

Opinion on the notification for prior checking from the Data Protection Officer of the Council of the European Union regarding the "Medical files" and "Clinic daybook" dossiers

Brussels, 29 May 2006 (Case files 2004-254 and 2005-363)

1. Procedure

On 20 July 2004 the European Data Protection Supervisor (EDPS) sent a letter to the Data Protection Officers asking them to contribute to the preparation of an inventory of data processing that might be subject to prior checking by the EDPS as provided for by Article 27 of Regulation (EC) No 45/2001. The EDPS requested notification of all processing operations subject to prior checking, including those that commenced before the Supervisor was appointed and for which checking could never be regarded as prior, but which would be subject to "ex-post" checking.

On 9 September 2004 the Council's Data Protection Officer presented the list of cases that required prior checking ex-post, in particular the case concerning medical files, insofar as they could contain data relating to health care (Article 27(2)(a)).

The European Data Protection Supervisor identified certain priority topics and selected a number of processing operations subject to prior checking ex-post that required notification. The "Medical files" dossier is among them.

Notification within the meaning of Article 27(3) of Regulation (EC) No 45/2001 (hereinafter referred to as "the Regulation") concerning the "Medical Files" (2004/254), together with notification concerning the "Clinic daybook" (2005/363), was given by the Data Protection Officer of the Council by letter received on 22 November 2005. For practical reasons, the EDPS deemed it desirable to deal with these two dossiers together¹.

Questions concerning both dossiers were put to the controller concerned in an e-mail from the Council's Data Protection Officer dated 28 November 2005, and replies were sent on 10 March 2006. Further information was incorporated into the dossier by e-mail on 7 March 2006 and information for the dossier on medical files was exchanged on 14 March 2006. Questions relating to both dossiers were put by e-mail on 27 April 2006 and the relevant replies were obtained by e-mail on 11 May 2006. In order to enable the DPO to provide the additional information and relevant comments, the deadline was suspended for a further 12 days.

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Although these dossiers are being dealt with together, the data subjects in the "Clinic daybook" dossier are solely those classed as internal staff members (namely officials, temporary and auxiliary staff and contractual agents). External staff concerned by the "Clinic daybook" dossier have been dealt with under the "Record of medical consultations of persons from outside the Institution" dossier (2005/380), the opinion on which was delivered on 4 May 2006. Although consultation forms are indeed drawn up for persons from outside the Institution, they cannot be included in the medical files for these persons, since such files do not exist.

2. Facts

Medical files at the Council are processed for the purposes of handling pre-recruitment medical examinations, annual medical check-ups, various types of leave (special leave, family leave, special leave in the event of serious illness of a child), assistance to disabled persons, family allowances (only in cases where the dependent child allowance is extended or doubled), procedures relating to invalidity committees and, lastly, handling medical consultation forms.

The data covered by the processing operation are the consultation forms concerning annual medical check-ups, GP reports, and medical reports drawn up by doctors in respect of additional examinations following pre-recruitment examinations, annual medical check-ups and visits to a GP. The consultation form resulting from a medical examination undertaken either at the initiative of the data subject or on the recommendation of the dispensary are also covered by the processing operation. The data subjects are officials, temporary staff and auxiliary staff at the Council.

For information purposes, the various procedures concerned are:

2.1. Pre-recruitment medical examination

The Staff Regulations refer to the pre-recruitment medical examination in Articles 28(e) (An official may be appointed only on condition that he is physically fit to perform his duties) and 33 (Before appointment, a successful candidate shall be medically examined by one of the institution's medical officers in order that the institution may be satisfied that he fulfils the requirements of Article 28(e)).

All future employees are required to fill in a form in their mother tongue and hand it to the doctor during their pre-recruitment medical examination. This document is placed in the official's medical file.

2.2. Annual medical check-up

Officials may opt to undergo the annual medical check-up provided for under Article 59(6) of the Staff Regulations either with the Institution's medical officer or with a medical practitioner of their choice.

During each annual medical check-up, the doctor will draw up a consultation form to monitor the medical condition of the person concerned throughout his career. Officials who prefer to be examined by a doctor of their own choice must submit a written request when they are summoned for the check-up. They will then receive the form and the medical examination report to be completed by their doctor. These two documents must be sent in an envelope marked "Medical information: Confidential" to the Medical Officer at the General Secretariat of the Council.

