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified (see, inter alia, judgment in *P and S*, C-579/13, EU:C:2015:369, paragraph 41).

It should, in that regard, be noted that electronic cigarettes display different objective characteristics from those of tobacco products.

First, the elements included in their respective composition are significantly different in several respects. Thus, according to Article 2(4) of Directive 2014/40, tobacco products are products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not.

By contrast, an electronic cigarette does not contain tobacco but is, as set out in Article 2(16) of that directive, a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. In addition, electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.

Refill containers are described, in the words of Article 2(17) of that directive, as a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette.

Secondly, it is common ground that the pattern of consumption of electronic cigarettes is also substantially different from the pattern of consumption of tobacco products. While tobacco products are consumed by the combustion of tobacco, electronic cigarettes function by the electrical or electromechanical vaporisation of the liquid contained in their refill containers.

Thirdly, unlike tobacco products, electronic cigarettes are relatively new products, whose risks to human health still need to be clarified.

Accordingly, it must be held that electronic cigarettes are not in the same situation as tobacco products for the purposes of the case-law cited in paragraph 35 of the present judgment.

Therefore, by submitting those cigarettes to a separate legal regime which is, moreover, less strict than the one applicable to tobacco products, the EU legislature cannot be said to have infringed the principle of equal treatment.

Since the arguments put forward in the order for reference regarding the failure to observe the principle of free competition have no elements that are independent of the arguments concerning the principle of equal treatment, reference should be made in this regard to the considerations set out in the preceding paragraphs of the present judgment.

It follows from the foregoing that consideration of the question referred for a preliminary ruling has disclosed no factor of such a kind as to affect the validity of Article 20 of Directive 2014/40 in the light of the principles of equal treatment and free competition.

The principles of proportionality and legal certainty

It is appropriate to examine, in the second place, the question referred for a preliminary ruling in so far as it concerns the validity of Article 20 of Directive 2014/40 or of some of its provisions in the light of the principles of proportionality and legal certainty.

– The validity of Article 20 of Directive 2014/40, in so far as it establishes a specific regime applicable to electronic cigarettes

It is apparent from the order for reference that the validity of Article 20 of Directive 2014/40 is contested by Pillbox on the ground that, given their less harmful or even beneficial nature for public health, electronic cigarettes should not be the subject of any specific rules and, even less so, of comparable rules which are even more strict than those applicable to tobacco products. In addition, the proportionality of the measures chosen pursuant to that article was not the subject of any impact assessment.

It should be borne in mind at the outset that, according to the settled case-law of the Court, the principle of

proportionality, which is one of the general principles of EU law, 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).

With regard to judicial review of the conditions referred to in the previous paragraph of the present judgment, the EU legislature must be allowed broad discretion in an area such as that at issue 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).

In addition, it should be noted that the question of health risks linked to the consumption of electronic cigarettes is the subject of heated debate between the parties to the present proceedings which rely, in support of their arguments, on multiple scientific studies and reports. Thus, whereas Pillbox claims that electronic cigarettes are to a large extent harmless to health and offer significant advantages as a substitute for tobacco products or support for cessation of tobacco use, the EU institutions and the governments which have intervened in the present proceedings consider that electronic cigarettes may create a nicotine addiction and lead to nicotine poisoning prompted by extended and intensive consumption or inadequate handling of the product. In addition, they argue that those cigarettes may become the point of entry to smoking for non-smokers, since they imitate and trivialise the action of smoking and thus increase its attractiveness. Moreover, the role given to electronic cigarettes as a support for cessation of tobacco use is questionable, since smokers may choose to consume both tobacco products and electronic cigarettes, with the result that electronic cigarettes in actual fact become a means of maintaining nicotine addiction.

It should be stated in this connection that the effects of electronic cigarettes on human health are a source of controversy internationally, as the WHO notes in a report of 1 September 2014 entitled 'Electronic nicotine delivery systems' ('the ENDS report'). That report states that some experts are in favour of those products, describing them as a means of reducing tobacco consumption, while others consider that those products could 'undermine efforts to denormalise tobacco use'. In the words of that report, electronic nicotine delivery systems represent 'an evolving frontier, filled with promise and threat for tobacco control'.

However, the ENDS report notes the existence of certain health risks related to the inhalation of nicotine and toxicants in aerosol and to nicotine exposure by means other than inhalation, in particular for children, adolescents, pregnant women and women of reproductive age.

The ENDS report also states that the scientific evidence for the effectiveness of electronic nicotine delivery systems as a method for quitting tobacco smoking is limited and does not allow conclusions to be reached. Likewise, the evidence available does not allow an affirmation or rejection of the 'gateway' and 'renormalisation' effects associated with the use of those delivery systems.

