



EDPS NEWSLETTER

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1. Opinion on pharmacovigilance

On 22 April 2009, the EDPS published an opinion on the Commission proposals to adjust the current legal framework for pharmacovigilance in the European Community (EC). Pharmacovigilance is the monitoring of adverse effects of medicinal products.

Although EC legislation on the matter already exists, there are important differences between the Member States in how **information on adverse effects** is collected, stored and further processed.

A crucial role in the whole pharmacovigilance process is played by the **European Medicines Agency** (EMA), which is responsible for keeping a centralised database ("EudraVigilance" database) in which information on adverse effects is stored.

In his opinion, the EDPS expresses concerns about the fact that, while it is clear that personal data are currently processed at all stages of the process, the existing legislation as well as the amendments proposed by the Commission almost completely ignore the existence of EC data protection rules. According to the EDPS, the **absence** of a thorough **data protection analysis** which is reflected in the legal framework is one of the weaknesses of the current system.

The EDPS furthermore expresses his doubts about whether the **use of data relating to identifiable persons** is actually always necessary. He therefore urges the legislator to assess this and to include in the legislation the obligation for all parties to determine for every single stage of the pharmacovigilance process whether the use of personal data is strictly necessary.

More detailed comments relate to the clarification of responsibilities between the different actors involved at national and European level, the need for harmonisation of the reporting system and the safeguarding of data protection and security requirements when regulating the accessibility of the information.

🔗 EDPS opinion ([pdf](#))

2. Opinion on the use of information technology for customs purposes

On 20 April 2009, the EDPS issued an opinion on the Initiative of the French Republic for a Council Decision on the use of information technology for customs purposes.

The draft Decision replaces the CIS Convention of 1995 and aims *inter alia* at:

- reinforcing **cooperation between customs authorities**, by laying down procedures under which customs authorities may act jointly and exchange personal and other data concerned with illicit trafficking activities, using new technology for the management and transmission of such information;
- enhancing **cooperation with Europol and Eurojust**, by granting those bodies access to the Customs Information System (CIS).

The EDPS is particularly interested in the developments concerning the Third Pillar part of the CIS given his **current role as the supervisory authority** for the central part of the First Pillar part of the system.

In his opinion, the EDPS:

- emphasises the need for ensuring a **coherent and comprehensive approach** to align the First and Third Pillar parts of the system;
- expresses regret as regards the **lack of explanatory documents** which could provide for some necessary clarification and information on the objectives and specificity of some of the provisions of the Proposal.
- calls for more attention to be devoted in the proposal to the need for **specific data protection safeguards**. He sees a number of issues where the practical implementation of data protection safeguards should be ensured better, in particular as to the application of the purpose limitation with regard to the use of data entered in the CIS. The EDPS considers this as an essential prerequisite for the improvement of the functioning of the Customs Information System;
- calls for a **coordinated model of supervision** to be inserted in the proposal. He underlines that for the sake of coherence and consistency the best approach is to apply the coordinated supervision model also to the Third Pillar part of the system. This model would also ensure consistency with other legal instruments governing the establishment and/or use of other large-scale IT systems, such as SIS II, VIS, Eurodac;
- calls for more explanation on the necessity and proportionality of giving **access to Eurojust and Europol**. He stresses the lack of explanatory information on this issue in the proposal;
- insists on reinforcing the provisions regarding the **transfer of data** to non-Member States or international organisations. This includes the need to ensure a uniform system of adequacy assessment.

🔗 EDPS opinion ([pdf](#))

3. Opinion on the collection of statistical information by the European Central Bank

On 8 April 2009, the EDPS adopted an opinion on a Recommendation of the Governing Council of the European Central Bank (ECB) concerning the collection of statistical information by the ECB. The opinion analyses the Recommendation and provides some further reflection on the relation between **statistical confidentiality** and **data protection**.

This Recommendation aims at the adoption of a Council Regulation amending Regulation (EC) No 2533/98 concerning the **collection of statistical information** by the ECB. The Recommendation's main purpose is to maintain the Regulation as an effective instrument to carry out the statistical information collection tasks of the European System of Central Banks.