2.3. Clinic daybook

The Council has a medical dispensary on its premises. Anybody working in the General Secretariat, whether directly or indirectly, can call on the services of the dispensaries, provided he or she is working on Council premises. The data subjects are officials, temporary staff, auxiliary staff, employees of external companies and visitors.

The daybooks/registers are pre-printed books used on a daily basis to keep track of visits by data subjects and the care and treatment provided to them. Consequently, the data processing involved is manual, its aim being to establish a daily register of medical diagnoses and of care and treatment

provided at the dispensaries.

The following identifiable data are contained in the daybook of persons reporting to the dispensary: the date and time, the name and position of the data subject, the reason for the visit, and a numerical code for consultations and symptoms designed to identify each consultation and symptom with a number for statistical management purposes. Other data included in the daybook relate to ECGs, accidents, appropriate care, any medication prescribed, vaccinations, subcutaneous and intramuscular injections where necessary, ultraviolet and infrared treatment, and audiometry. A list of the codes assigned to each treatment has been in use since 1 January 2006.

Data subjects who have been treated are not entitled to access to the daybook, nor do they enjoy rectification, blocking, erasure or objection rights. The explanation given for this is that data are entered when care or treatment is administered and simply reflect the treatment given. However, data subjects are entitled to a doctor's consultation certificate, issued at the request of the person in question and containing the data recorded in the daybook.

The persons responsible for the treatment are the doctors at the Council's Medical Department and its nurses, while the recipient of the treatment is the data subject in respect of whom the consultation certificate is issued.

The daybooks are kept in hard-copy form for a period of 15 years. They date back to 1997 and thus none have been destroyed to date.

The information contained in the daybooks is used to produce anonymous statistics. For instance, the numerical codes are used to denote consultations and symptoms as a means of ascertaining the most frequent reasons for visits. Besides serving epidemiological purposes, these statistics are used for resource allocation and for the department's annual activity report.

Security measures have been adopted. At the end of the working day the daybooks are stored in a cupboard, the key to which is available to the nurses alone. The cupboard is located inside the dispensary, accessible via an electronic lock that can only be used by Medical Department staff.

The consultation form for an unscheduled medical examination in respect of officials, temporary staff or contractual agents is thus placed in the medical file of the person who has come for a consultation. The form is subject to the same requirements in terms of length of storage and access, rectification and notification rights for the person concerned.

2.4. Occupational medicine

2.4.1. Special leave (illness of a relative in the ascending line or a spouse)

Internal Directive No 1/04, adopted on 1 April 2004, stipulates that officials, temporary staff and auxiliary staff will, on application, be granted special leave in the event of serious illness of a relative in the ascending line or a spouse, subject to certain conditions.

As regards the dossier under scrutiny here, officials, temporary staff and auxiliary staff are required to submit either a medical certificate (original copy) accompanied by a diagnosis or a detailed medical report to the Medical Department, which must then give its opinion as to the severity of the illness and, where appropriate, the chronic nature thereof.

The medical certificate or report must be <u>addressed directly to the Medical Department</u> and marked "for a request for special leave". The medical officer must give his opinion as to the severity of the

illness and, where appropriate, the chronic nature thereof. Once the Leave Department has been notified of the consent, special leave will be granted.

2.4.2. Family leave

In accordance with Article 42b of the Staff Regulations, any official whose spouse, relative in the ascending line, relative in the descending line, brother or sister is suffering from a <u>medically certified</u> serious illness or disability, is entitled to a period of family leave.

As regards the dossier under scrutiny here, it should be borne in mind that, except in emergencies, the application for family leave must be submitted two months before the date from which the official wishes to be granted family leave. The application form is available on INTRANET.

In accordance with the text of Article 42b, the aforementioned certificate must state explicitly that the illness or disability is <u>serious</u> and it must be sent to the institution's medical officer. A model of the cover note is available on INTRANET.

2.4.3. Special leave (serious illness of a child)

In the event of very serious illness of a child, as certified by a doctor, or hospitalisation of a child under 12 years of age, the person concerned may be granted up to five days' special leave. The Appointing Authority may grant one or two extensions, up to a maximum of 15 days per child and per calendar year, with the consent of the Council's medical officer.