In its written observations, Pillbox acknowledges that the liquid and vapour of electronic cigarettes contain toxic and carcinogenic components, but at lower levels than those present in tobacco products, and that additional scientific studies are necessary.

Under such circumstances, the EU legislature had to take account of the precautionary principle, according to which, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (judgment in *Neptune Distribution*, C-157/14, EU:C:2015:823, paragraphs 81 and 82).

The validity of Article 20 of Directive 2014/40 with regard to the principles of proportionality and legal certainty should be examined in the light of those considerations.

As regards, in the first place, the assertion that, given that they are less harmful than tobacco products, or even beneficial for public health, electronic cigarettes should not be the subject of any specific rules, it should be noted, first, that there are significant differences between the relevant rules of the Member States, as is apparent from recital 36 of Directive 2014/40. 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. 26 et seq. and Part 4, p. 2), mentions the uncertainties surrounding the various national legal regimes applicable to electronic cigarettes. It follows in particular that some Member States tend to compare them on a case-by-case basis to medicinal products, whereas others prohibit them and others do not regulate them in any way.

However, taking into account the growing market for electronic cigarettes and refill containers, noted in both recital 43 of Directive 2014/40 and in the ENDS report, the national rules relating to the conditions which those products must satisfy are in themselves liable, in the absence of harmonisation at Union level, to constitute obstacles to the free movement of goods (see, by analogy, judgment in *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 64).

Secondly, at its Sixth session held in Moscow from 13 to 18 October 2014, the Conference of the Parties to the FCTC invited, by decision of 18 October 2014 relating to electronic nicotine delivery systems and electronic non-nicotine delivery systems (FCTC/COP/6(9)), those parties to consider, in particular, prohibiting or regulating electronic nicotine delivery systems and electronic non-nicotine delivery systems, banning or restricting advertising, promotion and sponsorship of electronic nicotine delivery systems and fully monitoring the use of electronic nicotine delivery systems and electronic non-nicotine delivery systems.

Thirdly, the identified and potential risks linked to the use of electronic cigarettes, noted in the ENDS report and mentioned in paragraphs 52 and 53 of the present judgment, required the EU legislature to act in a manner consistent with the requirements stemming from the precautionary principle.

In those circumstances, in deciding to devote specific rules to the placing on the market of electronic cigarettes and refill containers, the EU legislature intended (i) to ensure the smooth functioning of the internal market as regards those products, taking as a base a high level of protection of human health, especially for young people, and (ii) to meet the obligations of the Union under the FCTC. By acting as such, the EU legislature did not manifestly infringe the limits of its discretion in the matter, in accordance with the case-law referred to in paragraph 49 of the present judgment.

As regards, in the second place, the argument that Article 20 of Directive 2014/40 is contrary to the principle of proportionality owing to the fact that it submits electronic cigarettes and refill containers to comparable, or even stricter, rules than those reserved for tobacco products, it should be observed that, as is apparent from paragraphs 36 to 43 of the present judgment, the former products can be distinguished from the latter products by their objective characteristics and by their novelty on the market concerned, which justifies the application to them of specific rules.

In those circumstances, a comparison between the rules applicable to tobacco products and those relating to electronic cigarettes and refill containers is irrelevant.

In the third place, it is admittedly true that the measures chosen by the EU legislature pursuant to Article 20 of Directive 2014/40 were not included among those which had been initially intended by the Commission in its 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 (COM(2012) 788 final) and were therefore not the subject of the impact assessment accompanying that proposal and referred to in paragraph 57 of the present judgment.

However, the Court has already held in this regard that such an impact assessment is not binding on either the Parliament or the Council (judgment in *Afton Chemical*, C-343/09, EU:C:2010:419, paragraph 57). Consequently, the EU legislature remains free to adopt measures other than those which were the subject of that impact assessment. Therefore, the mere fact that it adopted a different and, as the case may be, more onerous measure than the measures envisaged by the Commission in the impact assessment referred to in paragraph 57 of the present judgment is not such as to demonstrate that it manifestly exceeded the limits of what was necessary in order to achieve the stated objective.

Moreover, during the legislative process, the Parliament, the Council and the Commission took account of the available scientific evidence and the opinions of the interested parties. It is common ground that a number of consultations and meetings were organised at a late stage in that process precisely in order to collect the necessary information on the options available to the EU legislature. Thus, the Commission in particular conducted, on 25 November 2013, further discussions with associations representing the tobacco industry, in particular the Tobacco Vapor Electronic Cigarette Association (TVECA) and the Electronic Cigarette Industry Trade Association (ECITA). In addition, the Parliament's Committee on the Environment, Public Health and Food Safety held, on 19 March 2013, an open meeting with representatives of the industry concerned and also, on 7 May 2013, a workshop on electronic cigarettes with the participation of experts from the WHO, national authorities, scientists and consumer associations.

