Opinion of the European Data Protection Supervisor

on the amended Commission proposal for a Directive on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

THE EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16 thereof,

Having regard to the Charter of Fundamental Rights of the European Union, and in particular Articles 7 and 8 thereof,

Having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[1],

Having regard to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[2], and in particular Article 28(2) thereof,

HAS ADOPTED THE FOLLOWING OPINION:

1. INTRODUCTION

1.1. Consultation of the EDPS

1. On 18 March 2013, the Commission adopted an amended proposal concerning a Directive on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems (the proposed Directive).[3] This proposal was sent to the EDPS for consultation on 19 March 2013.

2. The EDPS welcomes the fact that he is consulted by the Commission and welcomes that a reference to this Opinion has been included in the preamble of the instrument. The EDPS regrets, however, that he was not consulted by the Commission during the preparation of or at least after the adoption of the original proposal from 1 March 2012[4].

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 8, 12.1.2001, p. 1.
[3] COM (2013) 168 final/2.
[4] COM (2012) 84 final.

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1.2. Objectives and scope of the proposal

3. In the explanatory memorandum to the proposed Directive, the Commission states that Member States are responsible for the organisation of their healthcare system and for the delivery of health services and medical care, including the allocation of resources assigned to them. In this framework, each Member State can take measures to manage the consumption of medicines, regulate their prices or establish the conditions of their public funding. A medicinal product authorised in accordance with EU legislation on the basis of its quality, safety and efficacy profile may therefore be subject to additional regulatory requirements at Member State level before it can be placed on the market or dispensed to patients under the public health insurance scheme.

4. Furthermore the Commission explains that Directive 89/105/EEC[5] was adopted to enable market operators to verify that national measures regulating the pricing and reimbursement of medicines do not contravene the principle of free movement of goods. To this end, Directive 89/105/EEC lays down a series of procedural requirements to ensure the transparency of pricing and reimbursement measures adopted by the Member States. Since the adoption of this directive market conditions have fundamentally changed, for instance with the emergence of generic medicines providing cheaper versions of existing products or the development of increasingly innovative (yet often expensive) research-based medicinal products. In parallel, the constant rise in public expenditure on pharmaceuticals in the last decades has encouraged Member States to devise more complex and innovative pricing and reimbursement systems over time.

5. The proposal for a Directive repealing the Council Directive 89/105/EEC was adopted by the Commission on 1 March 2012. The Commission states that negotiations in the Council Working Party on Pharmaceuticals and Medical Devices proved to be difficult, given the politically sensitive nature of the file.

6. The European Parliament adopted its position in first reading on 6 February 2013. As the result of the vote in Plenary and taking into consideration the position of the Member States in the Council, the Commission decided to amend its Proposal by adopting the proposed Directive, and to consult the EDPS.

1.3. Aim of the EDPS Opinion

7. This Opinion will focus on the following aspects of the proposed Directive relating to personal data protection: the applicability of data protection legislation, the publication of personal data of experts and members of certain bodies, the potential processing of patient health data through the access to market authorisation data and the proposed opportunity for the creation of databases at EU/member state level.

2. ANALYSIS OF THE PROPOSAL

2.1. Applicability of data protection legislation

8. In the draft Directive, processing of personal data will take place under various provisions concerning publication of personal information regarding experts and members of certain

[5] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system (OJ L 40, 11.2.1989, p. 8).

national decision-making bodies and under the provisions regarding access to market authorisation data under the proposed Directive. Both EU and national data protection legislation therefore apply.

9. Neither recitals nor substantive provisions of the proposed Directive mention applicable EU data protection legislation such as Directive 95/46/EC for processing carried out by national competent authorities and Regulation (EC) 45/2001 for processing carried out by EU Institutions and bodies. The EDPS considers that a reference to the applicable data protection legislation should be inserted in a substantive article of the proposed Directive. Such a reference is needed to clarify the relationship between the proposals and the EU framework for data protection. The proposed Directive should not be considered as derogation from the data protection framework, which remains fully applicable to the processing operations foreseen.