In the event of very serious illness of a child, the relevant medical certificate or medical report should be addressed directly to the Medical Department, marked "for special leave application". The medical officer must confirm the very serious nature of the illness in order for the special leave to be granted.

2.4.4. Assistance to disabled persons

In the context of policy on social assistance to disabled persons, officials, temporary staff and their dependants may receive support under the budget heading "Supplementary aid for the disabled".

The application for recognition of a disability must be lodged with the Appointing Authority. This application contains a detailed assessment by the person concerned, or by his representative, of the measures required to alleviate the effects of the disability and facilitate social integration. A medical report by the person's GP, under sealed cover and, where possible, suggesting the level of physical and/or mental incapacity, is submitted together with the application. The Appointing Authority forwards the medical report to the medical officer for an opinion.

Having conducted an examination of the disabled person if he sees fit, and on the basis of the legal provisions, the medical officer:

- notes that the minimum threshold has been reached, and
- establishes the period of validity of his opinion.

Having received the opinion of the medical officer, the Appointing Authority may refer the matter to the ad hoc committee, which assesses the social integration difficulties arising out of the disability and delivers its opinion on the measures advocated by the person concerned or by his representative to alleviate the effects of the disability.

It follows from this that the Medical Department is not directly involved with any assistance that

may be granted to families with a disabled child. This processing operation is a matter for the Welfare Office, not for the Medical Department. The Medical Department's involvement does not extend beyond issuing a favourable or unfavourable opinion on the medical grounds for the application on the basis of the medical reports it receives and forwarding that opinion to the Welfare Office.

2.4.5. Family allowances

Family allowances which are subject to an opinion from the medical officer are dealt with in Article 67(3) of the Staff Regulations (doubling of family allowances – *The dependent child allowance may be doubled by special reasoned decision of the appointing authority based on medical documents establishing that the child concerned is suffering from a mental or physical handicap which involves the official in heavy expenditure*) and in Article 2(5) of Annex 7 to the Staff Regulations (continued payment of the dependent child allowance – *Payment of the allowance in respect of a child prevented by serious illness or invalidity from earning a livelihood shall continue throughout the period of that illness or invalidity, irrespective of age).*

These applications are sent by the applicant to the Administration, which consults the Medical Department thereon. The latter refers to medical reports in order to grant its consent. The medical reports and medical opinion are kept in a special folder in the medical file of the official who has lodged the application.

2.5. Procedures relating to invalidity committees

A procedure may be initiated at the request of the Administration or the data subject.

The Invalidity Committee is composed of three doctors (the medical officer, the data subject's GP and a third doctor chosen by the other two) and refers to the reports provided by the GP on the one hand and by the third doctor on the other. All of these reports are placed in the medical file and remain confidential for the Administration. Once it has met, the Invalidity Committee delivers an opinion to the Appointing Authority, but does not refer to the medical grounds for its decision. The third doctor draws up the document setting out the medical grounds of which the Appointing Authority has not been notified; this document is then placed in the medical file. The conclusions, drafted and signed by all three doctors, are placed in the medical file. The person concerned is informed of the decision by letter and the Administration takes due note of the decision.

2.6. Other information contained in the notification and additional information

Staff is informed in accordance with Article 26a of the Staff Regulations of Officials of the European Communities. Implementation of that article of the Staff Regulations is complemented by Staff Note No 31/04 of 19 March 2004, which sets out the following principles:

Officials, temporary staff and auxiliary staff shall have the widest possible access to their medical files, under the following conditions:

- 1. The file must be consulted on the premises of the Medical Service of the institution, in the presence of a person designated by the Medical Service.
- 2. The official or other servant will be able to have access to psychiatric/psychological reports concerning him or her, through the intermediary of a doctor appointed by him or her.
- 3. The official or servant may not have access to personal notes by doctors if, under the terms of

Article 20(1)(c) of Regulation 45/2001 referred to above and on the basis of a case-by-case examination, this is necessary to guarantee the protection of the person concerned or the rights and freedoms of others.