It follows from the foregoing that consideration of the question referred in the light of the principles of proportionality and legal certainty has disclosed no factor of such a kind as to affect the validity of Article 20 of Directive 2014/40, in so far as it establishes a specific regime applicable to electronic cigarettes.

Nevertheless, it is necessary to examine in turn the grounds of invalidity referred to in the order for reference specifically concerning Article 20(2), (3), (4)(a) and (5) to (7) of Directive 2014/40 in the light of those principles.

– The validity of Article 20(2) of Directive 2014/40

It is apparent from the order for reference that the validity of Article 20(2) of Directive 2014/40 is contested on the ground that (i) that provision submits electronic cigarettes to a stricter authorisation regime than that applicable to tobacco products, (ii) that regime is, in any event, disproportionate since there are other less

onerous measures which are appropriate for the purpose of achieving the objective pursued by that provision, (iii) the six-month period laid down in the same provision is excessive in that it hinders innovation, and (iv) some of the information subject to notification, such as that referred to in point (d) of the second subparagraph of Article 20(2) of Directive 2014/40, is expressed too vaguely, which runs counter to the principle of legal certainty.

As regards, first, the argument that Article 20(2) of Directive 2014/40 submits electronic cigarettes to a stricter authorisation regime than that applicable to tobacco products, it must be held that that argument is based on a manifestly erroneous reading of that provision. That provision does not submit electronic cigarettes to an authorisation regime, but rather to a notification scheme. Unlike an authorisation regime, which obliges, as a general rule, manufacturers and importers to obtain the prior approval of the competent authority before being allowed to place the product concerned on the market, the regime provided for in Article 20(2) of Directive 2014/40 is significantly less onerous, since it requires only the lodging, by the manufacturers and importers of electronic cigarettes and refill containers, of a notification six months before the date planned for the placing on the market of any product of that type.

As regards, secondly, the allegedly disproportionate nature of that obligation, it should be observed first of all that, in accordance with recital 36 of Directive 2014/40, that obligation seeks to enable Member States to carry out their surveillance and control tasks. Such an approach is justified, in addition, by the requirements linked to the precautionary principle, noted in paragraph 55 of the present judgment, and by the invitation to the Parties to the FCTC to 'fully monitor' the use of that product, as noted in paragraph 59 of this judgment. It consequently seems appropriate for the purpose of achieving the objective pursued by that provision.

As for the question whether that obligation does not go beyond what is necessary to achieve that objective, it should be held that the alternative measure suggested by Pillbox, namely the setting, at EU level, of common standards applicable to electronic cigarettes and refill containers, does not seem, at this stage, to be a possible measure, as the Parliament, the Council and the Commission state, since the development of such standards presupposes as a matter of course the existence of sufficiently substantive data concerning the product at issue, which the EU legislature did not have at its disposal at the time of the adoption of Directive 2014/40.

Moreover, the six-month period laid down in the first subparagraph of Article 20(2) of that directive seeks to give the competent authorities sufficient time to examine all of the data which the manufacturers and importers have submitted to them. In view of the amount of information which is subject to notification and the uncertainties surrounding the consumption of electronic cigarettes, that period does not seem manifestly excessive.

The claim that that period is liable to undermine innovation in the sector concerned is not sufficiently substantiated to enable the Court to assess its relevance. In any event, similar — or even stricter — schemes applicable to other products, such as those established by Directives 2001/83 and 93/42, have not in any way prevented innovation in the area covered by those directives.

Therefore, the notification obligation laid down in Article 20(2) of Directive 2014/40 does not seem manifestly inappropriate or going manifestly beyond what is necessary to attain the objective pursued by that provision.

As regards, thirdly, the alleged breach of the principle of legal certainty, it is argued that the obligation to provide information on the nicotine doses and uptake 'when consumed under normal or reasonably foreseeable conditions', pursuant to point (d) of the second subparagraph of Article 20(2) of the directive, is not sufficiently precise, given that those values vary depending on the pattern of consumption of each user.

However, as observed by the Advocate General in point 92 of her Opinion, the information to be provided under that provision is clearly not information on the individual nicotine dose and uptake of specific consumers but the minimum, average and maximum levels normally expected from smoking an electronic cigarette.

In addition, it is open to the EU legislature to have recourse to a general legal framework which is, if necessary, to be made more precise at a later date. In the present case, it is precisely the Commission which must adopt, pursuant to Article 20(13) of Directive 2014/40, implementing acts laying down, inter alia, a common format for the notification provided for in paragraph 2 of that article.

