Court of Justice EU, 4 May 2016, Pillbox v Secretary of State for Health

ADVERTISING

No factors of such a kind as to affect the validity of Article 20 of Directive 2014/40 on the manufacture, presentation and sale of tobacco and related products

- **No infringement principle of equal treatment**

42. 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.

43. 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.

- **No infringement principle of proportionality and legal certainty**

57 […]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.

58. 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).

60. 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.

62. 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.

65. 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.

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Court of Justice EU, 4 May 2016

(R. Silva de Lapuerta, J.L. da Cruz Vilaça, A. Arabadjiev (Rapporteur), C. Lycourgos, J.-C. Bonichot)

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

1. 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).

2. 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

3. 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

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

'(7) 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.

...

...

(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. ...

...

(36) 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.

...

(38) 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.

(39) 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.

(40) 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.

(41) 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.

...

(43) 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.

(44) 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.

(45) 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.

...

(47) 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)].

(48) 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. ...'

5. 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:

...

(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].'

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

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

...

(16) "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;

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

7. 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:

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

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

(c) additives having colouring properties for emissions;

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

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

8. 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:

(a) 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;

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

(c) 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;

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

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

(f) 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;

(g) 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:

(a) 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;

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

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

(d) 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;

(e) 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;

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

(g) 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:

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

(i) 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;

(ii) contra-indications;

(iii) warnings for specific risk groups;

(iv) possible adverse effects;

(v) addictiveness and toxicity; and

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

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

(i) 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;

(ii) 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

(iii) carry 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;

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

5. Member States shall ensure that:

(a) 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;

(b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;
(c) 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;
(d) 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;
(e) 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:
(i) comprehensive data on sales volumes, by brand name and type of the product;
(ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
(iii) the mode of sale of the products; and
(iv) 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).
...'

9. 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

10. 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.

11. 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').

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

13. 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

14. 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.

15. 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).

16. 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).

17. 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).

18. 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).

19. 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).

20. 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.

21. 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.

22. 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.

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

24. 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).

25. 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.

26. 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).

27. 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.

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

29. 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.

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

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

Substance

32. 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

33. 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.

34. 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.

35. 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).

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

37. 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.

38. 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.

39. 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.

40. 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.

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

42. 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.

43. 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.

44. 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.

45. 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

46. 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

47. 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.

48. 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).

49. 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).

50. 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.

51. 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’*.

52. 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.

53. 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.

54. 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.

55. 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).

56. 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.

57. 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.

58. 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).

59. 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.

60. 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.

61. 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.

62. 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.

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

64. 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.

65. 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.

66. 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.

67. 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.

68. 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

69. 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.

70. 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.

71. 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.

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

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

80. 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

81. 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.
82. 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.
83. Article 20(3)(b) of Directive 2014/40 requires the nicotine-containing liquid not to contain nicotine in excess of 20 mg/ml.
84. 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.
85. 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.
86. 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.
87. 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.
88. 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.
89. The Parliament, the Council and the Commission dispute the merits of that claim and refer to other scientific studies.
90. 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.
91. 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.
92. 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.
93. 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.
94. 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.
95. 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.
96. 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.
97. 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.

98. 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.
99. 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.
100. 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.
101. 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.
102. 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
103. 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.
104. 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.
105. 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.
106. 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.
107. 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.
108. 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
109. 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.
110. 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.
111. 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.
112. 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.
113. 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.
114. 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]'*.

115. 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.

116. 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.

117. 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.

118. 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

119. 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.

120. 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.

121. 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.

122. 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.

123. 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).

124. 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.

125. 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.

126. 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.

127. 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.

128. 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.

129. 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.

130. 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).

131. 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

132. 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.

133. 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.

134. 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.

135. 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.

136. 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.

137. 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.

138. 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.

139. 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.

140. 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.

141. 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

142. 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.

143. 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.

144. 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).

145. 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).

146. 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).

147. 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.

148. 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.

149. 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).

150. 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.

151. 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

152. 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.

153. 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.

154. 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'*.

155. 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**).

156. 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.

157. 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**).

158. 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).
159. 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).
160. 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).
161. 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.
162. 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.
163. 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.
164. 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.
165. 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.
166. 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

167. 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]

* Language of the case: English.

OPINION OF ADVOCATE GENERAL KOKOTT
delivered on 23 December 2015 (1)
Case C‑477/14
Pillbox 38 (UK) Limited
(Request for a preliminary ruling from the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), United Kingdom)
(Approximation of laws — Article 20 of Directive 2014/40/EU — Manufacture, presentation and sale of tobacco and related products — Electronic cigarettes ('e-cigarettes') — Principle of proportionality — Principle of legal certainty — Principle of equal treatment — Principle of subsidiarity — EU fundamental rights — Freedom to conduct a business and right to property — Articles 16 and 17 of the Charter of Fundamental Rights)

I – Introduction

1. Hardly any EU legislation has led to such fierce legal disputes over the years as the various directives on the manufacture, presentation and sale of tobacco and related products in the European internal market. (2)
2. The most recent internal market harmonisation measure enacted in this area, Directive 2014/40/EU, (3) is no exception. It is currently occupying the Court in three parallel cases. However, the suitability of Article 114 TFEU (formerly Article 95 EC and Article 100a of the EEC Treaty) as a legal basis no longer plays the central role it did in earlier years, even though certain points of detail continue to be disputed. Interest is now focused on other legal questions, particularly in relation to the principle of proportionality, the principle of subsidiarity and EU fundamental rights.
3. A very basic problem ultimately underlies these legal questions, which involve huge economic interests and affect the lives of millions of Union citizens every day: what latitude does the Union legislature still have in ensuring that products may be placed on the market under uniform conditions throughout the European Union without losing sight of the fundamental

objective of a high level of health protection which has been enshrined prominently in primary law (Articles 9, 114(3) and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights of the European Union)?

4. In the present preliminary ruling proceedings, which originate from an action brought by Pillbox 38 (UK) Limited (4) in a UK court, the Directive as a whole is not under examination, only the new rules governing electronic cigarettes ('e-cigarettes') which have been introduced for the first time by the Union legislature in Article 20 of the Directive. By establishing those rules, the European Union has taken a significant step, even by international standards, towards resolving the delicate question of how, having due regard to the precautionary principle, to counter the possible health risks of e-cigarettes as a novel and still relatively little known product.

5. A further request for a preliminary ruling (5) — by the same court (but not the same judge) which referred the present case to the Court of Justice — concerns a number of specific provisions of the Directive and focuses in particular on the choice of Article 114 TFEU as the legal basis, the principle of subsidiarity, the principles of proportionality and legal certainty, questions relating to EU fundamental rights and problems connected with Articles 290 TFEU and 291 TFEU in respect of the delegation of regulatory and implementing powers to the Commission. On the other hand, the proceedings relating to an action for annulment brought by the Republic of Poland, (6) which are also pending, specifically concern the rules of Directive 2014/40 prohibiting menthol cigarettes. I am also delivering my Opinions in those two cases today.

II – The contested provisions of Directive 2014/40/EU

6. Article 20 of Directive 2014/40, under the heading 'Electronic cigarettes', includes the following provision:

'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/EC or to the requirements set out in Directive 93/42/EEC.

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:

(a) 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;

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

(c) 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;

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

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

(f) 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;

(g) 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:

(a) 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;

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

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

(d) 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;

(e) 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;

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

(g) 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:

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

(i) 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;

(ii) contra-indications;

(iii) warnings for specific risk groups;

(iv) possible adverse effects;

(v) addictiveness and toxicity; and

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

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

(i) 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;

(ii) 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

(iii) carry 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;

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

5. Member States shall ensure that:

(a) 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;

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

(c) 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;

(d) 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;

(e) audiovisual commercial communications to which Directive 2010/13/EU ... 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:

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

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

(iii) the mode of sale of the products; and

(iv) 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).

...'

III – The main proceedings and the reference for a preliminary ruling

7. Pillbox, an undertaking trading under the name 'Totally Wicked', manufactures and markets e-cigarettes. Before the referring court, the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), Pillbox has brought an action against the Secretary of State for Health (7) seeking to prevent the implementation of Article 20 of Directive 2014/40 in the United Kingdom.

8. In the main proceedings the Secretary of State maintains that Article 20 of the Directive is valid, but at the same time takes the view that he does not have the necessary information to defend that provision.

9. Against this background, the referring court decided that the Secretary of State was not required to produce submissions or evidence, but that it would ask the Court immediately about the validity of Article 20 of the Directive. By order of 6 October 2014, received on 27 October 2014, it referred the following question to the Court for a preliminary ruling pursuant to Article 267 TFEU:

Is Article 20 of Directive 2014/40/EU 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/or 17 of the Charter of Fundamental Rights?

10. Apart from setting out the wording of this question referred for a preliminary ruling, the order for reference simply summarises the legal arguments against Article 20 of the Directive made by Pillbox in the main proceedings 'so as to inform all persons who may wish to submit observations on the content of [Pillbox]'s challenge on the [directive]'. As the referring court regards Pillbox's claims as *'reasonably arguable'*, it considers it necessary to obtain a preliminary ruling from the Court.

11. In the written part of the preliminary ruling proceedings, written observations were submitted by Pillbox, the United Kingdom, Spanish and French Governments, the European Parliament, the Council of the European Union and the European Commission. The same parties were represented at the hearing on 1 October 2015.

IV – Admissibility of the request for a preliminary ruling

12. Before I examine the substance of the question referred, it is necessary briefly to consider the admissibility of this request for a preliminary ruling. First, the question arises whether the validity of the provisions of the Directive governing e-cigarettes may be challenged and reviewed before the Court in isolation. Second, it must be examined whether the circumstances under which the Court was seised in the present case are compatible with the spirit and the operation of the preliminary ruling procedure under Article 267 TFEU.

1. The restriction of the question of validity to a single article of the Directive

13. The referring court does not ask the Court about the validity of Directive 2014/40 as a whole, but only the validity of one single provision of that directive, namely Article 20 thereof.

14. According to settled case-law, the partial annulment of an EU act is possible only if the elements the annulment of which is sought may be severed from the remainder of the act (*'the requirement of severability'*). (8) There is no such severability where the partial annulment of the contested act would have the effect of altering its substance. (9) This case-law can be readily transposed to the review of the validity of an EU measure in preliminary ruling proceedings. (10)

15. The provision at issue, Article 20 of the Directive, contains special rules for e-cigarettes which are independent of the provisions applicable to conventional tobacco products. They were included in the directive at issue only for the sake of simplicity, but could just as easily have been contained in a separate directive. No evidence has been put forward before this Court to indicate that the provisions on e-cigarettes contained in the Directive and the rules on other products should stand and fall together, for reasons relating to legislative technique or for political reasons, for example. Therefore, even if in this case the Court were to declare Article 20 of the Directive to be invalid in whole or in part, the other provisions contained in the Directive, in particular those on conventional tobacco products, would still have their raison d'être and their scope would not be altered.

16. Accordingly, Article 20 must be considered to be a severable part of Directive 2014/40 and its possible annulment would not affect the substance of that directive.