10. The reference should explicitly provide as a general rule that Directive 95/46/EC and Regulation (EC) 45/2001 apply to the processing of personal data within the framework of the proposed Directive. Furthermore, the EDPS suggests that the reference to Directive 95/46/EC should specify that the provisions will apply in accordance with the national rules which implement Directive 95/46/EC.

2.2. Provisions concerning disclosure

2.2.1 Information concerning names and declarations of interest

11. The EDPS has in the past repeatedly expressed concerns about the interference with the right to the protection of their personal data caused by the publication of data (on the Internet). The Opinions on Insolvency proceedings[6] and the Opinions on the legislative package on the revision of the banking legislation, credit rating agencies, markets in financial instruments (MIFID/MIFIR) and market abuse[7] all deal extensively with this issue. Therefore, this section should be read in conjunction with those EDPS Opinions.

12. According to Article 16 of the proposed Directive, Member States shall ensure that the competent authorities make publicly available a regularly updated list of the members of their decision-making bodies, together with their declarations of interest. This provision also extends to members of bodies responsible for remedy procedures according to Article 8(2) of the proposed Directive. Furthermore, Recital 21 states that the purpose of this publication is to ensure the transparency, integrity and independence of the decision-making process within the national competent authorities.

13. These provisions have been introduced as a result of amendments adopted by the European Parliament in first reading and the Commission has included these provisions in the amended proposed Directive without carrying out an impact assessment or mentioning these provisions in the explanatory memorandum of the proposed Directive.

14. Although the EDPS understands the importance of a high degree of transparency in this context, he is not convinced that the provisions, as they are currently drafted, meet the legal standard for publication of personal data set by the Court of Justice in the *Schecke*

[6] EDPS Opinion of 27 March 2013, available at http://www.edps.europa.eu/EDPSWEB/edps/Consultation/OpinionsC.
[7] EDPS Opinions of 10 February 2012, available at http://www.edps.europa.eu/EDPSWEB/edps/Consultation/OpinionsC.

judgment.[8] As the publication of the personal data of members constitutes an interference with the right to the protection of personal data, following the court's ruling, a proper balance needs to be found between the various interests involved.

2.2.2. Necessity and proportionality of mandatory publication

15. In the *Schecke* judgment, the Court of Justice annulled the provisions of a Council Regulation and a Commission Regulation providing for the mandatory publication of information concerning beneficiaries of agricultural funds, including the identity of the beneficiaries and the amounts received. The Court held that the said publication constituted the processing of personal data falling under Article 8(2) of the European Charter of Fundamental Rights (the 'Charter') and therefore an interference with the rights recognised by Articles 7 and 8 of the Charter.

16. After analysing that '*derogations and limitations in relation to the protection of personal data must apply only in so far as is strictly necessary*', the Court went on to analyse the purpose of the publication and the proportionality thereof. It concluded that in that case there was nothing to show that, when adopting the legislation concerned, the Council and the Commission took into consideration methods of publishing the information which would be consistent with the objective of such publication while at the same time causing less interference with those beneficiaries' rights to respect for their private life and to the protection of personal data in particular.

17. In this regard, Articles 16 and Article 8 of the proposed Directive seem to be affected by shortcomings highlighted by the CJEU in the *Schecke* judgement. The EDPS is under the impression that the necessity and proportionality of the mandatory publication of a list of the members of Member State bodies, together with their declarations of interest are not clearly established since nothing in the text shows that alternative methods of disclosing the information which would be consistent with its objective while at the same time causing less interference with those beneficiaries' rights have been addressed by the Commission. It is not explained how the publication accessible to the public will better serve the desired objective of transparency than any other conceivable alternatives, such as limiting the access to the personal data to a well-defined group of interested parties or making the personal data available on request only.