In those circumstances, it cannot be held that the EU legislature has infringed the principle of legal certainty.

It follows from the foregoing considerations that the examination of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(2) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

– The validity of Article 20(3) of Directive 2014/40

It is apparent from the order for reference that the grounds relied on in support of the invalidity of Article 20(3) of Directive 2014/40 relate, in actual fact, only to the requirements imposed under points (a), (b) and (f) of that paragraph.

In relation, first of all, to Article 20(3)(a) of Directive 2014/40, it should be observed that, in the words of that provision, nicotine-containing liquid can be placed on the market only in dedicated refill containers not exceeding a volume of 10 ml and that, in disposable electronic cigarettes or in single use cartridges, the cartridges or tanks must not exceed a volume of 2 ml.

Article 20(3)(b) of Directive 2014/40 requires the nicotine-containing liquid not to contain nicotine in excess of

20 mg/ml.

Those requirements contribute to the objective of that directive 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 health, especially for young people.

So far as concerns, in the first place, whether those requirements are appropriate to attain that objective, it must be held that, in accordance with the Court's case-law recalled in paragraph 58 of the present judgment, the rules harmonising the composition of electronic cigarettes and refill containers are by their very nature appropriate for the purpose of removing the obstacles to the free movement of those goods.

In addition, the requirements set out in Article 20(3)(a) and (b) of Directive 2014/40 make it possible to limit the risks linked to exposure to nicotine. Therefore, they are also appropriate for ensuring a high level of protection of human health.

As regards, in the second place, the question whether such constraints go beyond what is necessary to attain the objective pursued by Directive 2014/40, it is necessary, on the one hand, to dismiss, for the reasons already set out in paragraphs 36 to 43 of the present judgment, the argument that the requirement laid down in Article 20(3)(a) of that directive is stricter than the rules applicable to tobacco products.

With regard, on the other hand, to Article 20(3)(b) of Directive 2014/40, Pillbox submits that, by fixing at 20 mg/ml the maximum nicotine yield which may be contained in the liquid of electronic cigarettes, the EU legislature acted on the basis of an incorrect scientific premiss. The EU legislature justified that value by the fact that it allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette, made using tobacco, during the time needed to smoke such a cigarette. According to Pillbox, such a premiss fails to have regard to the specific modus operandi of electronic cigarettes, since, whereas the nicotine content stated on packets of cigarettes made using tobacco concerns the amount of metabolised nicotine delivered into the smoker's bloodstream, the maximum nicotine yield chosen in Article 20(3)(b) of Directive 2014/40 refers to the 'physical' quantity of nicotine contained in the liquid of electronic cigarettes. By acting as such, the EU legislature significantly reduced the efficacy of electronic cigarettes as a substitute for tobacco products, contrary to the objective of protecting human health at a high level.

The Parliament, the Council and the Commission dispute the merits of that claim and refer to other scientific studies.

It is necessary to rule on that question, it being apparent from the file submitted to the Court that, in order to determine the maximum nicotine yield which may be contained in the liquid of electronic cigarettes, the EU legislature also relied on other objective evidence.

First, the need to impose a maximum nicotine value which may be contained in the liquid of electronic cigarettes is justified in the light of the risk, noted in the ENDS report, of overdose or poisoning.

Secondly, as stated by the Parliament, the Council, the Commission and the French and Spanish Governments, without being contradicted on that point, the information available at the time of the adoption of Directive 2014/40 showed that the large majority of electronic cigarettes sold on the internal market had a nicotine yield of less than 30 mg/ml.

Moreover, as the Parliament and the Commission state, Pillbox itself acknowledged, in an open letter sent to the Parliament on 8 July 2013, that a smoker who smokes on average 20 cigarettes made using tobacco per day needs 18 to 24 mg/ml of nicotine for his electronic cigarette to be a credible option as a replacement for so-called 'traditional' tobacco products.

Thirdly, the placing on the market of electronic cigarettes whose liquid contains more than 20 mg/ml of nicotine is not prohibited under EU law. As is apparent from the second subparagraph of Article 20(1) of Directive 2014/40, read in the light of recital 36 of that directive, such products may, depending on the circumstances, be placed on the market within the European Union under the conditions and according to the procedures laid down by Directives 2001/83 and 93/42.

In providing for such a possibility, the EU legislature took into account the need, for some consumers, on account of their state of dependence or their habits, to use, as an aid to quit smoking, electronic cigarettes containing a nicotine concentration which is higher than that allowed by Article 20(3)(b) of Directive 2014/40.