2. The circumstances in which the Court was seised

17. However, consideration must also be given to whether the circumstances in which the Court was seised in this case could affect the admissibility of the request for a preliminary ruling.

a) Reference to the Court before the expiry of the period for the implementation of the Directive

18. It is immaterial, first of all, that the request for a preliminary ruling was made at a time when the period for the implementation of the Directive had not yet expired and no national implementing measures had yet entered into force. (11) The principle of effective legal protection, which is also enshrined in Article 47 of the Charter of Fundamental Rights and finds expression in the second subparagraph of Article 19(1) TEU, specifically requires that individuals be able to obtain the judicial review of EU measures which are of concern to them, without having first to break the law. (12) Against this background, the possibility which exists in United Kingdom law, and has been used many times, of judicial review in combination with a possible reference to the Court for a preliminary ruling during the phase in which EU directives are implemented in national law should be welcomed in principle.

b) The alleged hypothetical nature of the question referred and the alleged artificial character of the main proceedings

19. Furthermore, the argument put forward by the Parliament, the Commission and France that the question referred to the Court is purely hypothetical and based on merely artificial main proceedings is not very convincing.

20. The starting point for considering this issue should be that questions referred 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 actual 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. (13)

21. The Parliament, the Commission and France are correct to state that the description of the facts in the main action contained in the order for reference is extremely brief and, in particular, does not include any detailed information about the nature of the e-cigarettes placed on the market by Pillbox. Nevertheless, it is clear that Pillbox sells e-cigarettes in the European internal market under the brand 'Totally Wicked'. There is therefore no doubt that in principle Pillbox's products fall within the scope ratione materiae of the Directive and the undertaking will be faced with a new legal situation after the Directive has been implemented in the United Kingdom. The question referred is therefore by no means manifestly hypothetical.

22. Contrary to the view taken by the Parliament, the Commission and France, a merely artificial legal dispute cannot be considered to exist in the present case. (14) It is true that in the main proceedings the defendant, the Secretary of State, has thus far made no substantiated defence submissions. However, it is solely for the national court or tribunal to decide at what stage in the main proceedings to make a request for a preliminary ruling to the Court of Justice; (15) this can happen even before an inter partes hearing in the main proceedings. (16)

23. Specifically in a situation like the present case, the Court has ruled, moreover, that a disagreement — and thus a genuine legal dispute — between the parties must be taken to exist wherever the authorities of the Member State concerned have declared their intention to implement the contested directive. (17) Such an intention can be inferred in this case from the fact that the Secretary of State expressly declared in the main proceedings that he considered Article 20 of the Directive to be valid. Under these circumstances, the question referred is certainly not based on a manifestly artificial legal dispute.

c) The possible absence of doubts on the part of the referring court itself as to the validity of the Directive

24. On the other hand, much greater weight must be given to the objection raised by the Parliament, the Commission and France that the referring court itself has not expressed doubts as to the validity of the Directive but, in its request for a preliminary ruling, merely presents to the Court the criticisms made by Pillbox.

25. In fact, in essence, the order for reference simply summarises the legal arguments against Article 20 of the Directive made by Pillbox in the main proceedings 'so as to inform all persons who may wish to submit observations on the content of [Pillbox]'s challenge on the [Directive]'.

26. It should be noted in this regard that the national court cannot simply forward an individual's complaints to the Court, but must adopt as its own the questions it refers to the Court for a preliminary ruling. (18) It is settled case-law that preliminary ruling proceedings under Article 267 TFEU do not constitute a means of redress available to the parties to a case pending before a national court themselves, but a procedure for cooperation and dialogue between the national court and the Court of Justice. (19)

27. Accordingly, it is for the national court itself to decide whether a question raised before it on the validity of an EU measure is necessary to enable it to give judgment in the main proceedings. (20) The fact that the validity of an EU act is contested before a national court is not in itself sufficient to warrant referral of a question to the Court for a preliminary ruling. (21) In principle, national courts are required to assist with the enforcement of EU law, including Directive 2014/40. (22)

28. In addition, the spirit of cooperation which must prevail in the operation of the preliminary reference procedure means that the national court is to set out in its order for reference the reasons why it considers such a reference to be necessary (23) (see also Article 94(c) of the Rules of Procedure of the Court of Justice).

29. Measured against these conditions, the order for reference with which the Court is confronted in this case is certainly far from exemplary.

30. Nevertheless, the national court has indicated that it regards Pillbox's claims as *'reasonably arguable'* and therefore considers it necessary to obtain a preliminary ruling from the Court.

31. Those statements indeed represent the absolute minimum of the information which must be provided by a national court in order to meet the conditions governing admissibility in the preliminary ruling procedure. In combination with Pillbox's arguments reproduced in the order for reference, however, they form a sufficient basis for the Court and for those entitled to take part in the proceedings under Article 23 of the Statute to submit observations on the legal problems raised in this case.

32. In view of the importance of the principle of effective legal protection (Article 47 of the Charter of Fundamental Rights) in the EU legal order, (24) the admissibility of requests for a preliminary ruling to review the validity of EU measures should not be subject to excessively strict conditions, particularly in cases like the present one in which, in the absence of the possibility of bringing a direct action, preliminary ruling proceedings are the only way for the undertakings concerned to obtain a judicial review at Union level and to present their case before the Court. (25)

33. All in all, this request for a preliminary ruling can therefore still be considered to be admissible despite the defects attached to the order for reference in this regard.

V – Substantive assessment of the question referred

34. By its reference the High Court of Justice asks the Court to review the validity of Directive 2014/40 from four different perspectives: in light of the principle of proportionality, the principles of equal treatment and free competition, the principle of subsidiarity, and by reference to the EU fundamental

rights under Articles 16 and 17 of the Charter of Fundamental Rights. These aspects of the request for a preliminary ruling all stem from arguments against the implementation of the Directive raised by Pillbox in the main proceedings before the High Court of Justice.

35. The issue of equal treatment should be examined first because it has repercussions on the way the other aspects of this request for a preliminary ruling are dealt with.

A – The principles of equal treatment and free competition

36. It must be clarified, first of all, whether Article 20 of the Directive is consistent with the principle of equal treatment under EU law. Pillbox makes the criticism that Article 20 imposes a higher regulatory burden on e-cigarettes than on conventional tobacco cigarettes even though e-cigarettes are *'by far and away the safer product'*. In the view of Pillbox, the effect of this alleged disparate treatment, for which no objective justification has been advanced, is to create a distortion of competition in the market, contrary to Article 3 TEU read in conjunction with Articles 106 TFEU, 116 TFEU and 119 TFEU and Protocol No 27 to the EU Treaty and to the FEU Treaty.

37. The statements made by the referring court regarding free competition, like those made by Pillbox itself, do not raise any new points when compared with the submissions on the principle of equal treatment and in particular do not reveal any separate reasoning. I will therefore focus below solely on the issue of equal treatment, although my statements also apply mutatis mutandis to the principle of free competition.

38. It must be recalled that the principle of equal treatment is a general principle of EU law, enshrined in Articles 20 and 21 of the Charter of Fundamental Rights. (26) It cannot be interpreted and applied differently depending on the area of law in question.

39. According to settled case-law, that principle requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified. (27)

40. It is completely undisputed that the Directive lays down, in Article 20 thereof, a number of special rules governing e-cigarettes which differ appreciably in several respects from the provisions applicable to conventional tobacco products.

41. Contrary to the view taken by Pillbox, however, this difference in treatment is not detrimental to manufacturers and importers of e-cigarettes. On the contrary, the conditions which apply under Article 20 of the Directive to the placing on the market of e-cigarettes in the European internal market — in particular the notification scheme (28) and warnings, (29) but also the absence of a prohibition of characterising flavours (30) — are, overall, less strict than those to be respected by manufacturers and importers of conventional tobacco products, even though a few of the rules applying to e-cigarettes and their refill containers are more onerous. (31)

42. For this reason alone, there is certainly no failure to comply with the principle of equal treatment to the detriment of manufacturers and importers of e-cigarettes. This has been rightly observed by the EU institutions participating in the preliminary ruling proceedings and some of the participating Member States.

43. Irrespective of this, acceptance of the existence of a failure to comply with the principle of equal treatment would in any case presume that the situations concerned are comparable, having regard to all the elements which characterise them. (32)

44. In this regard, a comparison should be made of the two types of product, having regard to all relevant circumstances. It must be borne in mind in this connection both whether the two kinds of products are in a comparable situation with reference to the purpose of the provisions at issue and whether they are similar in their objective characteristics.

45. First of all, it is settled case-law that the elements which characterise different situations, and hence their comparability, must in particular be determined and assessed in the light of the subject-matter and purpose of the European Union act which makes the distinction in question. The principles and objectives of the field to which the act relates must also be taken into account. (33)

46. The overall objective of Directive 2014/40 is to guarantee the circulation of both conventional tobacco products and e-cigarettes in the European internal market whilst ensuring a high level of health protection. (34)

47. However, the mere fact that the Union legislature pursues the same fundamental objective for both types of product — conventional tobacco products and e-cigarettes — does not allow the assumption to be made that the internal market harmonisation measures enacted by the Directive should necessarily be identical for both kinds of products.

48. It should be borne in mind that there are objective differences between the two types of product (35) — even though undeniably there exists a competitive relationship between them — which justify the inclusion of completely different provisions in the Directive in order to pursue a common purpose.

49. First, these differences relate to the physical nature of conventional tobacco products and e-cigarettes and the way in which they are consumed: combustion of tobacco on the one hand and electrical vaporisation of a (normally nicotine-containing and possibly flavoured) liquid on the other. Second, and above all, those differences between the two kinds of products can be seen from the fact that conventional tobacco products are well known on the market and their health risks have been widely researched, whilst a feature of e-cigarettes, at least at present, is that they are novel and — in large parts of the population — still relatively unknown.

50. All these differences suggest that at the time the Directive was adopted e-cigarettes were in a special situation, (36) as a result of which it was not only

permissible, but even necessary, for the Union legislature to treat them differently in certain respects from conventional tobacco products; it is not therefore possible successfully to claim a failure to comply with the principle of equal treatment. (37)

51. This is all the more so if e-cigarettes are compared with the other stimulants mentioned by Pillbox, such as coffee or alcohol. In terms of physical nature, the way in which they are consumed and consumer habits, the differences between those products and e-cigarettes are much greater and more obvious than the differences between e-cigarettes and conventional tobacco products. Furthermore, when compared with caffeinated and alcoholic beverages, e-cigarettes are, as has already been mentioned, a novel and relatively unknown product, which in itself justifies special treatment.

52. In summary, the claim that Article 20 of the Directive fails to comply with the principles of equal treatment and free competition must therefore be rejected.

B – The principle of proportionality and certain related considerations connected with the rule of law

53. By far the most space in the request for a preliminary ruling from the High Court of Justice and also in the observations submitted by the parties is devoted to the principle of proportionality. Following a complaint raised by Pillbox, the referring court asks the Court about the proportionality of various aspects of the provisions on e-cigarettes laid down in Article 20 of the Directive. Mention is also made in passing, in respect of certain elements of those provisions, of the principle of legal certainty, in particular the requirements of the principle of precision, and an allegedly defective statement of reasons.