18. While the proposed Directive does not specify the medium on which the information should be published, in practice, it is likely that the publication will take place on the Internet. Internet publications raise specific issues and risks concerning in particular the need to ensure that the information is kept online for no longer than is necessary and that the data cannot be manipulated or altered. The use of internal/external search engines also entail the risk that the information could be taken out of context and channelled through and outside the web in ways which cannot be easily controlled.

19. The EDPS recommends that the legislators carefully assess the necessity and proportionality of the proposed system and verify whether the publication obligation goes beyond what is necessary to achieve the public interest objective pursued and whether there are not less restrictive measures to attain the same objective.

[8] Joined Cases C-92/09 and C-93/09, *Volker und Markus Schecke GbR v Land Hessen; Eifert v Land Hessen*, [2012] All E.R. (EC) 127, CJ.

2.2.3. The additional question of adequate safeguards

20. Subject to the outcome of the aforementioned necessity and proportionality test, the publication obligation should in any event be supported by adequate safeguards to ensure respect of the rights of the persons concerned to object, the security/accuracy of the data and their deletion after an adequate period of time.

21. The proposed Directive does not make reference to relevant articles in Directive 95/46/EC regarding data protection safeguards and does not explain the conditions of application of existing safeguards to the specific issue of measures relating to transparency, integrity and independence of the decision-making process within the national competent authorities. The EDPS considers that the proposed Directive should have foreseen adequate safeguards in order to ensure a fair balance between the different interests at stake. It should ensure that the rights of the data subjects are respected in a proactive manner. A proactive approach should imply that data subjects are informed by the data controller (in this case the national competent authority) beforehand of the fact that their names and declarations of interest are going to be published, and that they are granted the right to object under Article 14 of Directive 95/46/EC on compelling legitimate grounds.[9] The EDPS recommends amending the text in this sense.

2.3. Access to data collected for market authorisation purposes

22. Article 13(2) of the proposed Directive gives the competent authorities the right to request and have full access to data generated during the marketing authorisation process [...] so that they can assess the relative efficacy as well as the short- and long-term effectiveness, where appropriate, of a medicinal product. According to Article 13 (3), the competent authorities shall also be able to use the available data or generate additional relevant data [...]. These rights are also mentioned in recital 17 of the proposed Directive.

23. It is unclear from the text of the proposed Directive whether these market authorisation data sets will contain personal data and if so whether they will contain sensitive data such as patient health data. Neither the explanatory memorandum nor the impact assessment report provides any guidance on this matter. If personal data of patients or other actors in the market authorisation procedure is included among the market authorisation data, the access and use of this data would constitutes processing of personal (potentially sensitive) data in the meaning of Directive 95/46/EC.

24. The term 'data generated during the marketing authorisation process' is not defined in the proposed Directive. As the market authorisation process of medicinal products both at national and EU-level is built up around clinical trials, the EDPS assumes that access to market authorisation data will also mean access to at least some clinical trials data submitted during the market authorisation process.

25. This will presumably include primarily anonymised data derived from patient health data. It is not clear, however, based on the current legislative framework and the proposed Directive, whether this data may also include key-coded patient data or other directly or indirectly identifiable patient health data. As these would continue to be considered personal data, a clarification of this situation in the proposed Directive would be important. In this respect the EDPS would like to refer to the recent EDPS Opinion on

[9] See EDPS Opinion of 10 April 2007 on the financing of the Common Agricultural Policy, OJ 2007 C134/1 OJ C 134, 16.6.2007, p. 1–3.

Clinical trials[10] where he recommended inserting a provision in the proposed legislation that clearly defines in which situations and subject to what safeguards information containing patient health data will be processed and stored in clinical trials databases.

26. The proposed Directive does not provide justification for the need for directly or indirectly identifiable personal data of patients to be processed for the purpose of pricing and reimbursement decisions. Unless such a need is clearly demonstrated, or unless it is demonstrated that the data processed cannot be (fully) anonymised, the EDPS recommends full anonymisation (and high level of aggregation) of any patient data included in the market authorisation data as the most effective solution for the protection of personal data. Correct application of state-of-the-art anonymisation techniques would imply that no personal data are processed and Directive 95/46/EC would therefore be no longer applicable. The EDPS recommends amending the text in this sense.