All of those elements show that the EU legislature balanced the various interests by taking several factors into account and without exceeding the limits of its broad discretion.

Consequently, it is not apparent that, by adopting Article 20(3)(a) and (b) of Directive 2014/40, the EU legislature acted arbitrarily or manifestly exceeded the limits of what was appropriate and necessary in order to achieve the objective which it pursued, namely that of facilitating the smooth functioning of the internal market for electronic cigarettes and refill containers, taking as a base a high level of protection of health, especially for young people.

Next, as regards Article 20(3)(f) of Directive 2014/40, it is apparent from the order for reference that its validity is contested with regard to the principle of legal certainty. In view of the fact that the doses delivered by electronic cigarettes vary from one consumer to the other depending on the manner of use of those products, the requirement that those cigarettes must deliver nicotine doses 'at consistent levels under normal

conditions of use' is lacking in clarity.

It is apparent from recital 39 of Directive 2014/40 that that requirement seeks inter alia to avoid the risk of accidental consumption of high doses of nicotine.

It must be held that, read in the light of that objective, Article 20(3)(f) of that directive defines with sufficient clarity the result to be achieved, namely that each inhalation releases the same quantity of nicotine under identical conditions of use, including the strength of the inhalation.

The fact that that provision does not prescribe any specific method or process for the purposes of the fulfilment of that requirement does not mean, however, that it infringes the principle of legal certainty.

In the absence of any legislation in this connection at Union level, it is for the Member States or, depending on the circumstances, for the manufacturers themselves to choose a reliable method capable of ensuring compliance with that requirement.

It follows from the foregoing that consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(3) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

– The validity of Article 20(4)(a) of Directive 2014/40

It is apparent from the order for reference that the validity of Article 20(4)(a) of Directive 2014/40 is contested on the ground that it is disproportionate to require the unit packages of electronic cigarettes and refill containers to contain a separate leaflet given that the information required might also be set out on the packaging of the product and that there is no analogous requirement in relation to cigarettes made using tobacco.

In that regard, it should be observed, first, that the number and nature of some of the information which has to be set out in a separate leaflet, such as the information relating to contra-indications, warnings for specific risk groups and possible adverse effects, are such that it seems unlikely that the information can be set out in a sufficiently visible and legible way on the packaging alone, particularly as the packaging must include, pursuant to Article 20(4)(b) of Directive 2014/40, the list of all ingredients contained in that product and the health warnings required.

Secondly, a leaflet separate from the packaging of the product and including information such as that mentioned in the previous paragraph of the present judgment enables consumers to have that information at their disposal even after having thrown that packaging away.

Thirdly, the argument as to the absence of any analogous requirement applicable to cigarettes made using tobacco cannot succeed for the reasons set out in paragraphs 36 to 43 of the present judgment.

In those circumstances, it is not apparent that, by adopting Article 20(4)(a) of Directive 2014/40, the EU legislature manifestly exceeded the limits of what is appropriate and necessary in order to achieve the objective pursued by that directive.

It must therefore be held that consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(4)(a) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

– The validity of Article 20(5) of Directive 2014/40

Article 20(5) of Directive 2014/40 essentially prohibits commercial communications and sponsorship for electronic cigarettes and their refill containers if those practices seek directly or indirectly to promote those products.

It is apparent from the order for reference that the validity of that provision is contested on the ground that it has a disproportionate impact on a developing market, whereas tobacco products have benefited for years from advertising enabling them to establish themselves on a long-term basis on the market. In addition, it is alleged that the prohibition is drafted in wide terms in order to include the sale of electronic cigarettes online, whereas no prohibition of that kind applies to tobacco products.

The prohibition laid down in Article 20(5) of Directive 2014/40 seeks to ensure that a uniform regime for the trade in electronic cigarettes within the internal market is applied, while ensuring a high level of protection of human health, taking account of the uncertainties surrounding that product and the requirements stemming from the precautionary principle.

In that regard, it must be held, first, that that prohibition is appropriate for the purpose of achieving that objective. It is apparent from recital 43 of the directive that disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes hinder the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. In the absence of measures adopted at Union level, those disparities are likely to increase over the coming years, also taking into account the rapid expansion of the market for electronic cigarettes and refill containers.

Moreover, Article 20(5) of Directive 2014/40 means that consumers — not least young people who are particularly sensitive to advertising — are confronted with fewer commercial inducements to purchase and consume electronic cigarettes with the result that they are less exposed to the identified or potential risks to human health to which those products could give rise.

So far as concerns, secondly, the necessity of that prohibition, it should be noted that, by its decision

mentioned in paragraph 59 of the present judgment, the Conference of the Parties to the FCTC urged '[the p]arties to consider banning or restricting advertising, promotion and sponsorship of [electronic nicotine delivery systems]'.