1. General remarks on the principle of proportionality

54. According to settled case-law, the principle of proportionality is one of the general principles of EU law. It requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not go beyond what is necessary in order to achieve those objectives; (38) 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. (39)

55. It should be borne in mind in connection with the judicial review of the proportionality of EU measures that the extent of the EU legislature's discretion may prove to be limited, depending on a number of factors, where fundamental rights are at issue. Those factors include in particular, the area concerned, the nature of the fundamental right at issue, the nature and seriousness of the interference and the object pursued by the interference. (40)

56. In the present case, the fundamental right of freedom to conduct a business (Article 16 of the Charter of Fundamental Rights) is affected, which I will consider in a different connection further below. (41) According to settled case-law, the freedom to conduct a business may 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 (42) and the Union legislature has a broad discretion in an area which involves political, economic and social choices and in which it is called upon to undertake complex assessments and evaluations. (43)

57. It is undeniable that in adopting Directive 2014/40 the Union legislature was faced with precisely these kinds of complex economic, social and political questions and, moreover, this is not seriously called into question by any of the parties. Consequently, the Union legislature had to be allowed a broad discretion in respect of the assessments underlying the Directive, not least with regard to the measures which are best able to achieve the high level of health protection prescribed in the European internal market (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), especially since forecasts of future market activity may be reviewed as to their plausibility at most.

58. That discretion means that an infringement of the principle of proportionality by the Union legislature can be taken to exist only where the EU measure concerned is manifestly disproportionate, that is to say, where it is manifestly inappropriate for attaining the legitimate objectives pursued, goes manifestly beyond what is necessary to achieve those objectives or entails disadvantages which are manifestly disproportionate to its objectives. (44) On the other hand, it is irrelevant whether the measure adopted in the legislative act is the only conceivable measure or even only the most appropriate.

59. Subject to that proviso, a review should be conducted of the proportionality of the provisions on e-cigarettes laid down in Article 20 of the Directive.

60. Before I turn to the specific provisions of Article 20 of the Directive on which the request for a preliminary ruling focuses, a few remarks should be made, based on the criticisms raised by Pillbox, on the precautionary principle and impact assessments for legislative proposals by the EU institutions.

a) The precautionary principle

61. Pillbox has endeavoured in the proceedings before the Court to present e-cigarettes as largely harmless and to highlight their benefits in comparison with conventional tobacco products, in particular for heavy smokers as an alternative to consuming conventional tobacco cigarettes.

62. On the other hand, the EU institutions and the Member States participating in the preliminary ruling proceedings have stressed the health risks that may stem from e-cigarettes, not least the risk of nicotine poisoning from excessively long and intensive use or from incorrect handling of e-cigarettes, as well as the risk of nicotine addiction in general. (45) In particular, they consider that e-cigarettes can develop into a gateway to nicotine addiction (*'gateway effect'*). As the

consumption of e-cigarettes also mimics and normalises the action of smoking (*'normalisation effect'*), (46) with the growing attractiveness of e-cigarettes social acceptance of smoking in general could increase. Lastly, it is to be feared that some consumers will use both e-cigarettes and conventional tobacco cigarettes (*'dual use'*), which could make it more difficult for habitual smokers to escape nicotine addiction and make it easier for non-smokers — in particular adolescents and young adults — to start smoking, thus acting as a gateway to nicotine addiction.

63. Both sides rely on scientific studies in support of their respective arguments. However, both sides also recognise that further research into e-cigarettes is still required in order to establish a more reliable basis for evaluating this novel product and the risks to human health which it may cause.

64. Be that as it may, in assessing the lawfulness of Directive 2014/40, and in particular the proportionality of the provisions on e-cigarettes contained in Article 20 thereof, it is ultimately immaterial whether the health risks mentioned by the Union legislature — which seem very plausible to me personally — can be proven with sufficient accuracy in the current state of scientific research.

65. The Union legislature was required to take account of the precautionary principle when it adopted the Directive. (47) Precisely 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 if the risk materialises, the precautionary principle justifies the adoption of restrictive measures, provided those measures are non-discriminatory and objective. (48)

66. The recommendations drawn up within the framework of the World Health Organisation (WHO), (49) which call for the worldwide adoption of restrictive measures for e-cigarettes, are nothing other than an expression of the precautionary principle.

67. Against this background, it was perfectly reasonable and possibly even necessary, in accordance with the precautionary principle, to include restrictive provisions on e-cigarettes in the Directive, especially since under primary law a high level of health protection was to be ensured (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and second sentence of Article 35 of the Charter of Fundamental Rights).

b) The alleged failure to conduct an impact assessment

68. In addition, Pillbox criticises the fact that the text of Article 20 of the Directive adopted by the Union legislature was never the subject of an impact assessment.

69. It is true that in its proposal for a directive the Commission had used a different, stricter regulatory model for e-cigarettes. It had supported the idea of treating e-cigarettes essentially as medicinal products. (50)

70. However, this does not mean that the less strict rules on e-cigarettes which were ultimately adopted at the end of the legislative procedure and which can now be found in Article 20 of the Directive were created in a *'vacuum'*, as it were, and were enacted without any impact assessment.

71. On the contrary, the evidence on which the Commission relied in its impact assessment (51)– even though it was not binding on the Union legislature (52) — was a useful basis for the less strict provisions laid down in Article 20 of the Directive. (53) Aside from this, it is recognised that the Parliament and the Council may have recourse to additional sources of information in the legislative procedure. (54) It is not disputed in the present case that during the course of the legislative procedure the competent institutions obtained further information on the issue of e-cigarettes and, in particular, that the Commission conducted further consultations on the subject with interest groups and the Parliament held its own hearings. (55)

72. If the law-making EU institutions were limited to adopting only provisions which were specifically the subject of an impact assessment by the Commission, the freedom enjoyed by the Parliament and the Council would be restricted appreciably and the legislative procedure would be rendered largely meaningless. (56)

2. The proportionality and precision of specific parts of Article 20 of the Directive

73. Aside from the general remarks made immediately above relating to the principle of proportionality, the request for a preliminary ruling raises a number of detailed questions concerning the proportionality and precision of specific parts of Article 20 of the Directive, based on the complaints made by Pillbox in the main proceedings. I will now turn to these questions.

74. I will start by saying that, like the European Parliament, I consider the provisions contained in Article 20 of the Directive to be relatively moderate, not only in comparison with the rules applicable to conventional tobacco products in the European internal market, but also by international standards. (57)

a) The duty to submit a notification (Article 20(2) of the Directive)

75. First, Pillbox objects to the *'authorisation scheme'* for e-cigarettes allegedly introduced by the Union legislature. (58)

76. As can be seen from a brief glance at Article 20(2) of the Directive, however, that claim is based on a fundamental misunderstanding of the provision at issue. In reality, by that provision the Union legislature did not introduce an authorisation scheme, but a simple notification scheme for e-cigarettes combined with a six-month standstill obligation. This is confirmed, moreover, by the submissions of all the other parties.

77. Contrary to the view expressed by Pillbox at the hearing, the notification scheme together with the six-month standstill obligation also does not act as a de facto authorisation scheme. E-cigarettes can be placed on the market after six months unless the competent authority takes action during that period. An

authorisation scheme, by contrast, would be much more onerous for manufacturers and importers and, in particular, require them in each individual case to wait until they receive a positive decision from the competent authority.

i) The proportionality of the notification scheme

78. As has already been mentioned, e-cigarettes are a novel and — for large parts of the population at least — still relatively little known product for which there is a rapidly developing market. (59)

79. On the basis of the data and scientific evidence available during the legislative procedure, it was not manifestly wrong or unreasonable for the Union legislature to accept that e-cigarettes possibly cause risks to human health and that that product could — above all in the case of adolescents and young adults — develop into a gateway to nicotine addiction and, ultimately, traditional tobacco consumption. (60)

80. Under those circumstances, it would seem clear that the competent authorities have a legitimate interest in monitoring e-cigarettes, in particular if account is taken of the precautionary principle. (61)

81. A notification scheme like that provided for in Article 20(2) of the Directive can undoubtedly make it easier for Member States to carry out their surveillance and control tasks with regard to e-cigarettes.

82. Of the conceivable sovereign interferences with the freedom to conduct a business (Article 16 of the Charter of Fundamental Rights), a notification scheme of this kind is a comparatively moderate measure which, above all, appears to be much less restrictive than a traditional authorisation scheme, for example.

83. On the other hand, the definition by the Union legislature of product standards for e-cigarettes, raised by Pillbox in the preliminary ruling proceedings — beyond the standards which are in any case laid down in Article 20(3) of the Directive — cannot seriously be regarded as a more moderate alternative to the duty to submit a notification introduced by Article 20(2) of the Directive. First of all, the definition of product standards constitutes a much more severe interference with the freedom to conduct a business than the mere duty to give notification of a product. Second, the definition of such standards requires a sufficiently strong basis in terms of data and evidence regarding the product in question. Because e-cigarettes are relatively novel and unknown, the Union legislature could, however, reasonably consider that such data and evidence is not yet sufficiently available at present. Only through the notification scheme can it be gradually obtained.

84. Pillbox's argument that the notification scheme for e-cigarettes under Article 20(2) of the Directive is stricter than the provisions applying to conventional tobacco products in Article 5 and 6 of the Directive must also be rejected. On the contrary, as the EU institutions participating in the preliminary ruling proceedings have rightly stated, the reporting requirements for e-cigarettes are less extensive than for conventional tobacco products, in particular as regards additives. (62)

85. A much more meaningful comparison is between the notification scheme for e-cigarettes introduced by Article 20(2) of the Directive and the duty to submit a notification for novel tobacco products under Article 19 of the Directive. Those two provisions are similar in all material respects. The Union legislature has therefore established a coherent overall system for novel and little known products, whether tobacco products or e-cigarettes.

86. Furthermore, it is unclear to what extent the mere duty to submit a notification for a novel product in the category of e-cigarettes could hamper innovation, as Pillbox claims. On the contrary, such a notification scheme may encourage innovation. It is an incentive for the undertakings concerned to act responsibly on the market and to place on the market only products about which there is sufficient evidence to guarantee appropriate quality and safety levels which can, if necessary, stand up to official verification. This has been pointed out by the Commission in particular in the preliminary ruling proceedings. I would add that any official verification allows manufacturers and importers of e-cigarettes an additional opportunity to satisfy themselves of the regularity of their own internal quality controls, although it cannot, of course, result in responsibility being shifted to the relevant authority.