2.3.1. Potential processing of patient data concerning health

27. As stated above, access to market authorisation data would imply access to, for example, raw data from clinical trials. Clinical trials are by nature dependent on the processing and storage of personal data of patients at different levels (local, national and European). Personal data of patients participating in clinical trails is data relating to the health of the persons concerned since they reveal information about medicine use and associated health problems.

28. The EDPS wishes to underline that the processing of health data (considered "special" or "sensitive") is subject to stricter data protection standards laid down in Article 8 of Directive 95/46/EC and its implementing national laws. Among the possible legal grounds for the processing of personal data relating to health, Article 8(3) of Directive 95/46 is applicable in this case. These provisions lift the prohibition of processing health related data if the processing is '*required* for the purpose of preventive medicine [...]'.

29. The importance of protecting such data has repeatedly been emphasised by the European Court of Human Rights in the context of Article 8 of the European Convention of Human Rights. The Court has stated: '*The protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention*'[11].

30. If personal data concerning health is intended to be processed under the proposed Directive, the EDPS recommends inserting a reference to Article 8 of Directive 95/46/EC in the provisions concerning access to market authorisation data.

31. Furthermore, the processing of personal data concerning health should always be accompanied by specific safeguards to ensure fair processing and to prevent any undue impact on the data subjects. The EDPS therefore recommends (as stated above in section 2.3.) inserting a provision in the proposed Directive that clearly defines in which situations and subject to what safeguards information containing patient health data will be processed.

[10] See EDPS Opinion of 19 December 2012 on the Commission proposal for a Regulation on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC available on the EDPS Website under: http://www.edps.europa.eu/EDPSWEB/edps/Consultation/OpinionsC.

[11] See ECHR 17 July 2008, I v Finland (appl. No 20511/03), paragraph 38 and ECHR 25 November 2008, Armonas v Lithuania (appl. No 36919/02), paragraph 40.

2.3.2. Compatible use of market authorisation data[12]

32. The Proposal provides for the processing for the purposes of reimbursement and pricing decisions of personal data that was collected for a different purpose (clinical trials and market authorisation). This raises questions regarding purpose limitation, a concept that has been analysed in detail in a recent Opinion of the Article 29 Working Party[13]. In addition, the issue arises whether it is necessary and proportionate to use patient data for those secondary purposes, or whether it would be sufficient (and more proportionate) to only use (fully) anonymised datasets.

33. The principle of purpose limitation protects data subjects by setting limits on how data controllers are able to use personal data, while at the same time offering them some degree of flexibility. The concept of purpose limitation has two main building blocks: personal data must be collected for 'specified, explicit and legitimate' purposes (purpose specification) and not be 'further processed in a way incompatible' with those purposes (compatible use).

34. In the present case, the EDPS will concentrate his analysis on compatible use since this case concerns data that has already been collected for a different purpose (in particular, for purposes of conducting a clinical trial within the market authorisation procedure).

35. Further processing for a different purpose does not necessarily mean that this purpose is incompatible: compatibility needs to be assessed on a case-by-case basis. A substantive compatibility assessment requires an assessment of all relevant circumstances. In particular, account should be taken of the following key factors[14]:

    1) the relationship between the purposes for which the personal data have been collected and the purposes of further processing. In this case the purposes of market authorisation and pricing and reimbursement decisions are related although they do not directly stem from and are not directly in furtherance of the initial purpose for which the data was collected;

    2) the context in which the personal data have been collected and the reasonable expectations of the data subjects as to their further use. In this case the data has been collected for purposes of a clinical trial (that is, for research and medicinal safety purposes to ensure that the medications on trial can be safely used). It is doubtful whether the data subject whose health data were collected during a clinical trial would have reasonable expectations that the data will be processed not only for market authorisation, but also for pricing and reimbursement, and may possibly be submitted to a different competent authority for evaluation;