In those circumstances, it is not apparent that, by adopting Article 20(5) of Directive 2014/40, the EU legislature manifestly exceeded the limits of what is necessary in order to achieve the objective pursued by that directive.

The fact that tobacco products have been able to benefit for many years from advertising campaigns cannot under any circumstances constitute a reason requiring the EU legislature to allow such campaigns also for electronic cigarettes. On the contrary, as soon as it became aware of serious scientific information alleging the existence of potential risks to human health to which a relatively new product on the market might give rise, the EU legislature was required to act in accordance with the precautionary principle in the second sentence of Article 35 of the Charter, Article 9 TFEU and Articles 114(3) TFEU and 168(1) TFEU which require it to ensure a high level of protection of human health in the definition and implementation of all Union policies and activities.

As for the objection that Article 20(5) of Directive 2014/40 also prohibits the sale of electronic cigarettes online, it should be held that that objection is based on a manifestly erroneous reading of that provision. Nothing in the wording of that provision suggests that it seeks to prohibit that means of marketing in any way. On the contrary, it is apparent from Article 20(6) of Directive 2014/40, which refers to Article 18 of that directive, that the directive does not impose such a prohibition, but leaves it to the discretion of the Member States to prohibit or to allow, under certain conditions, cross-border distance sales, including the sale over the internet of electronic cigarettes and refill containers.

It must therefore be concluded that consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(5) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

– The validity of Article 20(6) of Directive 2014/40

Article 20(6) of Directive 2014/40 provides that Article 18 of the directive is to apply to cross-border distance sales of electronic cigarettes and refill containers. Article 18 of the directive provides that Member States may prohibit cross-border distance sales of tobacco products to consumers and imposes a series of common rules on the Member States which do not prohibit those sales.

It is apparent from the order for reference that the validity of Article 20(6) of Directive 2014/40 is contested on the ground that, in the first place, it infringes the principle of proportionality, since there are less onerous but equally appropriate measures in order to achieve the objective pursued by that directive, such as the introduction of age limits applicable specifically to the consumption of electronic cigarettes, and, in the second place, the EU legislature did not justify the extension of the rule laid down in Article 18 of that directive to trade in electronic cigarettes.

As regards, in the first place, the allegedly disproportionate nature of the rule laid down in Article 20(6) of Directive 2014/40, it should be noted that the objective of that provision is made clear in recital 33 of that directive, 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, secondly, entail an increased risk of young people getting access to those products. Those considerations apply *mutatis mutandis* to electronic cigarettes and to refill containers, as demonstrated by the reference made in Article 20(6) of the directive to Article 18 of the same directive.

The latter provision accordingly seeks to enable the Member States to ensure that the rules on conformity laid down by Directive 2014/40 in relation to electronic cigarettes and refill containers are not circumvented, whilst taking as a basis a high level of human health protection, particularly for young people.

The Court has already held that an EU measure adopted on the basis of Article 114 TFEU may incorporate provisions seeking 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).

By allowing the Member States to prohibit the cross-border distance sales of electronic cigarettes and refill containers and by imposing certain common rules on the Member States which do not prohibit those sales, the measures laid down in Article 20(6) of Directive 2014/40 are appropriate for the purpose of achieving the objective identified in paragraph 122 of the present judgment.

As regards whether those measures are strictly necessary, it should be noted that that provision does not impose a prohibition on the cross-border sale of electronic cigarettes and refill containers, but leaves it to the discretion of the Member States to prohibit such sales or to allow them under certain conditions.

Article 20(6) of Directive 2014/40 thus enables the Member States to adapt their action on the basis of relevant scientific advances and the development of the relevant market.

It has not been established that the introduction of age limits applicable specifically to the consumption of electronic cigarettes, recommended by Pillbox as a less onerous measure, constitutes an efficient way of ensuring a high level of human health protection, particularly for young people, having regard in particular to

the fact that such a measure may be easily circumvented in a cross-border distance sale.

In those circumstances, it is not apparent that the rule laid down in Article 20(6) of Directive 2014/40 goes manifestly beyond what is appropriate and necessary to achieve the objective pursued by that directive.

As regards, in the second place, the alleged lack of reasoning underlying that provision, it is true that recital 33 of Directive 2014/40 refers only to tobacco products. However, the fact that Article 20(6) of Directive 2014/40 merely refers, as regards electronic cigarettes and refill containers, to the rules laid down in Article 18 of that directive shows that the EU legislature considered that the reasoning set out in that recital applies *mutatis mutandis* to the cross-border sale of electronic cigarettes and refill containers.