Access to medical files has been discussed above. Rectification, blocking, erasure and objection rights are dealt with in Section 5 of the Council Decision of 13 September 2004 adopting implementing rules concerning Regulation (EC) No 45/2001 of the European Parliament and of the Council 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. Section 5 of that document sets out the procedures for enabling data subjects to exercise their rights. The notification further specifies that no time-limit has been set for the blocking or erasure of data.

Only hard copies of the files are kept. The medical file is a single dossier comprising separate parts relating in particular to the annual medical check-up and the results (reports) of the complementary examinations.

The people liable to receive the data are the doctors of the Medical Department, the data subjects, external doctors appointed by data subjects and other Community institutions or bodies in the event of a change or transfer of post.

Personal data are kept for 30 years after the data subjects have left the service; there are three specific cases:

- 1. up to the age of 75 and 30 years after the end of professional activities in the case of workers who have been exposed to ionising radiation;
- 2. 40 years after exposure in the case of workers who have been exposed to carcinogens or mutagens;
- 3. 30 years after exposure in the case of workers who have been exposed to biological agents;

Files are archived when data subjects leave the service. To date, no file has been deleted owing to the lack of precise instructions regarding their destruction. The summary minutes of the 243rd meeting of the Heads of Administration on 6 October 2005 point out that "no medical file has ever been destroyed by the Community institutions. The Commission, which has already started to digitise personal files, intends to digitise medical files as well."

Storage for historical, statistical or scientific purposes has been excluded.

The measures taken to ensure security of processing essentially involve storing the files in locked cupboards within offices which are accessible only by means of magnetic badges held exclusively by the Medical Department staff (i.e. the doctors and secretariat). The same applies to archived files. The cupboard keys are themselves locked in a cupboard which can be opened only with a magnetic badge.

The files are classified by date of birth; the dates are obtained from the GPWin program. GPWin is a database which is not accessible to all officials. It is managed by the Directorate for Personnel and Administration and contains data relating to each official, including, *inter alia*, his or her surname, forename, date of birth, status under the Staff Regulations, family status and office address.

The Medical Department intends to establish a database for handling the administrative follow-up of medical files. An electronic file will be created for the purposes of administrative follow-up of the medical files managed by the Medical Department. Some of the data will also be used to produce the standard prescriptions and notes which were previously drawn up manually. If a complementary examination is prescribed, the file will mention it as a date referring to the medical file without specifying the examination's purpose. More personal and sensitive notes will continue to be written and

signed as appropriate by the doctor responsible for the file.

All the information currently contained in the manually managed files is to be entered into the database. To save time, it is planned to transfer certain data – of an entirely administrative nature, such as surname, forename, date of birth, nationality and office address – from the current GPWin managed by the Administration and to enter certain items of information from the data processed by the Medical Department, such as the date on which data subjects underwent a medical fitness test and took up their appointment.

3. Legal aspects

3.1. Prior checking

The notification received on 22 November 2005 relates to processing of personal data ("any information relating to an identified or identifiable natural person" – Article 2(a)). The data processing in question is carried out by an institution in the exercise of activities which fall within the scope of Community law (Article 3(1)).

The processing is manual for the moment but the processed data form part of a filing system, which in this case consists of the files containing the consultation fiches and the various certificates provided within the framework of social medicine. Furthermore, the processing will be partially automated as soon as a database is set up to enable administrative follow-up of these medical files by means of electronic files. The processing operation relating to the "Clinic daybook" dossier is manual, but the information is transferred to the data subject's medical file. Article 3(2) is thus applicable in this case.

The processing therefore falls within the scope of Regulation (EC) No 45/2001.

Article 27(1) of Regulation (EC) No 45/2001 makes "processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes" subject to prior checking by the European Data Protection Supervisor.

Processing is also subject to the provisions of Article 27(2)(a): "The following processing operations are likely to present such risks: processing of data relating to health (...)", which is the case here since the data undoubtedly fall within the scope of "data relating to health" and medical data.

In principle, checks by the European Data Protection Supervisor should be performed before the processing operation is implemented. In this case, as the European Data Protection Supervisor was appointed after the system was set up, the check necessarily has to be performed ex post. This does not alter the fact that it would be desirable for the recommendations issued by the European Data Protection Supervisor to be implemented. However, the check should be regarded as a genuine prior check as regards aspects relating to the follow-up database being set up.