    3) the nature of the personal data in this case is potentially sensitive patient health data and the impact of the further processing on the data subjects is severe by nature in case of processing of this category of personal data[15];

    4) the safeguards adopted by the controller to ensure fair processing and to prevent any undue impact on the data subjects. In this case no specific safeguards are mentioned in the proposed Directive. However, the fact that market authorisation

[12] See Article 29 Working Party Opinion 03/2013 of 2 April 2013 on purpose limitation, p. 21-27.
[13] See Article 29 Working Party Opinion 03/2013 of 2 April 2013 on purpose limitation.
[14] See Article 29 Working Party Opinion 03/2013 of 2 April 2013 on purpose limitation, p. 21-27.
[15] See above section 2.3.1.

data (which includes clinical trials data) may be used for purposes of pricing and reimbursement decisions, is specifically mentioned in the proposal.

36. The EDPS does not see the further processing of non-anonymised data as justified in this case and recommends that Article 13 of the proposed Directive should include a requirement to fully anonymise any patient data included in the market authorisation data before this data is transferred to the competent authority for any further processing for purposes of pricing and reimbursement decisions.

2.4 Potential establishment of a price information database

37. The EDPS notes that Recital 20 of the proposed Directive states that the Commission and the Member States might investigate possibilities to co-operate in the view of setting up and maintaining a price information database on medicinal products and relevant conditions so as to provide a Union-wide added value in terms of price transparency while respecting the Member States' competences in this field.

38. Depending on which information that is to be included in this database, processing of personal data might take place, even processing of sensitive patient health data.

39. At this stage, the EDPS would like to remind the legislator that a recital is not sufficient to provide a legal basis for the establishment of a database including personal data, at EU or MS level. For this, a binding legal provision would be necessary[16].

40. In addition to legal and formal requirements, there are many data protection risks to take into account when contemplating the setting up and maintaining a price information database on medicinal products and relevant conditions, potentially including (sensitive) personal data(e.g. data quality and reliability, confidentiality, access restrictions, further use and purpose limitation principle, etc). Article 33 of the proposed Data Protection Regulation[17] foresees for many processing operations, including for those on health data, that data protection impact assessments (DPIA) should be carried out before launching any new database. The EDPS therefore recommends that the Commission carries out such a DPIA in advance, before any further action is undertaken in this context.

3. CONCLUSIONS

The EDPS makes the following recommendations:

- insert references to the applicable data protection legislation in a substantive article of the proposed Directive. Such a reference should provide as a general rule that Directive 95/46/EC and Regulation (EC) 45/2001 apply to the processing of personal data within the framework of the proposed Directive. Furthermore, the EDPS suggests that the reference to Directive 95/46/EC should specify that the provisions will apply in accordance with the national rules which implement Directive 95/46/EC;

- assess the necessity of the proposed system in Article 16 of the proposed Directive for the mandatory publication of names and declarations of interest of experts, members of decision making bodies and members of bodies responsible for remedy procedures and verify whether the publication obligation does not go beyond what is necessary to

[16] see Article 52(1) of the Charter of Fundamental Rights of the European Union.
[17] COM (2012) 11 final.

achieve the public interest objective pursued, and whether there are any less restrictive measures to attain the same objective. Subject to the outcome of this proportionality test, the publication obligation should in any event be supported by adequate safeguards to ensure respect of the rights of the persons concerned to object, the security/accuracy of the data and their deletion after an adequate period of time;

- insert a reference to Article 8 of Directive 95/46/EC in Article 13 of the proposed Directive concerning access to market authorisation data, if personal data concerning health is intended to be processed and insert a provision in the proposed Directive that clearly defines in which situations and subject to what safeguards information containing patient health data will be processed;

- include in Article 13 of the proposed Directive a requirement to fully anonymise any patient data included in the market authorisation data before this data is transferred to the competent authority for any further processing for purposes of pricing and reimbursement decisions;

- carry out a data protection impact assessment in advance, before any further action is undertaken with a view to launching any new database.

Done in Brussels, 30 May 2013

(**signed**)

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