87. Lastly, the six-month standstill obligation which accompanies notification under the second sentence of Article 20(2) of the Directive also does not appear to be excessive in any way, considering that, in view of the risks possibly caused by e-cigarettes, the competent authorities must have a reasonable time, if necessary, to verify all the information provided by manufacturers and importers, in particular information on ingredients, emissions, toxicological data and production processes, so that in serious cases they are able to take action in good time and even before the marketing of the product in question. (63) It should be noted in passing that the Union legislature has also prescribed such a notification procedure with a six-month standstill obligation for the placing on the market of certain cosmetic products. (64)

88. All in all, the notification scheme for e-cigarettes with a standstill obligation laid down by the Union legislature in Article 20(2) of the Directive therefore seems to strike a fair balance between the competent authorities' legitimate interest in monitoring and the freedom to conduct a business for manufacturers and importers of e-cigarettes. There is no reason why it should not be compatible with the principle of proportionality.

ii) The complaint that the duties imposed on the notifying parties are insufficiently precise

89. In addition, Pillbox claims that some of the information which is required of manufacturers and importers within the framework of their duty to submit a notification infringes the principle of legal certainty because it is too imprecisely formulated. Specifically, Pillbox mentions *'information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions'* within the meaning

of Article 20(2)(d) of the Directive and the *'addictiveness'* of e-cigarettes. Pillbox states that the nicotine dose and nicotine uptake from smoking an e-cigarette depend on the personal needs and manner of use of individual consumers.

90. However, this argument is also not pertinent.

91. As regards *'addictiveness'*, that term is not used at all in Article 20(2) of the Directive, either in point (d) or elsewhere.

92. With regard to the other wordings to which Pillbox objects, the information to be provided under Article 20(2)(d) of the Directive 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 e-cigarette. A responsible manufacturer or importer must be able to provide such figures if it does not wish to be accused of placing on the market an unpredictable product with possibly unforeseeable health risks.

93. Generally speaking, it is in the nature of things that imprecise legal terms are used in legislation. That applies a fortiori to rules in directives, which always need to be transposed into national law (see the third paragraph of Article 288 TFEU) and for that reason any remaining uncertainties as to detail can be clarified within the scope available to the Member States for implementation into national laws, regulations and administrative provisions. Furthermore, Article 20(13) of the Directive permits the Commission to define a common format for notifications by manufacturers and importers under Article 20(2), which may, if required, help to further clarify the nature and form of the information required of undertakings.

94. Against this background, it is not evident that Article 20(2) of the Directive, in particular point (d) thereof, infringes the principle of legal certainty.

b) Maximum nicotine content (Article 20(3)(b) of the Directive)

95. Article 20(3)(b) of the Directive provides that nicotine-containing liquid in e-cigarettes and in any single-use cartridges or refill containers may have nicotine content of not more than 20 mg/ml. Pillbox considers that provision to be disproportionate and feels that it is placed at a disadvantage compared with manufacturers of conventional tobacco products. The undertaking expresses the view that the provision is counter-productive from the point of view of the high level of health protection pursued by the Directive, as the effectiveness of e-cigarettes as a substitute for conventional tobacco products requires a higher nicotine content. (65)

96. It should be noted, first of all, that in connection with internal market harmonisation measures under Article 114 TFEU the Court has recognised the setting of limits for dangerous substances by the Union legislature, provided those limits encourage the circulation of products in the European internal market whilst at the same time ensuring a high level of health protection. (66)

97. In setting the limit for a specific substance, the Union legislature enjoys a broad margin of discretion; however, the limit may not be set arbitrarily but must be based on objective considerations, take into consideration the latest scientific evidence and respect the precautionary principle.

98. As the EU institutions participating in the preliminary ruling proceedings have argued convincingly, in setting the contested limit of 20 mg/ml of nicotine, consideration was given to both the latest scientific evidence available during the legislative procedure regarding possible health risks and safety problems from e-cigarettes and also evidence on consumer habits in the use of e-cigarettes and conventional tobacco products.

99. In particular, during the legislative procedure account was taken of the fact that the nicotine-containing liquid in e-cigarettes and their refill containers causes specific risks which could be linked to careless or improper handling of that liquid — possibly even by children (67) — or to excessively long and intensive consumption, (68) in particular the risk of nicotine poisoning.

100. At the same time, it was taken into consideration in the legislative procedure that the majority of currently popular e-cigarettes and their refill containers have a nicotine content of no more than 18 mg/ml, which is even below the future limit of 20 mg/ml set in the Directive.

101. The nicotine limit of 20 mg/ml was thus the result of weighing up current evidence regarding risks and consumer habits in connection with e-cigarettes and their refill containers. It is comparable, moreover, to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. (69)

102. In the preliminary ruling proceedings before the Court, no submissions have been made which might even begin to cast doubt on this assessment by the Union legislature.

103. Pillbox essentially confines itself in this regard to claiming that, as a substitute for conventional tobacco products, sales of e-cigarettes with a nicotine content higher than 20 mg/ml should be permitted.

104. This argument cannot, however, call into question the lawfulness of Article 20(3)(b) of the Directive.

105. E-cigarettes with a particularly high nicotine content which are placed on the market as an aid to quit smoking for heavy smokers of conventional tobacco products are not normal consumer items. According to the scheme of the Directive, as the EU institutions participating in the preliminary ruling proceedings before the Court have explained, the placing on the market of this category of e-cigarettes is not absolutely prohibited, but they may be sold in the European internal market only subject to the special requirements applying to medical devices. (70)

106. It lay within the discretion of the Union legislature to draw the line, at the level of 20 mg/ml, between normal consumer products and more strictly regulated medical devices.

107. Against this background, there are, in short, no objections to Article 20(3)(b) of the Directive in respect

of its compatibility with the principle of proportionality.

c) The requirement that nicotine doses be delivered at a consistent level (Article 20(3)(f) of the Directive)

108. Article 20(3)(f) of the Directive provides that under normal conditions of use e-cigarettes must deliver the nicotine doses at consistent levels. Pillbox objects that that provision is insufficiently defined, and thus infringes the principle of legal certainty, because the nicotine dose and the nicotine uptake from smoking an e-cigarette depend on the personal needs and manner of use of individual consumers. Furthermore, there are no comparable requirements for conventional tobacco products.

109. This criticism is mistaken.

110. As regards the principle of legal certainty, Pillbox's complaint must be rejected for the same reasons as the complaint concerning Article 20(3)(d) of the Directive. (71)

111. With respect to the comparison with conventional tobacco products, it should be noted that e-cigarettes require specific provisions in so far as specific problems and health risks are linked to their consumption, even if those provisions derogate from the rules applicable to conventional tobacco products. The Council, the Commission and Spain in particular correctly point out in this connection the risk of nicotine poisoning from excessively long and intensive use or from incorrect handling of e-cigarettes. (72) It is this particular risk that justifies the requirement, specifically laid down for e-cigarettes in Article 20(3)(f) of the Directive, that nicotine doses must be delivered at a consistent level.

112. Should manufacturers and importers be unable to ensure that e-cigarettes marketed by them deliver the nicotine doses at a consistent level, this would be an indication that their product is dangerous and unpredictable, which would not justify more moderate measures by the Union legislature, but possibly more restrictive measures.

d) The leaflet (Article 20(4)(a) of the Directive)

113. Under Article 20(4)(a) of the Directive, unit packets of e-cigarettes or refill containers must include a leaflet with information on various subjects, such as information on addictiveness and toxicity and instructions for use and storage. Pillbox considers this to be disproportionate and feels that it is placed at a disadvantage compared with manufacturers of conventional tobacco products, as they are not required to enclose a leaflet with their products.

114. The aim of the rules on the leaflet, as has already been explained, is to encourage the circulation of e-cigarettes and their refill containers in the European internal market whilst at the same time guaranteeing a high level of health protection.

115. The reason why leaflets are prescribed solely for e-cigarettes and their refill containers is connected with the particular characteristics of those products compared with conventional tobacco products. This has been argued convincingly by the EU institutions participating in the preliminary ruling proceedings and some of the participating Member States.

116. Unlike conventional tobacco products, e-cigarettes and their refill containers are novel and — among large parts of the population — also still relatively unknown. In addition, there are specific problems connected with the nature of e-cigarettes which do not occur to the same degree with conventional tobacco products: first, the technical issues related to the functioning and the proper use of e-cigarettes and their refill containers and, second, the specific risk of nicotine poisoning from excessively long and intensive use or from incorrect handling of e-cigarettes.

117. All these considerations justify the imposition of a more extensive duty to provide information for e-cigarettes than for conventional tobacco products.

118. Contrary to the view taken by Pillbox, simply printing the information in question on the packaging of e-cigarettes and their refill containers is not a possible less restrictive measure. First, there is too much and too extensive information for it to be displayed visibly and legibly on the packaging alone, even on relatively large packaging. Second, if the information were printed on the packaging, this would reduce the space available for the list of ingredients and the necessary warnings prescribed for such packaging by Article 20(4)(b) of the Directive, as for conventional tobacco products. Third, a separate leaflet increases the likelihood that the consumers will still retain the information contained therein regarding the correct use of e-cigarettes even if they have already disposed of the packaging.

119. Accordingly, the rules on the leaflet under Article 20(4)(a) of the Directive do not infringe the principle of proportionality.

e) The prohibition on advertising (Article 20(5) of the Directive)

120. Article 20(5) of the Directive lays down a very extensive prohibition of commercial communications and sponsorship for e-cigarettes and their refill containers if those practices seek to promote sales or they affect them directly or indirectly. This prohibition, which for reasons of simplicity I will refer to hereinafter as the *'prohibition on advertising'*, is questioned by the referring court, on the basis of the complaint raised by Pillbox, in respect of its proportionality.

121. It should be pointed out immediately in this regard that in the past the Court has considered a prohibition on advertising for conventional tobacco products to be compatible with the principle of proportionality. (73) No arguments at all have been put forward in the present preliminary ruling proceedings to suggest that a fundamentally different assessment should now be made of the contested prohibition on advertising for e-cigarettes.

122. The prohibition on advertising is intended to ensure that the same conditions apply to the trade in e-cigarettes throughout the European internal market and, at the same time, that a high level of health protection is ensured. As has already been mentioned a number of

times, the Union legislature could legitimately take the view that e-cigarettes represent a potential risk for human health.

123. A prohibition on advertising like that laid down in Article 20(5) of the Directive is capable of countering that risk. Such a prohibition means that consumers — not least the target group of adolescents and young adults who are particularly sensitive to advertising — are confronted with fewer commercial inducements to purchase and consume e-cigarettes with the result that they are also less exposed to possibly associated health risks.

124. Such a prohibition on advertising is also necessary to ensure a high level of health protection. This approach taken by the Union legislature is not least consistent with the recommendations drawn up within the framework of the WHO. (74)

125. There are no evident measures which would be less restrictive than a prohibition on advertising and which would be equally capable of creating uniform trading conditions in the European internal market and also of ensuring a high level of health protection, nor have any such measures been suggested to the Court.

126. Contrary to the view taken by Pillbox, the contested prohibition on advertising is certainly no stricter than the one already in force for conventional tobacco products (75) but is comparable to it in all material respects. The uniformity of the relevant provisions sought by the Union legislature helps to ensure coherence between the restrictions on advertising applying to e-cigarettes and conventional tobacco products.

