

Executive summary of the 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 full text of this Opinion can be found in English, French and German on the EDPS website: <http://www.edps.europa.eu>)

(2014/C 32/09)

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')⁽¹⁾. 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⁽²⁾.

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⁽³⁾ 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 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⁾ COM(2013) 168 final/2.

⁽²⁾ COM(2012) 84 final.

⁽³⁾ 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).

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.

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) No 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 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 at Brussels, 30 May 2013.

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