In his analysis, the EDPS:

- welcomes that the proposed amendments contain a specific reference to the data protection legal framework but underlines the need for **further clarification** of some concepts common to data protection and statistics;
- considers that the **purpose limitation principle** should be ensured in the widening of scope of the Regulation;
- stresses the need to assess the necessity of processing payment statistics which may contain personal information about natural persons;
- suggests that **access** to statistical information **for research purposes** should be provided in such a way that the reporting agent cannot be identified, either directly or indirectly, when account is taken of all relevant means that might reasonably be used by a third party.

🔗 EDPS opinion ([pdf](#))

4. Comments on the Commission data protection guidelines for the Internal Market Information System

On 26 March 2009, the Commission adopted its Recommendation on the data protection guidelines for the Internal Market Information System ("IMI"), a large-scale IT system operated by the Commission to facilitate information exchanges between competent authorities in Member States in the area of internal market legislation.

The Recommendation complements the Commission's Decision on the data protection aspects of IMI (2008/49/EC) ("**IMI Decision**"). It provides practical guidance to IMI coordinators and competent authorities in the Member States how to comply with data protection rules when using IMI. The Guidelines are the result of close cooperation between the services of the Commission and the EDPS.

The Recommendation is the first deliverable of the step-by-step approach agreed in an exchange of letters between the Commission and the EDPS last year. In 2010, a Commission report will assess the data protection situation in IMI as well as the content and timeliness of any future measures, including the possible adoption of a legal instrument.

The EDPS believes that the Commission's Recommendation is a good first step towards developing a comprehensive legal framework for IMI. Additional Community legislation must be enacted when further experience is gained with IMI, but in any event, before IMI's complexity, its user base and the number of information exchanges that occur within it, reach a critical mass.

🔗 EDPS letter to DG MARKT (7 April 2009) ([pdf](#))

🔗 [IMI Data Protection Guidelines](#)

5. European Parliament Second Reading vote on E-Privacy

Mostly positive news on substance, but as things stand at present, the status of the review of the ePrivacy Directive is an open question. The extent to which it will become law in its current or in a new form is unclear. As further explained below, this is not due to changes to the ePrivacy Directive itself, but result of the outcome of the EP vote on another part of the Telecoms Package.

Procedural issue

On 6 May 2009, the European Parliament (EP) voted on the Telecoms Package, which includes the ePrivacy Directive. The vote was cast on an agreement between the EP and Council on the text of the five Directives that make up the Telecoms Package. Had the EP Plenary fully endorsed the inter-institutional agreement, the Telecom Package would have become law. While the EP Plenary adopted the compromise as far as the ePrivacy and Universal Service Directives are concerned (referred to as the "Harbour Report"), it rejected one aspect of the Telecom package (an article of the Framework Directive contained in the "Trautmann Report"), and instead, adopted language that differed from the agreement with Council. This unexpected outcome has left the situation of the whole Telecom Package in a standstill.

Legally, the ball is now in the Council's court. Indeed, it is up to the Council, perhaps in its next June 12 meeting, to accept the EP amendment to the Framework Directive, put the whole Telecom Package for re-negotiation within the context of the conciliation procedure or, alternatively, limit discussions to the Framework Directive. In any event, negotiations probably would not start until autumn with the new Parliament.

Balance on substance

Although the compromise agreement, as far as the ePrivacy Directive is concerned, could certainly be further improved, in most of the issues it offers a satisfactory approach. The EDPS is pleased to see that a large number of his recommendations made during the legislative process are reflected in it. This is the case, for example, regarding the mandatory notification for personal data breaches, which is one of the core elements of the Directive. In this area, the structure and standards applying to security breaches are workable without neglecting the data protection and privacy safeguards. It is regrettable, however, that its application is limited to ISPs and network operators. One would hope that the Commission, in consultation with the EDPS, will soon put forward proposals setting up mandatory notification requirements applicable to all sectors, as the Commission has undertaken to do in a declaration annexed to the text adopted by the EP.

The EDPS also welcomes additional data protection safeguards included in Article 5.3 (so called "cookies article"). In particular, he welcomes its application to situations where access to information and the storage of information in the users' terminal equipment is carried out through software provided on external storage, the deletion of the words "facilitating" and the replacement of the "right to object" by the "right to accept", all of which reinforce the data protection and privacy safeguards.