127. If the Union legislature had adopted a less strict prohibition on advertising for e-cigarettes than for conventional tobacco products, this could, realistically, have led to a circumvention of the prohibition of advertising for those tobacco products. It would also have to be feared that, because of advertising, e-cigarettes would be subject to increased sales and consumption and — above all among adolescents and young adults — develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption. (76)

128. Furthermore, it cannot be assumed, in view of the importance of health protection, that the economic disadvantages for undertakings like Pillbox associated with the prohibition on advertising would be disproportionate to the expected advantages for human health, especially considering that, whilst the prohibition on advertising under Article 20(5) of the Directive is very broad, it is certainly not all-embracing. Member States are free, for example, to continue to permit poster advertising and local advertising in kiosks and shops.

129. Pillbox's argument that in the past manufacturers of conventional tobacco products have been able to establish their market position through aggressive advertising, whereas this is now no longer possible to the same degree for e-cigarette manufacturers, is not very convincing.

130. The Union legislature cannot be compelled, by operation of law, to repeat the errors of the past. It cannot be required to exempt a novel product, for which there are reasonable fears of risks to human health according to current evidence, from restrictions on advertising merely in order to permit manufacturers of that product to establish themselves on the market like their long-established competitors. Otherwise, purely commercial interests of individual undertakings would prevail over health protection even though human health has considerably greater importance in the value system under EU law (see, in this regard, Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights).

131. Finally, Pillbox claims that Article 20(5) of the Directive not only prohibits advertising for e-cigarettes, but also completely eliminates the internet as a sales channel for such products.

132. This last argument is based on a manifestly incorrect interpretation of the contested provision. As all the institutions participating in the preliminary ruling proceedings have rightly stated, Article 20(5) of the Directive contains only a prohibition on advertising, and not a prohibition on internet sales. This becomes particularly clear if that provision is read in its context and regard is had to Article 20(6) of the Directive. There — and only there — is provision made for the possibility for Member States to restrict cross-border distance sales of e-cigarettes and refill containers. (77) It can also be seen from Article 18(1)(c) of the Directive, to which Article 20(6) refers, that the Directive does not seek to prohibit entirely the use of websites for marketing e-cigarettes and refill containers, but even takes them as a given.

133. In summary, the prohibition on advertising under Article 20(5) of the Directive cannot therefore be regarded as disproportionate.

f) Cross-border distance sales (Article 20(6) of the Directive)

134. In making reference to Article 18 of the Directive, Article 20(6) of the Directive permits the Member States to prohibit cross-border distance sales of e-cigarettes and their refill containers to consumers in the same way as sales of conventional tobacco products. This provision is questioned by the referring court, on the basis of a complaint raised by Pillbox, in two respects. It is claimed, first, that insufficient reasons are stated and, second, that there are less restrictive means, in particular fixing age limits for distance sales customers.

i) The duty to state reasons

135. With regard, first, to the duty to state reasons (second paragraph of Article 296 TFEU), it is true that, according to its wording, recital 33 in the preamble to the Directive, which explains the provisions concerning distance sales, actually refers only to conventional tobacco products.

136. However, as is clear from the other materials available to the Court, in particular the Commission staff's impact assessment, (78) there is a flourishing

cross-border trade in e-cigarettes, with the internet as an important sales channel. Manufacturers and importers of e-cigarettes, who are most affected by these provisions, are certainly not unaware of this fact.
137. Against this background, the Union legislature's conclusion which underlies the Directive, namely that e-cigarettes and conventional tobacco products should be treated in the same way as regards cross-border distance sales, did not require a separate and express explanation in the preamble. It is self-evident that the statements regarding conventional tobacco products in recital 33 in the preamble to the Directive can be applied directly to e-cigarettes and that for precisely this reason the provision made in Article 18 of the Directive was extended to e-cigarettes by the reference made in Article 20(6).
138. In any case, the statement of reasons for an EU measure which is intended to enact rules of general application may be confined to indicating the general situation which led to its adoption and the general objectives which it is intended to achieve; the statement of reasons must merely clearly disclose the essential objective pursued by the measure in question. (79)
139. That is the case in this instance. Thus, it cannot seriously be claimed that insufficient reasons are stated in the Directive in respect of the provisions governing the cross-border distance sales of e-cigarettes.

ii) Substantive assessment of the provisions governing distance sales

140. From a substantive point of view, it should be noted that the possibility of a prohibition on distance sales, as is provided for in Article 20(6) in conjunction with Article 18 of the Directive, pursues a two-fold objective. (80) The first aim is to prevent the Directive being circumvented by distance sales of products which do not satisfy the requirements laid down in the Directive. The second aim is to protect young consumers in particular from the health risks associated with the consumption of nicotine-containing products.
141. It may well be that — as Pillbox claims — not all the relevant studies point to e-cigarettes being particularly attractive to adolescents and young adults. Nevertheless, in accordance with the precautionary principle, it was not manifestly incorrect or unreasonable for the Union legislature to assume a particular danger for young people and to take that as a reason for restrictive provisions governing distance sales.
142. On the other hand, the statements made by the referring court, like those made by Pillbox, are confined to mentioning age limits — in particular the requirement that distance sales customers be adults — as a less restrictive alternative to a blanket prohibition on distance sales for e-cigarettes.
143. It should be noted in this regard that in a proportionality test consideration may be given to possible less restrictive means than the measure adopted by the Union legislature only if they are equally suitable for achieving the objective pursued by the EU measure in question. (81)
144. That is not the case with the abovementioned age limits. As the EU institutions participating in the proceedings and several of the participating Member States have argued convincingly, age limits in trade, and especially in distance sales trade, can be easily circumvented and it is extremely difficult to monitor compliance.
145. First, it is possible that minors will be supplied with e-cigarettes by adults from their family or from their circle of friends and acquaintances. Second, even a requirement that only adults may purchase e-cigarettes cannot ensure that young consumers who have only recently reached the relevant age limit will be properly protected from the risks of nicotine consumption. However, as has been convincingly argued in the preliminary ruling proceedings, not only minors but also young adults who have reached the age of majority (above all the age group between 18 and 25 years) are at particular risk because commencement of consumption of nicotine-containing products can also often still occur and is observed in the phase up to the age of 25.
146. Aside from this, any kind of age limit would not be capable of achieving the second abovementioned objective of the provisions, namely to prevent the Directive being circumvented by distance sales of products which do not satisfy the requirements laid down in the Directive.
147. Furthermore, the contested provisions governing distance sales are also not disproportionate on the ground that in Article 20(6) of the Directive the Union legislature did not impose a general Union-wide prohibition on cross-border distance sales of e-cigarettes, but merely granted Member States the possibility to introduce such prohibitions themselves and thus selectively to restrict the free movement of goods in this area.

iii) Interim conclusion

148. Against this background, Article 20(6) of the Directive does not give rise to any objections in respect of its compatibility with the duty to state reasons and the principle of proportionality.

g) Annual reporting obligations (Article 20(7) of the Directive)

149. Lastly, Article 20(7) of the Directive provides that Member States must require manufacturers and importers of e-cigarettes and their refill containers to submit certain information each year, in particular their sales figures and any market studies carried out. Pillbox takes the view that these annual reporting obligations are too imprecise and that they are disproportionately strict compared with the obligations applying to tobacco products. The competent authorities should instead conduct their own market research surveys.
150. With regard to the proportionality of the reporting obligations it should be borne in mind that e-cigarettes are novel and still comparatively unknown products, in the monitoring of which the competent authorities at Union level and at national level have a legitimate interest, especially in view of the dangers to health, which have already been mentioned several times, and

the risks which could reasonably be caused by e-cigarettes. (82)

151. Market studies, which, in the view of Pillbox, the competent authorities could be responsible for conducting, would be less suitable for compiling the necessary information, and thus for facilitating the monitoring of the products in question, on account of the associated expenditure, the costs incurred and the lack of public access to much of the underlying data.

152. On the other hand, under the contested provision, expenditure and costs for the undertakings concerned are kept within limits as the reporting obligations under Article 20(7) of the Directive relate only to information which comes from their own internal resources and about which, in all likelihood, they already collect data; furthermore, the undertakings' market studies are to be submitted only in the form of executive summaries and only if such studies have actually been carried out. Such a provision can hardly be regarded as excessively onerous for the undertakings.

153. Pillbox's argument that e-cigarette manufacturers and importers are subject to stricter reporting obligations under Article 20(7) of the Directive than manufacturers and importers of conventional tobacco products is also incorrect. The opposite is true. The reporting obligations for conventional tobacco products under Articles 5 and 6 of the Directive also extend to ingredients, certain additives and emission quantities, which is not the case for e-cigarettes under Article 20(7) of the Directive.

154. Lastly, Pillbox's claim of insufficient precision in Article 20(7) of the Directive does not appear very convincing. As has already been mentioned, (83) it is in the nature of a directive that its provisions still need to be transposed into national law (third paragraph of Article 288 TFEU). Accordingly, it is for the Member States, within the framework of the scope available to them when implementing the Directive into their national laws, regulations and administrative provisions, to determine the precise nature and form for the communication of data which is subject to the reporting obligation under Article 20(7) of the Directive.

155. All in all, there are also therefore no doubts as to the compatibility of Article 20(7) of the Directive with the principles of precision and proportionality.

C – The principle of subsidiarity

156. The third part of the question referred concerns the principle of subsidiarity, which is enshrined in the second sentence of Article 5(1) TEU in conjunction with Article 5(3) TEU.

157. Under that principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union may act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level (Article 5(3) TEU).

158. Since the Union does not have a general competence to regulate the internal market (84) and the internal market falls within the area of shared competences between the Union and its Member States (Article 4(2)(a) TFEU), the principle of subsidiarity applies to harmonisation measures pursuant to Article 114 TFEU, including the directive at issue. (85)

159. Compliance with the principle of subsidiarity is subject to legal review by the Courts of the European Union. (86) That review covers two aspects in particular: first, the substantive compatibility of EU measures with the principle of subsidiarity and, second, their statement of reasons having regard to the principle of subsidiarity. The order for reference touches on both aspects only briefly, based on the complaints raised by Pillbox in the main proceedings. Accordingly, my statements regarding the principle of subsidiarity in the present case will therefore be more concise than in my other two Opinions delivered today, to which I would like to refer for further analysis. (87)

1. Substantive compatibility of the Directive with the principle of subsidiarity

160. First of all, there is a suggestion in the order for reference that the principle of subsidiarity might be infringed because a number of national parliaments filed reasoned opinions in accordance with Article 6 of the Protocol on the application of the principles of subsidiarity and proportionality (88) during the legislative procedure. (89)

161. This argument is not very convincing. There was an insufficient number of objections regarding subsidiarity in those opinions to trigger the *'yellow card'* procedure under Article 7(2) of Protocol No 2. Furthermore, such objections are based less on a legal assessment than on a political assessment of the draft legislation submitted by the Commission, with the result that they are less meaningful for the purposes of the judicial review. In addition, in the present case hardly any of the reasoned opinions actually contained any substantive statements regarding the point at issue here, namely e-cigarettes.

162. Second, the order for reference questions whether there was a sufficiently disparate legal treatment in the Member States to justify the inclusion of provisions governing e-cigarettes in the Directive.

