Reports of Cases

OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 23 December 2015 [1]

Case C-477/14

Pillbox 38 (UK) Limited
v
The Secretary of State for Health
(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.

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'.

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;

4 — 'Pillbox'.

5 — Case C-547/14 *Philip Morris Brands and Others*.

6 — Case C-358/14 *Poland* v *Parliament and Council*.

(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.

7 — The United Kingdom Minister for Health.

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.

A – *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.

B – *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.

1. 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.

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 *France and 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).

2. 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.

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).

3. 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.

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).

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.

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).

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]

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.

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.

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.

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.

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).

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.

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).

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.

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).

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.

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.

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

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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.

82 — See, in this regard, points 78 to 80 of this Opinion.

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]

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).

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.

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.

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.

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).

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.

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.

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]

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.

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.

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).

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.

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.