Perspectives

The EDPS hopes that the co-legislators will soon sort out the current impasse regarding the Telecoms Package. Whatever solution is finally reached, it is important to ensure that it does not diminish the data protection and privacy safeguards embodied in the current compromise text. Given the difficult negotiations involved in agreeing the revised text of the ePrivacy Directive, the limited time available in conciliation and the possibility of renewed pressures to soften data privacy safeguards, the EDPS is concerned that the text on ePrivacy might be opened up for further discussion at this point.

☞ EDPS comments of 16 February 2009 on Universal service and e-Privacy ([pdf](#))

☞ EDPS letter of 4 February 2009 on the scope of e-Privacy ([pdf](#))

☞ EDPS second opinion of 9 January 2009 on e-Privacy ([pdf](#))

☞ EDPS comments of 2 September 2008 on Universal service and e-Privacy ([pdf](#))

☞ EDPS opinion of 10 April 2009 on e-Privacy ([pdf](#))

6. News on EDPS prior checking of personal data processing

Processing of personal data by the EU administration that is likely to result in specific risks for the people concerned (the data subjects) is subject to a prior check by the EDPS. This procedure serves to establish whether or not the processing is in compliance with Regulation (EC) No 45/2001, which lays down the data protection obligations of the EU institutions and bodies.

6.1 Information management between OLAF and the Commission in the framework of the Memorandum of Understanding

On 23 March 2009, the EDPS adopted a prior-check opinion on the processing operations relating to management of information between OLAF and the Commission within the framework of the Memorandum of Understanding (MoU).

The MoU organises the exchange of information between OLAF and the Commission concerning the internal surveys of OLAF. It covers:

- the transmission of the information provided by OLAF to the Commission within the framework of the internal surveys;
- the communication of this information, in a confidential way and according to the practical needs, to the responsible Commissioners and to the Directors-General concerned.

This information often includes personal data. This is only basic information which by no means includes all the data of surveys conducted by OLAF. OLAF is selective in the information that it provides to the Commission at the time of the opening or in the process of surveys. This enables the Commission (the Commissioner and the relevant service) to have the necessary information to take precautionary measures - if circumstances justify it - in order to protect the financial interests and the reputation of the institution.

The main recommendations of the EDPS cover the data retention period, information and rights of access and rectification granted to data subjects. In relation to the information to be given to the data subject, the EDPS stressed that since the Commission itself also processes the information provided by OLAF, the Commission should also inform the data subject of the processing. It follows that the data subject should be given the right of access and rectification.

🔗 EDPS opinion ([pdf](#)) (FR)

6.2 Processing of requests to waive the immunity from legal proceedings, inviolability of the premises and archives of the Communities - European Commission

On 25 March 2009, the EDPS issued an opinion concerning a data processing by the European Commission's Investigation and Disciplinary Office (IDOC) with respect to requests from national authorities to lift up immunities granted to civil servants. IDOC has implemented a process for analysing such requests from national authorities. The outcome of such process is to inform the decision of the competent authority to authorize or not (i) that a staff member appears in courts, (ii) access to the European Commission's premises, and/or (iii) access to the European Commission's archives.

Upon express request from the national authority, in the interest of the legal proceedings, the information of the data subject concerning such request may be postponed until a decision is taken by the national authority.

While the EDPS concluded that the data processing operations are in line with Regulation (EC) No 45/2001, the EPDS made the following main recommendations:

- **data retention time-periods:** the EDPS asked that the time-period for retaining data concerning requests to lift up immunities is re-assessed taking into account factors such as discontinuation of the national legal proceedings, acquittal of the person. In cases where disciplinary investigations are started, IDOC shall also adapt the data retention period taking into account factors such as the discontinuation of the disciplinary proceedings.
- **recipients of data:** IDOC shall clearly specify the exact categories of persons who are authorized access to the data and the purpose for which they are authorized such access;
- **transfers of data:** any transfer of data to external recipients outside the European institutions and bodies shall be noted down as well as the legal basis authorizing such transfer;
- **data subjects' rights:** when the secrecy of the procedure is not requested by the national authority, the data subject shall be able to provide his/her views on the matter before the AIPN takes a decision.

🔗 EDPS opinion ([pdf](#)) (FR)

6.3 Voice logging at Joint Research Centre Institute for Energy - European Commission

On 29 April 2009, the EDPS published an opinion on a notification for prior checking received from the Data Protection Officer of the Commission on Voice Logging at the Joint Research Centre Institute for Energy (JRC-IE) in Petten.