The two notifications from the Council's Data Protection Officer were received through the post on 22 November 2005. Under Article 27(4) of the Regulation, the European Data Protection Supervisor had to deliver his opinion within two months. Taking into account the 128-day suspension, the European Data Protection Supervisor had to deliver his opinion by 31 May 2006 at the latest (23 January plus 128 days of suspension) under Article 27(4) of the Regulation.

Judgment of the Court of Justice of the European Communities of 6 November 2003, Lindqvist, C-101/01, [2003] ECR I-12973.

3.2. Legal basis and lawfulness of the processing operation

The legal basis for the data processing is to be found in Article 1e, Article 28(e), Article 33, Article 59(6), Articles 42b and 57, Article 67(3) and Article 59(4) of the Staff Regulations of Officials of the European Communities and Annex V and Article 2(5) of Annex VII thereto. Likewise, although they have not been mentioned, the legal basis for the processing operation also includes Article 12(d) and Article 13 (temporary staff), Article 55(d) (auxiliary staff) and Article 82(d) and Article 83 (contractual staff) of the Conditions of Employment of Other Servants (CEOS). The Council is consequently entitled to set up a system for managing the various procedures pertaining to medical files. The legal basis is therefore valid.

As regards the Clinic daybook, the Council also applies Article 10 of the CEOS, which states that Article 1e of the Staff Regulations applies by analogy to temporary staff.

Lastly, within the framework of the powers conferred by Article 207 TEC relating to the Council, complemented by the article of the Council's Rules of Procedure authorising it to take the measures necessary to ensure its smooth running, the Council applies a Vade-Mecum which provides that "anybody working in the General Secretariat, whether directly or indirectly, can call on the services of the dispensaries provided he or she is working on the Council premises".

Alongside the legal basis for the two dossiers in relation to Regulation (EC) No 45/2001, the lawfulness of the processing operation must also be considered. Article 5(a) of Regulation (EC) No 45/2001 stipulates that "the processing [must be] necessary for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities (...) or in the legitimate exercise of official authority vested in the Community institution". Management of the medical files of the staff concerned falls within the legitimate exercise of official authority vested in the institution; the processing operation is therefore lawful.

Moreover, data relating to health are among the data which Article 10 of Regulation (EC) No 45/2001 classes as "special categories of data".

3.3. Processing of special categories of data

Under Article 10 of the Regulation, the processing of personal data concerning health is prohibited unless grounds can be found in Article 10(2) and (3) of Regulation (EC) No 45/2001. The case under consideration very clearly relates to the processing of personal data on health.

Article 10(2)(b) ("Paragraph 1 [prohibition of the processing of data concerning health] shall not apply where (...) processing is necessary for the purposes of complying with the specific rights and obligations of the controller in the field of employment law insofar as it is authorised by the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof (...)") applies in the case in point. The Council, in its capacity as employer, is complying with Article 10(2)(b) by processing the data submitted.

Lastly, in the case in point, certain health-related data are processed by Council doctors. Owing to the nature of the data involved, which concern health, Article 10(3) (special categories of data) of Regulation (EC) No 45/2001 applies in this instance. It provides that "Paragraph 1 [prohibition of the processing of data concerning health] shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent

obligation of secrecy". On account of their position, the doctors are subject to the obligation of professional secrecy and are the sole recipients of the data. That provision further implies that there must be functional separation of these doctors; this is the case, since the Medical Department is a functionally separate part of the Council's Personnel Division (separate Medical Department). In this instance, Article 10(3) of the Regulation is duly complied with.

However, the EDPS would draw attention to the fact that all administrative departments responsible, within the framework of social medicine, for processing files containing certificates issued by medical staff are themselves bound by professional secrecy. The EDPS recommends that they be reminded of that obligation.

3.4. Data quality

Data must be "adequate, relevant and not excessive" (Article 4(1)(c) of Regulation (EC) No 45/2001). The processed data described at the beginning of this opinion should be regarded as fulfilling these conditions in relation to the processing operation.