163. This doubt seems to be directed less at the principle of subsidiarity than at Article 114 TFEU. It is possibly based on the misassumption that the conditions for recourse to Article 114 TFEU as a legal basis for the adoption of internal market harmonisation measures and the requirements for the principle of subsidiarity are the same. That is not the case though. It is true that many of the considerations arising in connection with Article 5(3) TEU are similar to those that are also relevant in connection with Article 114 TFEU. However, they are not fully congruent.

164. Article 114 TFEU specifies whether the Union actually has a competence to adopt internal market harmonisation measures. By contrast, the principle of subsidiarity under Article 5(3) TEU determines whether and in what manner the Union exercises that competence in a specific case. In other words, the distribution of competences between the Union and the

Member States is based on Article 114 TFEU, while the principle of subsidiarity lays down legally binding guidelines for the EU institutions in using their competences (Article 5(1) TEU).

165. For the practical implementation of the principle of subsidiarity under Article 5(3) TEU a two-stage test must be carried out:

– First, the EU institutions must satisfy themselves that they are acting only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States (negative component of the test).

– Second, action by the Union is permissible only if and in so far as the objectives of the proposed action can, by reason of the scale or effects of the proposed action, be better achieved at Union level (positive component of the test).

These two components of the subsidiarity test ultimately address a single question from two different angles, namely whether action should be taken at Union level or at national level in order to achieve the envisaged objectives.

166. Neither the referring court in its request for a preliminary ruling nor Pillbox in its submissions to the Court examine these two components of the subsidiarity test in any way.

167. In so far as Pillbox — and along similar lines the referring court — wishes to cast doubt on the existence of a cross-border problem, it should be pointed out that, at the time of the adoption of the Directive, the national laws, regulations and administrative provisions on e-cigarettes differed significantly. Whilst some Member States had a blanket prohibition on sales of e-cigarettes, in others there was a prohibition on advertising for e-cigarettes, whilst others still classified them as medicinal products. (90) Against the background of such fundamental differences in the applicable national laws, the question raised by Pillbox as to whether different product standards applied to e-cigarettes in the Member States must be regarded as completely irrelevant.

168. In view of the fundamental differences between the Member States' rules on e-cigarettes, the flourishing cross-border trade in that field, (91) the novelty of the products in question (92) and the rapid development of the sector, (93) the Union legislature cannot be accused of having committed a manifest error of assessment if it takes the view that there is a problem that has a cross-border dimension with respect to e-cigarettes, which cannot be resolved by measures taken by the Member States alone, but requires action to be taken at Union level. (94)

169. This impression is reinforced if consideration is also given to the recommendations drawn up within the framework of the WHO, which call for the worldwide adoption of restrictive measures for e-cigarettes. (95) Such an international context must be borne in mind in connection with the question whether and in what manner the EU institutions exercise the competences conferred on them.

170. In summary, on the basis of the statements made by the referring court and by Pillbox, no substantive infringement of the principle of subsidiarity can therefore be established.

2. Adequate statement of reasons for the Directive having regard to the principle of subsidiarity

171. Third, it is asserted in the order for reference that the Union legislature has adduced insufficient evidence that the subsidiarity requirements are met in the present case. Ultimately, it is thus claimed that the Directive is vitiated by a defective statement of reasons.

172. The Court has consistently held that the statement of reasons required by the second paragraph of Article 296 TFEU must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the Union institution which adopted the measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Court to exercise its power of review. (96)

173. Where compliance with the principle of subsidiarity is under examination, it must be clear from the statement of reasons for the EU measure whether the Union legislature gave sufficient consideration to questions relevant to the principle of subsidiarity and, if so, what conclusions it reached with regard to subsidiarity.

174. Surprisingly, the order for reference does not address the actual statement of reasons for the Directive contained in its preamble, but refers — on the basis of the criticism raised by Pillbox — solely to paragraph 3.7 of the explanatory memorandum for the Commission's proposal for a directive. (97) It is alleged that that passage does not indicate the product safety requirements for e-cigarettes which applied at the time in the different Member States, but focused solely on the problem of the classification of e-cigarettes as medicinal products or as tobacco products.

175. I find it difficult to see to what extent this argument can be relevant specifically to the issue of the adequate statement of reasons for the Directive having regard to the principle of subsidiarity.

176. Aside from this, it should be borne in mind that, according to settled case-law, the statement of reasons for an EU measure is not required to go into every relevant point of fact and law. In addition, the question whether the obligation to provide a statement of reasons has been satisfied must be assessed with reference not only to the wording of the measure but also to its context and the whole body of legal rules governing the matter in question. (98) This applies a fortiori where — as in this case — it is intended to adopt rules having general application, the statement of reasons for which may be restricted to a fairly general description of the main features of the provision in question and of the objectives pursued by it. (99)

177. It is self-evident that regard cannot be had solely to paragraph 3.7 of the explanatory memorandum for the Commission proposal, which is mentioned by the referring court, but consideration must also be given to

other materials. First of all, other passages within the explanatory memorandum for the Commission proposal were available to the Union legislature, in particular paragraph 3.9.2, entitled 'Subsidiarity'. Second, it was able to rely on the comprehensive preparatory work by the Commission staff in connection with the impact assessment (100) for that legislative proposal. The disadvantages of disparate national provisions and the benefits of action at Union level are discussed in detail not only in the passages dedicated specifically to the principle of subsidiarity, but also in numerous other parts of those two texts.

178. It is thus adequately documented that the legislative bodies had comprehensive material on which they could base their evaluation of compliance with the principle of subsidiarity.

179. Accordingly, all told, the allegation of a defective statement of reasons for the Directive having regard to the principle of subsidiarity is not valid.

3. Interim conclusion

180. All in all, an infringement of the principle of subsidiarity cannot therefore be established from either a substantive or a procedural point of view.

D – EU fundamental rights

181. With the fourth and last part of its question, the referring court is seeking clarification whether Article 20 of the Directive infringes the rights of e-cigarette manufacturers and retailers under Articles 16 and 17 of the Charter of Fundamental Rights. This subquestion stems from the complaint raised by Pillbox in the main proceedings that implementation of the Directive in national law would infringe the undertaking's freedom to conduct a business and its right to property. Pillbox claims in this connection that Article 20 of the Directive, and above all the *'complete ban on commercial advertising'* found in Article 20(5), prevents the proper promotion of its business and the dissemination of its trademark.

1. The freedom to conduct a business (Article 16 of the Charter of Fundamental Rights)

182. Under Article 16 of the Charter of Fundamental Rights, the freedom to conduct a business in accordance with EU law and national laws and practices is recognised.

183. As is apparent from the explanations relating to that provision, 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, 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. (101)

184. Undoubtedly, the provisions contained in Article 20 of the Directive, and in particular the prohibition on advertising in Article 20(5) of the Directive, result in an interference with the freedom to conduct a business of economic operators like Pillbox. Advertising is an important means for undertakings to maintain or expand their market position and to enter new markets. It is more difficult for an operator to exercise its freedom to conduct a business if it is not permitted to advertise its products or may do so only to a limited degree.

185. However, in accordance with the Court's case-law, the freedom to conduct a business is not absolute, but must be viewed in relation to its social function. (102)

186. 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.

187. Article 20 of the Directive satisfies these requirements fully.

188. The requirement of legal enactment is fulfilled by Article 20 of the Directive, an express legal provision in an EU legislative act. (103)

189. From a substantive point of view, as has already been mentioned, the freedom to conduct a business may 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. (104) This has an impact in particular on the way in which Article 52(1) of the Charter requires the principle of proportionality to be implemented. (105) As has already been explained in more detail above, (106) the Union legislature enjoys a broad discretion in this regard.

190. This applies all the more where — as in the present case — a fair balance must be found between purely economic interests, as expressed in the freedom to conduct a business, and the protected interest of public health, which has particularly high importance in the value system under EU law. As is clear from Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU, but also from the second sentence of Article 35 of the Charter, a high level of health protection must always be ensured in defining and implementing Union policies and activities in all areas. (107)

191. With this in mind, the measures provided for in Article 20 of the Directive, in particular the prohibition on advertising under Article 20(5), are compatible with the principle of proportionality. (108)

192. Lastly, the essence of the freedom to conduct a business (Article 52(1) of the Charter) is also not infringed. (109) Even though advertising of e-cigarettes is largely prohibited under Article 20(5) of the Directive, it is still possible for the economic operators concerned to manufacture e-cigarettes and to market them in compliance with the requirements under Article 20 of the Directive. They are also certainly permitted to make use of their respective trade marks. The prohibition on advertising under Article 20(5) of the Directive does limit inter-brand competition, but it does not impair the essential function of a trade mark, which is to guarantee the identity of the origin of the goods in question.

193. All in all, the freedom to conduct a business is not therefore infringed.

2. The right to property (Article 17 of the Charter of Fundamental Rights)

194. Article 17 of the Charter of Fundamental Rights establishes the right to property, and Article 17(2) of that provision expressly protects intellectual property.

195. However, rules like those in Article 20 of the Directive — in particular the prohibition on advertising under Article 20(5) — do not constitute any interference with the right to property.

196. It is settled case-law that the protection of the right to property guaranteed under EU law, as now established in Article 17 of the Charter of Fundamental Rights, does not apply to mere commercial interests or opportunities, the uncertainties of which are part of the very essence of economic activity. (110) An economic operator cannot claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by measures taken by the Union legislature will be maintained. (111)

197. The situation is the same in respect of Article 1 of Additional Protocol No 1 to the ECHR, which must be taken into consideration pursuant to the first sentence of Article 52(3) of the Charter and Article 6(3) TEU. According to the case-law of the European Court of Human Rights, the guarantee of the right to property enshrined therein also does not encompass the protection of mere earning prospects. (112)

198. However, Pillbox ultimately refers precisely to such earning prospects, which are not encompassed by the right to property, when it submits that Article 20 of the Directive, in particular the prohibition on advertising under Article 20(5), impairs its future opportunities for marketing e-cigarettes in the European internal market.

199. With regard specifically to the trade mark under which Pillbox places its e-cigarettes on the market, that trade mark does indeed enjoy protection under Article 17(2) of the Charter as part of Pillbox's intellectual property. The prohibition on advertising under Article 20(5) of the Directive may in fact also limit Pillbox's opportunities to use its trade mark. However, that restriction of the use of the trade mark is justified — as has already been explained in connection with Article 16 of the Charter (113) — having regard to the desired high level of health protection.

200. Since it is still possible, moreover, to use the trade mark as such in marketing e-cigarettes, notwithstanding the prohibition on advertising, Pillbox's intellectual property is not affected in its essence by Article 20 of the Directive.

201. The right to property is not therefore infringed.

VI – Conclusion

202. In the light of the foregoing considerations, I suggest that the Court answer the questions referred by the High Court of Justice (Administrative Court) as follows:

Examination of the question referred has not revealed any factors such as to affect the validity of Article 20 of Directive 2014/40/EU.

1 – Original language: German.

