

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

2012/0035(COD) - 30/05/2013 - Document attached to the procedure

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 opinion focuses on the following aspects of the proposed directive relating to personal data protection:

Applicability of the data protection legislation: 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;

Publication of data concerning experts and members of certain organisations: subject to the outcome of a 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::

Potential processing of data concerning the health of patients due to access to data regarding market authorisation data: new provisions should be introduced in order to:

- clearly define in which situations and subject to what safeguards information containing patient health data will be processed, as well as safeguards in this regard;
- provide for 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.

Creation of databases at EU.Member State levels: a data protection impact assessment should be carried out in advance, before any further action is undertaken with a view to launching any new database.