It is apparent, in this respect, from the Court's case-law that the statement of reasons for a measure of general application may be limited to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it intends to achieve, on the other (see, inter alia, judgment in *Inuit Tapiriit Kanatami and Others* v *Commission*, C-398/13 P, EU:C:2015:535, paragraph 29).

It must therefore be held that consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(6) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

– The validity of Article 20(7) of Directive 2014/40

Article 20(7) of Directive 2014/40 obliges manufacturers and importers of electronic cigarettes and refill containers to submit each year, to the competent authorities of the Member States, certain data enabling those authorities to monitor the development of the market.

The validity of that provision is disputed on the ground, first, that it imposes a disproportionate burden on manufacturers and importers of electronic cigarettes and refill containers, when manufacturers and importers of tobacco products are not subject to any similar obligation, and that other less onerous measures, such as market surveys, would make it possible to monitor the development of that market. Secondly, the obligation to provide information on the 'preferences of various consumer groups' lacks clarity and therefore infringes the principle of legal certainty.

It is apparent from recital 44 of Directive 2014/40 that the objective of Article 20(7) of the directive is to enable the Commission and the Member States to collect comprehensive information on the development of the market for electronic cigarettes and refill containers in order to perform their regulatory tasks.

Since the appropriateness of that measure is not disputed, it is important to establish, first, whether that measure goes manifestly beyond what is necessary to achieve that objective.

In that regard, the Court must reject, first of all, the objection that that obligation is disproportionate solely because manufacturers and importers of tobacco products are not subject to any similar obligation. Unlike tobacco products, for which the competent authorities already have detailed information on account of their long-standing presence on the market and the scientific studies of which they were the subject, the placing on the market of electronic cigarettes and refill containers could, and indeed should, be the subject of increased monitoring because of the novelty of those products and the uncertainties regarding the risks to human health borne by their consumers.

It should be observed, next, that the data which the manufacturers and importers of electronic cigarettes and refill containers must provide under Article 20(7) of Directive 2014/40, namely the sales volumes and mode, the preferences of various consumer groups, the main types of existing users and summaries of any relevant market surveys carried out, directly relate to their business activities, with the result that they are better placed to provide those data. In addition, since those data are clearly of relevance for the development of the trade strategies of the manufacturers and importers of those products, it seems probable that they are frequently collected by them. It does not appear, therefore, that that obligation imposes on those manufacturers and importers a manifestly excessive burden.

Lastly, as regards the option of prescribing surveys of the market concerned as a less onerous measure, it suffices to note that there is nothing to prevent the competent authorities or the manufacturers and importers of electronic cigarettes and refill containers from carrying out such surveys for the purposes of monitoring the market or collecting certain information covered by Article 20(7) of Directive 2014/40. However, such surveys can provide only part of the relevant data for market surveillance purposes and cannot act as a substitute for more accurate, reliable and exhaustive information coming directly from the manufacturer or the importer.

In respect of, in the second place, the alleged lack of clarity regarding the contours of the obligation to provide information on the 'preferences of various consumer groups' referred to in Article 20(7)(ii) of Directive 2014/40, it is already apparent from paragraphs 78 and 101 of the present judgment that it is not necessary for a legislative act to itself provide details of a technical nature, such as, inter alia, the definition of the methodology which it is necessary to apply in order to collect any such data and, moreover, in the absence of any legislation in this connection at Union level, it is for the Member States to choose a reliable method for the enforcement of the relevant obligations.

It follows from the foregoing that consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20(7) of Directive 2014/40 in the light of the principles of proportionality and legal certainty.

In the light of all the considerations set out in paragraphs 47 to 140 of the present judgment, it must be held that consideration of the question referred has disclosed no factor of such a kind as to affect the validity, in whole or in part, of Article 20 of Directive 2014/40 in the light of those principles.

The validity of Article 20 of Directive 2014/40 in the light of the principle of subsidiarity

By its question, the referring court is asking the Court, in the third place, to examine the validity, in whole or in part, of Article 20 of Directive 2014/40 in the light of the principle of subsidiarity.

The referring court refers in this connection to the fact that several national parliaments have taken the view that the draft directive was not consistent with the principle of subsidiarity and for that reason issued reasoned opinions pursuant to Protocol (No 2) on the application of the principles of subsidiarity and proportionality, annexed to the TEU and to the TFEU ('Protocol (No 2)'), and, moreover, that the existence of differences at national level as regards the rules applicable to electronic cigarettes and to refill containers has not been sufficiently demonstrated.

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) 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).

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).

Subsequently, responsibility for the monitoring of compliance with that principle 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 Protocol (No 2).