2 – See, in this regard, in particular judgments in Germany v Parliament and Council (C‑376/98, EU:C:2000:544); British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741); Arnold André (C‑434/02, EU:C:2004:800); Swedish Match (C‑210/03, EU:C:2004:802); Germany v Parliament and Council (C‑380/03, EU:C:2006:772), and Commission v Denmark (C‑468/14, EU:C:2015:504).

3 – 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); 'Directive 2014/40' or simply 'the Directive'.

4 – 'Pillbox'.

5 – Case C‑547/14 Philip Morris Brands and Others.

6 – Case C‑358/14 Poland v Parliament and Council.

7 – The United Kingdom Minister for Health.

8 – Judgments in Jamet v Commission (37/71, EU:C:1972:57, paragraph 11); Commission v Verhuizingen Coppens (C‑441/11 P, EU:C:2012:778, paragraph 38); Commission v Parliament and Council (C‑427/12, EU:C:2014:170, paragraph 16), and Commission v Council (C‑425/13, EU:C:2015:483, paragraph 94).

9 – Judgments in France v Parliament and Council (C‑244/03, EU:C:2005:299, paragraph 13); Commission v Verhuizingen Coppens (C‑441/11 P, EU:C:2012:778, paragraph 38); Commission v Parliament and Council (C‑427/12, EU:C:2014:170, paragraph 16), and Commission v Council (C‑425/13, EU:C:2015:483, paragraph 94); see, in the same vein, judgment in Franceand Others v Commission (C‑68/94 and C‑30/95, EU:C:1998:148, paragraphs 257 to 259).

10 – See also the Opinion of Advocate General Trstenjak in AJD Tuna (C‑221/09, EU:C:2010:500, point 112 with footnote 69). See, further, judgments in Eurotunnel and Others (C‑408/95, EU:C:1997:532); Intertanko and Others (C‑308/06, EU:C:2008:312); Schecke and Eifert (C‑92/09 and C‑93/09, EU:C:2010:662); Association Belge des Consommateurs Test-Achats and Others (C‑236/09, EU:C:2011:100), and AJD Tuna (C‑221/09, EU:C:2011:153), in each of which the Court took a view on the validity of specific provisions of EU measures following a request for a preliminary ruling from a national court, although it did not comment expressly on the abovementioned issue of admissibility.

11 – Judgments in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 33) and Intertanko and Others (C‑308/06, EU:C:2008:312, paragraphs 33 to 35).

12 – See to this effect, with regard to the fourth paragraph of Article 263 TFEU, judgments in Telefónica v Commission (C‑274/12 P, EU:C:2013:852, paragraph 27) and T & L Sugars and Sidul Açúcares v Commission (C‑456/13 P, EU:C:2015:284, paragraph 29).

13 – Judgment in Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 25); see also judgments in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraphs 34 and 35); Afton Chemical (C‑343/09, EU:C:2010:419, paragraphs 13 and 14), and Association Kokopelli (C‑59/11, EU:C:2012:447, paragraphs 28 and 29); with regard to the presumption of relevance, see also judgment in Beck and Bergdorf (C‑355/97, EU:C:1999:391, paragraph 22).

14 – See the leading judgment in this regard in Foglia v Novello (104/79, EU:C:1980:73).

15 – Judgments in Irish Creamery Milk Suppliers Association and Others (36/80 and 71/80, EU:C:1981:62, paragraph 5); AGM-COS.MET (C‑470/03, EU:C:2007:213, paragraph 45 in conjunction with paragraph 42), and Coleman (C‑303/06, EU:C:2008:415, paragraph 29).

16 – Judgment in Corsica Ferries (C‑18/93, EU:C:1994:195, paragraph 12) and case-law cited.

17 – Judgment in Afton Chemical (C‑343/09, EU:C:2010:419, paragraph 15); see, to this effect, judgment in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 36).

18 – See, to this effect, order in Adiamix (C‑368/12, EU:C:2013:257, paragraphs 22 and 32); see also judgment in IATA and ELFAA (C‑344/04, EU:C:2006:10, paragraphs 30 and 31).

19 – Judgments in SAT Fluggesellschaft (C‑364/92, EU:C:1994:7, paragraph 9); Cartesio (C‑210/06, EU:C:2008:723, paragraphs 90 and 91), and Consiglio Nazionale dei Geologi (C‑136/12, EU:C:2013:489, paragraph 28).

20 – Judgments in SMW Winzersekt (C‑306/93, EU:C:1994:407, paragraph 15); British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 34); Afton Chemical (C‑343/09, EU:C:2010:419, paragraphs 13 and 14); Association Kokopelli (C‑59/11, EU:C:2012:447, paragraph 28), and order in Adiamix (C‑368/12, EU:C:2013:257, paragraph 16).

21 – Judgment in IATA and ELFAA (C‑344/04, EU:C:2006:10, paragraph 28) and order in Adiamix (C‑368/12, EU:C:2013:257, paragraph 17).

22 – See, in this regard, Opinion 1/09 (EU:C:2011:123, paragraph 68).

23 – Judgment in IATA and ELFAA (C‑344/04, EU:C:2006:10, paragraph 31) and order in Adiamix (C‑368/12, EU:C:2013:257, paragraphs 21, 22, 27 and 32).

24 – See judgments in Les Verts v Parliament (294/83, EU:C:1986:166, paragraph 23); Inuit Tapiriit Kanatami and Others v Parliament and Council (C‑583/11 P, EU:C:2013:625, paragraphs 90 and 91), and Schrems (C‑362/14, EU:C:2015:650, paragraph 60).

25 – With regard to the importance of the preliminary ruling procedure in such cases, see judgments in Unión de Pequeños Agricultores v Council (C‑50/00 P, EU:C:2002:462, paragraphs 38 to 40); Inuit Tapiriit Kanatami and Others v Parliament and Council (C‑583/11 P, EU:C:2013:625, paragraphs 92 to 96); Telefónica v Commission (C‑274/12 P, EU:C:2013:852, paragraphs 27 to 29), and T & L Sugars and Sidul Açúcares v Commission (C‑456/13 P, EU:C:2015:284, paragraphs 29 to 31).

26 – Judgments in Akzo Nobel Chemicals and Akcros Chemicals v Commission (C‑550/07 P, EU:C:2010:512, paragraph 54) and Sky Italia (C‑234/12, EU:C:2013:496, paragraph 15); see, in the same vein, judgment in Ruckdeschel and Others (117/76 and 16/77, EU:C:1977:160, paragraph 7).

27 – Judgments in Arcelor Atlantique et Lorraine and Others (C‑127/07, EU:C:2008:728, paragraph 23); S.P.C.M. and Others (C‑558/07, EU:C:2009:430, paragraph 74); Akzo Nobel Chemicals and Akcros Chemicals v Commission (C‑550/07 P, EU:C:2010:512, paragraph 55); Sky Italia (C‑234/12, EU:C:2013:496, paragraph 15), and P and S (C‑579/13, EU:C:2015:369, paragraph 41).

28 – See Article 20(2) of the Directive and below, point 84 of this Opinion.

29 – See Article 20(2)(b) and (c) of the Directive, compared with Articles 8 to 10 of the Directive, which apply to conventional tobacco products.

30 – See, in this regard, in particular recital 47 in the preamble to the Directive, which makes clear that the Directive does not harmonise the use of flavours in e-cigarettes and refill containers, but leaves the responsibility for adopting such rules with the Member States. In contrast, Article 7 of the Directive lays down a prohibition on characterising flavours for conventional tobacco products.

31 – See, in particular, the rules on the leaflet in Article 20(4)(a) of the Directive (see also below, points 113 to 119 of this Opinion).

32 – Judgment in Arcelor Atlantique et Lorraine and Others (C‑127/07, EU:C:2008:728, paragraph 25).

33 – Judgments in Arcelor Atlantique et Lorraine and Others (C‑127/07, EU:C:2008:728, paragraphs 25 and 26); Association Belge des Consommateurs Test-Achats and Others (C‑236/09, EU:C:2011:100, paragraph 29); Ziegler v Commission (C‑439/11 P, EU:C:2013:513, paragraph 167), and Feakins (C‑335/13, EU:C:2014:2343, paragraph 51).

34 – See, in particular, the end of Article 1 and recitals 5, 6, 8 and 36 in the preamble to the Directive.

35 – With regard to the requirement of a comparison of the objective characteristics of the different products at issue and their use, see judgments in Rewe-Zentrale des

Lebensmittel-Großhandels (45/75, EU:C:1976:22, paragraph 12); John Walker (243/84, EU:C:1986:100, paragraph 11); Arnold André (C‑434/02, EU:C:2004:800, paragraph 69), and Swedish Match (C‑210/03, EU:C:2004:802, paragraph 71).

36 – In this regard the present case differs fundamentally from Poland v Parliament and Council (C‑358/14; see my Opinion delivered today in that case, points 50 to 57), in which different types of flavoured cigarettes are under comparison.

37 – See, to this effect, judgments in Arnold André (C‑434/02, EU:C:2004:800, paragraphs 64 and 69) and Swedish Match (C‑210/03, EU:C:2004:802, paragraphs 66 and 71), with regard to the differences between chewing tobacco and conventional tobacco products.

38 – Judgments in Maizena and Others (137/85, EU:C:1987:493, paragraph 15); United Kingdom v Council (C‑84/94, EU:C:1996:431, paragraph 57); British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 122); Digital Rights Ireland (C‑293/12 and C‑594/12, EU:C:2014:238, paragraph 46), and Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 67).

39 – Judgments in Schräder HS Kraftfutter (265/87, EU:C:1989:303, paragraph 21); Jippes and Others (C‑189/01, EU:C:2001:420, paragraph 81), and ERG and Others (C‑379/08 and C‑380/08, EU:C:2010:127, paragraph 86); see also judgment in Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 91).

40 – Judgment in Digital Rights Ireland (C‑293/12 and C‑594/12, EU:C:2014:238, paragraph 47).

41 – See below, points 182 to 193 of this Opinion.

42 – Judgment in Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 46).

43 – Judgments in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 123); S.P.C.M. and Others (C‑558/07, EU:C:2009:430, paragraph 42); Vodafone and Others (C‑58/08, EU:C:2010:321, paragraph 52), and Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 67).

44 – Judgment in Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraphs 74, 81 and 91); see, to this effect, judgments in Vodafone and Others (C‑58/08, EU:C:2010:321, paragraph 52); S.P.C.M. and Others (C‑558/07, EU:C:2009:430, paragraph 42), and Afton Chemical (C‑343/09, EU:C:2010:419, paragraph 46).

45 – The Court recognises that nicotine causes addiction and its toxicity is not disputed (judgments in Arnold André, C‑434/02, EU:C:2004:800, paragraph 50, and Swedish Match, C‑210/03, EU:C:2004:802, paragraph 52).

46 – In its observations Pillbox too mentions ‘behavioural aspects of smoking’.

47 – See, to this effect, judgment in Alliance for Natural Health and Others (C‑154/04 and C‑155/04, EU:C:2005:449, paragraph 68), in which the Court states that the Union legislature must ‘take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health’.