This case concerns the recording of incoming and outgoing calls, as well as records of the calling telephone number, the called telephone number, date, time and length of the conversation at the JRC-IE. The purpose is to be able to check the content of the calls to the lines concerned in the event of an operational incident, emergencies and to be able to evaluate emergency training exercises at a later stage. These calls may also furnish evidence for investigations into potential threats to the institution.

The EDPS opinion particularly examines the lawfulness of the processing operation as the recording of calls is a violation to the principle of confidentiality of communications. The EDPS acknowledges that the processing is lawful as based on mandatory national legislation applicable in the field of nuclear facilities. The EDPS also makes recommendations on the information to the persons concerned notably to external persons calling the switchboard and who must be informed that the communication will be recorded for security purposes at the start of the call.

🔗 EDPS opinion ([pdf](#))

7. Events

7.1 European Commission's Data Protection Conference, 19-20 May 2009, Brussels

The European Commission organises a personal data use and protection conference to look at new challenges for privacy. Interested individuals, business leaders, consumer associations, academics, data protection supervisors and public authorities from both the EU and third countries are invited to take part.

Peter Hustinx, EDPS, is due to deliver a speech on the theme "Transparency and notification in the age of Internet". Giovanni Buttarelli, Assistant Supervisor, will also intervene on the following topic: "Towards a Charter on digital data protection and freedom of information?".

🔗 More information on the European Commission's [Data Protection webpage](#)

7.2 Data Retention Conference, 14 May 2009, Brussels

This one-day conference focused on the evaluation of the Data Retention Directive. Main topics of discussions included the impact of the retention of telecommunication and Internet data under the Directive, the liability of service providers and the application of the Directive from a Member State perspective.

EDPS staff members participated to the event and Peter Hustinx, Supervisor, delivered a speech entitled "Ensuring the right balance between law enforcement and data protection" (see below, section 8.).

☞ More information at: <http://www.dataretention2009.eu/>

7.3 First Euro-Ibero American Data Protection Seminar on "Protection of Minors", Cartagena de Indias, Colombia, 26-28 May 2009

☞ More information at: www.aecidcf.org.co; www.agpd.es

8. Speeches and articles

- "Ensuring the right balance between law enforcement and data protection", speech ([pdf](#)) delivered by Peter Hustinx, EDPS, at the Data Retention Conference "Towards the evaluation of the Data Retention Directive", Brussels, 14 May 2009.
 - "The Changing landscape of European liberty & security", speech ([pdf](#)) delivered by Giovanni Buttarelli, Assistant Supervisor, at the Centre for European Policy Studies, Brussels, 28 April 2009.
 - Peter Hustinx, "Protection of personal data on-line: the issue of IP addresses", article ([pdf](#)) published in Revue Légicom, 15 April 2009, No. 42.
 - "Intelligent data protection for intelligent transport system", speech ([pdf](#)) delivered by Giovanni Buttarelli, Assistant Supervisor, at the European Economic and Social Committee hearing on the deployment of intelligent transport systems, Ostrava, 26 March 2009.
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9. New Data Protection Officers

Each EC institution and body has to appoint at least one person as Data Protection Officer (DPO). These officers have the task of ensuring in an independent manner the internal application of Regulation (EC) No 45/2001.

Recent appointments:

- Donatella PIATTO, European Research Council Executive Agency (ERC)
- Evangelos TSAVALOPOULOS, Research Executive Agency (REA)

☞ See full list of [DPOs](#).

9. Colophon

This newsletter is issued by the European Data Protection Supervisor - an independent EU authority established in 2004 to:

- monitor the EU administration's processing of personal data;
- give advice on data protection legislation;
- co-operate with similar authorities to ensure consistent data protection.

Postal address:

EDPS - CEPD
Rue Wiertz 60 - MO 63
B-1047 Brussels
BELGIUM

Office:

Rue Montoyer 63
Brussels
BELGIUM

Contact details:

Tel: +32 (0)2 283 19 00
Fax: +32 (0)2 283 19 50
e-mail: see [contact page](#) on the website

EDPS - The European guardian of personal data protection
www.edps.europa.eu