As regards, in the first place, judicial review of compliance with the procedural safeguards provided for in Protocol (No 2), it should be observed that the reasoned opinions issued in the present case by the national parliaments pursuant to that protocol are part of the mechanism in connection with the political monitoring of compliance with that principle established by that protocol. In that context, the Court must review only compliance with the procedural safeguards provided for by that protocol. However, in the present case, the Court has not received any such request.

As regards, in the second place, the substantive conditions laid down in Article 5(3) TEU, the Court must examine 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.

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).

So far as concerns the consideration, expressed in the order for reference, that it has not been demonstrated to the requisite legal standard that there were differences at national level as regards the rules applicable to electronic cigarettes and to refill containers, it suffices to observe that the existence of such differences has already been noted in paragraphs 57 and 112 of the present judgment.

It follows from the foregoing that consideration of the question referred for a preliminary ruling has disclosed no factor of such a kind as to affect the validity, in whole or in part, of Article 20 of Directive 2014/40 in the light of the principle of subsidiarity.

The validity of Article 20 of Directive 2014/40 in the light of Articles 16 and 17 of the Charter

By its question, the referring court is asking the Court, in the fourth place, to examine the validity of Article 20 of Directive 2014/40, and in particular paragraph 5 thereof, in the light of Articles 16 and 17 of the Charter.

According to the order for reference, the prohibition on commercial communications imposed by Article 20(5) of Directive 2014/40 is such as to hinder Pillbox's business activity, in breach of Articles 16 and 17 of the Charter.

As regards, in the first place, Article 16 of the Charter, it should be noted that, in the words of that article, 'the freedom to conduct a business in accordance with Union law and national laws and practices is recognised'.

The protection afforded by Article 16 of the Charter covers the freedom to exercise an economic or commercial activity, the freedom of contract and free competition, as is apparent from the explanations relating to that article, which, in accordance with the third subparagraph of Article 6(1) TEU and Article 52(7) of the Charter, have to be taken into consideration for the interpretation of the Charter (judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 42).

In the present case, in so far as the prohibition on commercial communications imposed by Article 20(5) of Directive 2014/40 does not allow economic operators to promote their products, it constitutes an interference with the freedom of those operators to conduct a business.

However, in accordance with the case-law of the Court, the freedom to conduct a business does not constitute

an unfettered prerogative, but must be examined in the light of its function in society (see, to that effect, judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 45).

The freedom to conduct a business may thus be subject to a broad range of interventions on the part of public authorities which may limit the exercise of economic activity in the public interest (judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 46).

That circumstance is reflected, inter alia, in the way in which Article 52(1) of the Charter requires the principle of proportionality to be implemented (judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 47).

In accordance with Article 52(1) of the Charter, any limitation on the exercise of the rights and freedoms recognised 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, must be necessary and actually meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others (judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 48).

In that regard, it must be noted that the limitation at issue was laid down by Article 20(5) of Directive 2014/40, that is to say by law, for the purpose of Article 52(1) of the Charter, and that it does not affect the essence of the freedom to conduct a business. Neither that provision of the directive nor indeed any other of its provisions prevents economic operators from manufacturing and marketing electronic cigarettes and refill containers in compliance with the conditions laid down in that regard by the directive.

For the reasons set out in paragraphs 109 to 118 of the present judgment, nor does the interference found exceed the limits of what is appropriate and necessary to achieve the legitimate objectives pursued by Directive 2014/40.

As regards, in the second place, Article 17 of the Charter, which enshrines the right to property, it should be observed that, in accordance with the second paragraph of that article, that right also relates to intellectual property.

In so far as Pillbox relies on an interference with the management of its commercial property, including its brand name, it is sufficient to note that Article 20 of Directive 2014/40 in no way hinders the use of its intellectual property in connection with the marketing of its products, with the result that the essence of its property right essentially remains intact. Moreover, for reasons analogous to those set out in paragraphs 109 to 118 of the present judgment, that interference does not exceed the limits of what is appropriate and necessary to achieve the legitimate objectives pursued by Directive 2014/40.

It follows from the foregoing that consideration of the question referred has disclosed no factor of such a kind as to affect the validity, in whole or in part, of Article 20 of Directive 2014/40 in the light of Articles 16 and 17 of the Charter.

It follows from all of the foregoing considerations that the answer to the question referred for a preliminary ruling is that consideration of the question referred has disclosed no factor of such a kind as to affect the validity, in whole or in part, of Article 20 of Directive 2014/40.

Costs

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:

Consideration of the question referred has disclosed no factor of such a kind as to affect the validity of Article 20 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.

[Signatures]

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* Language of the case: English.