48 – Judgments in United Kingdom v Commission (C‑180/96, EU:C:1998:192, paragraph 99); Commission v Denmark (C‑192/01, EU:C:2003:492, paragraphs 52 and 53); Commission v France (C‑333/08, EU:C:2010:44, paragraph 93); Afton Chemical (C‑343/09, EU:C:2010:419, paragraphs 60 to 62), and Acino v Commission (C‑269/13 P, EU:C:2014:255, paragraph 57).

49 – See the Decision of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, adopted at its Sixth session in Moscow on 18 October 2014, FCTC/COP/6(9). The decision is entitled ‘Electronic nicotine delivery systems and electronic non-nicotine delivery systems’ (ENDS/ENNDS) and states: ‘The Conference of the Parties … INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health’ (see, in particular, point 3 of that decision).

50 – See Article 18 of the Commission’s 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, submitted on 19 December 2012, COM(2012) 788 final.

51 – Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular Part 1, p. 77 et seq.

52 – Judgment in Afton Chemical (C‑343/09, EU:C:2010:419, paragraph 57).

53 – The Court sometimes also pays attention to such Commission impact assessments in reviewing the validity of EU measures (see, for example, judgment in Vodafone and Others, C‑58/08, EU:C:2010:321, paragraphs 55 and 65).

54 – See, to this effect, judgment in Afton Chemical (C‑343/09, EU:C:2010:419, paragraphs 39 and 40).

55 – With regard to the consideration of any hearings or workshops conducted by the Parliament, see for example judgment in Afton Chemical (C‑343/09, EU:C:2010:419, paragraphs 35 and 36).

56 – See, to this effect — albeit in a different context — my Opinion in Inuit Tapiriit Kanatami and Others v Commission (C‑398/13 P, EU:C:2015:190, point 31).

57 – According to a report presented in 2014 at the Conference of the Parties to the WHO Framework Convention on Tobacco Control, the sale of nicotine-containing e-cigarettes was banned completely in 13 of the 59 States that regulate them (Conference of the Parties to the WHO Framework Convention on Tobacco Control, Electronic Nicotine Delivery Systems, Report by WHO, 21 July 2014, FCTC/COP/6/10 [2014], paragraph 31).

58 – Pillbox's observations state that '[t]he EU legislature has adopted a disproportionate approach by putting in place an authorisation scheme for electronic cigarettes'.
59 – This latter point is also made in the first sentence of recital 46 in the preamble to the Directive.
60 – See, in this regard, recital 43 in the preamble to the Directive.
61 – See, in this regard, recital 36 in the preamble to the Directive and, with regard to the precautionary principle, points 64 to 67 of this Opinion.
62 – Under Article 5 of the Directive, manufacturers and importers of tobacco products are required to submit to their competent authorities, inter alia, a list of all ingredients, and quantities thereof, used in the manufacture of those products; that duty is more extensive than the obligation applying to e-cigarettes under Article 20(2)(b) of the Directive. In addition, under Article 6 of the Directive, enhanced reporting obligations apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list; Article 20 of the Directive does not provide for such enhanced reporting obligations for e-cigarettes.
63 – See also, in this regard, the first sentence of Article 23(2) of the Directive, under which Member States must ensure that tobacco and related products which do not comply with the Directive are not placed on the market.
64 – Article 16(3) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009 L 342, p. 59).
65 – In support of its argument Pillbox refers to scientific evidence according to which nicotine from e-cigarettes is metabolised in the smoker's body differently from nicotine from conventional tobacco products. However, this is disputed by other parties, in particular the Council, which also rely on scientific evidence.
66 – Judgment in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, in particular paragraph 126), with reference to Article 95 EC.
67 – See also, in this regard, recital 40 in the preamble to the Directive.
68 – An e-cigarette can be smoked for a much longer time without interruption and many more drags can be taken than from a conventional tobacco product.
69 – Recital 38 in the preamble to the Directive.
70 – See, in this regard, the second subparagraph of Article 20(1) of the Directive, under which the Directive does not apply to electronic cigarettes and refill containers that are subject to the requirements set out in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).
71 – See above, points 92 and 93 of this Opinion.
72 – See above, point 99 and footnote 68 of this Opinion.
73 – Judgment in Germany v Parliament and Council (C‑380/03, EU:C:2006:772, paragraphs 144 to 158).
74 – See the Decision of the Conference of the Parties to the WHO Framework Convention on Tobacco Control of 18 October 2014 (cited in footnote above), which states: 'The Conference of the Parties … URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS' (see in particular point 4 of that decision).
75 – See, in this regard, Articles 3 and 5 of Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ 2003 L 152, p. 16), which should be read in conjunction with the definitions contained in Article 2(b) and (c) of that directive.
76 – See, in this regard, recital 43 in the preamble to the Directive.
77 – See immediately below, points 134 to 148 of this Opinion.
78 – Impact Assessment, submitted on 19 December 2012, Doc. SWD (2012) 452 final, see part 1, p. 16 et seq.
79 – See, to this effect, judgments in United Kingdom v Council (C‑150/94, EU:C:1998:547, paragraphs 25 and 26); AJD Tuna (C‑221/09, EU:C:2011:153, paragraph 59), and Inuit Tapiriit Kanatami and Others v Commission (C‑398/13 P, EU:C:2015:535, paragraph 29).
80 – See, in this regard, recital 33 in the preamble to the Directive.
81 – Judgments in Arnold André (C‑434/02, EU:C:2004:800, paragraph 55) and Swedish Match (C‑210/03, EU:C:2004:802, paragraph 56).
82 – See, in this regard, points 78 to 80 of this Opinion.
83 – See above, point 93 of this Opinion.
84 – Judgment in Germany v Parliament and Council (C‑376/98, EU:C:2000:544, paragraph 83).
85 – See also the earlier case-law relating to the period before the entry into force of the Treaty of Lisbon; judgments in British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraph 179) and Vodafone and Others (C‑58/08, EU:C:2010:321, paragraph 75).
86 – See, in particular, judgments in Germany v Parliament and Council (C‑233/94, EU:C:1997:231, paragraphs 23 to 29); British American Tobacco (Investments) and Imperial Tobacco (C‑491/01, EU:C:2002:741, paragraphs 177 to 185); Vodafone and Others (C‑58/08, EU:C:2010:321, paragraphs 72 to 79), and Estonia v Parliament and Council (C‑508/13, EU:C:2015:403, paragraphs 44 to 55).
87 – See my Opinions delivered today in Poland v Parliament and Council (C‑358/14, points 137 to 188) and Philip Morris Brands and Others (C‑547/14, paragraphs 270 to 299).
88 – Protocol No 2 to the EU Treaty and the FEU Treaty ('Protocol No 2').

89 – On the basis of the Commission's draft directive reasoned opinions were filed by the Parliaments of Bulgaria, the Czech Republic, Denmark, Greece, Italy, Portugal, Romania and Sweden.

90 – See, in this regard, the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD (2012) 452 final, in particular part 4, p. 2, and p. 15 to 22.

91 – See above, point 136 of this Opinion.

92 – See above, point 49 of this Opinion.

93 – This latter aspect is also highlighted in the first sentence of recital 46 in the preamble to the Directive.

94 – See in particular, in this regard, recital 60 in the preamble to the Directive.

95 – See the Decision of the Conference of the Parties to the WHO Framework Convention on Tobacco Control of 18 October 2014 (cited above in footnote 49), which — as has already been mentioned — states: 'The Conference of the Parties … INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health' (see in particular point 3 of that decision).

96 – Judgments in Atlanta Fruchthandelsgesellschaft and Others (II) (C‑466/93, EU:C:1995:370, paragraph 16); AJD Tuna (C‑221/09, EU:C:2011:153, paragraph 58), and Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 70).

97 – COM(2012) 788 final, submitted by the Commission on 19 December 2012.

98 – See again judgments in Atlanta Fruchthandelsgesellschaft and Others (II) (C‑466/93, EU:C:1995:370, paragraph 16); AJD Tuna (C‑221/09, EU:C:2011:153, paragraph 58), and Gauweiler and Others (C‑62/14, EU:C:2015:400, paragraph 70); see also judgment in Estonia v Parliament and Council (C‑508/13, EU:C:2015:403, paragraphs 58, 59 and 61).

99 – See, to this effect, judgments in United Kingdom v Council (C‑150/94, EU:C:1998:547, paragraphs 25 and 26); AJD Tuna (C‑221/09, EU:C:2011:153, paragraph 59), and Inuit Tapiriit Kanatami and Others v Commission (C‑398/13 P, EU:C:2015:535, paragraph 29).

100 – Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD (2012) 452 final, in particular part 4, p. 15 to 22.

101 – Judgments in DEB (C‑279/09, EU:C:2010:811, paragraph 32) and Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 42).

102 – Judgments in Deutsches Weintor (C‑544/10, EU:C:2012:526, paragraph 54) and Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 45).

103 – See also, to this effect, judgment in Digital Rights Ireland (C‑293/12 and C‑594/12, EU:C:2014:238, paragraph 38 et seq.), in which the Court considered whether a directive was consistent with fundamental rights and found no infringement of the requirement of legal enactment under Article 52(1) of the Charter of Fundamental Rights.

104 – Judgment in Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 46).

105 – Judgment in Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 47).

106 – See above, points 55 to 58 of this Opinion.

107 – With regard to the importance of health protection, see also, most recently, judgments in Deutsches Weintor (C‑544/10, EU:C:2012:526, in particular paragraphs 45 to 47) and Léger (C‑528/13, EU:C:2015:288, in particular paragraph 57).

108 – See, in this regard, my detailed statements on the proportionality of various parts of Article 20 of the Directive in points 53 to 155 of this Opinion above; with specific regard to advertising, see also judgment in Deutsches Weintor (C‑544/10, EU:C:2012:526, paragraphs 49 and 56, with reference to a prohibition on advertising for alcoholic beverages).

109 – See, to this effect, judgment in Deutsches Weintor (C‑544/10, EU:C:2012:526, paragraphs 56 to 58).

110 – Judgments in Nold v Commission (4/73, EU:C:1974:51, paragraph 14); FIAMM and Others v Council and Commission (C‑120/06 P and C‑121/06 P, EU:C:2008:476, paragraph 185); Sky Österreich (C‑283/11, EU:C:2013:28, paragraph 34), and Inuit Tapiriit Kanatami and Others v Commission (C‑398/13 P, EU:C:2015:535, paragraph 60).

111 – Judgments in Faust v Commission (52/81, EU:C:1982:369, paragraph 27); Swedish Match (C‑210/03, EU:C:2004:802, paragraph 73), and Alliance for Natural Health and Others (C‑154/04 and C‑155/04, EU:C:2005:449, paragraph 128).

112 – ECHR, judgments of 13 June 1979 in Marckx v. Belgium (ECLI:CE:ECHR:1979:0613JUD000683374, § 50); of 11 January 2007 in Anheuser-Busch v. Portugal (ECLI:CE:ECHR:2007:0111JUD007304901, § 64); and of 13 March 2012 in Malik v. United Kingdom (ECLI:CE:ECHR:2012:0313JUD002378008, § 93).

113 – See in particular points 184 and 192 of this Opinion.