Even though certain standard data such as the name, date of birth and personnel number will always be present in medical files, the precise content of a medical file will of course vary according to the case. However, there must be some guarantee that the principle of data quality is complied with. This could take the form of a general recommendation to the persons handling the files asking them to ensure that this rule is observed. Furthermore, great care must be taken during processing to ensure that non-authorised persons are not sent or given access to purely medical data.

The quality of data contained in the medical questionnaire filled in by potential or actual staff must also be safeguarded. Any information requested must be relevant to the purpose for which the data are collected. The questionnaire on medical fitness may serve the purpose only of determining whether or not a person is physically and mentally fit to perform his or her duties.

This therefore raises the issue as to what can be considered as medical data which are likely to have an impact on performance of the data subject's duties. In any case, the type of data will vary according to the type of function (office work or other, for example). The EDPS would draw attention to the fact that the relevance of some of the data collected via the form for assessing the fitness of the data subject to perform his or her duties needs to be demonstrated; the EDPS questions the relevance of certain items of information, such the medical history and current state of health of the siblings, spouse and children and the use of contraceptives by female data subjects. The EDPS recommends that the data in the questionnaire on medical fitness be assessed in the light of data protection principles.

In cases T-121/89 and T-13/90, the Court of First Instance found that "the medical officer of the institution may base his finding of unfitness not only on the existence of present physical or psychological disorders but also on a medically justified prognosis of potential disorders capable of jeopardizing the normal performance of the duties in question in the foreseeable future". Even though the ruling was subsequently annulled by the Court (C-404/92), this interpretation of the concept of "fitness" was not challenged. While terms such as "potential disorders" and "foreseeable future" are somewhat vague for the purposes of data protection, relevance of the data with respect to the normal performance of duties must be proven. The link between a potential disorder and fitness to carry out one's duties has to be demonstrated. It should therefore be borne in mind that only data which are relevant in terms of medical fitness to carry out his or her duties may be requested from the candidate.

As regards annual medical check-ups carried out by a medical practitioner chosen by the official

(Article 59(6) of the Staff Regulations), the Medical Department's need to receive the medical report and copies of complementary examinations carried out must be demonstrated. It is worth considering whether the main objective of the medical check-up cannot be attained by means of a statement from the medical practitioner certifying the official's state of health and establishing whether or not certain examinations have been carried out.

Furthermore, the Council should consider whether requiring that the diagnosis be included with the medical certificate in the procedure relating to serious illness of a spouse or relative in the ascending line might not be excessive and whether a detailed medical report would not be sufficient³.

Lastly, the file created for the purposes of administrative follow-up of medical files poses a problem with certain of the data mentioned, in particular the "purpose of prescriptions". Staff members responsible for managing these electronic files will have access to purely medical data. The EDPS recommends that the data contained in the prescriptions table relating to the purpose of the prescriptions should be deleted.

Under Article 4(1)(d) of the Regulation, personal data must be "accurate and, where necessary, kept up to date", and "every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified."

The data in this case include doctors' notes and the results of medical examinations. It is not easy to ensure or assess the accuracy of data of this nature. However, the EDPS would emphasise that the institution must take every reasonable step to ensure that data are up to date and relevant. For example, to ensure that medical records are complete, any other medical opinions submitted by the data subject must also be kept in the file. Particular attention should be given to supporting documents relating to assistance for disabled people, family allowances which are prolonged in specific cases and the Invalidity Committee procedure, in particular as regards updating of data. The same applies to family leave, which may be prolonged up to a maximum of nine months.

Some officials in the various administrative units (Welfare Office, Appointing Authority, Leave Department) have access to certain data relating solely to entitlement to payment of specific allowances and can thus preserve the quality of the information. Furthermore, the persons responsible for administrative follow-up of medical files by means of electronic files will have an essential role to play in updating administrative information relating to the data subject and in compiling and updating the medical file itself.

In this instance, Article 4(1)(d) of the Regulation is duly complied with. The data subject is made aware of his or her rights to access and rectify data in order to ensure that the file remains as comprehensive as possible. These rights are the second means of ensuring data quality. They are discussed in section 3.9 below.

Furthermore, the data must be *processed fairly and lawfully* (Article 4(1)(a) of Regulation (EC) No 45/2001). The matter of lawfulness has been reviewed above. Given the sensitivity of the subject, fairness warrants considerable attention. It is linked to the information to be given to the data subject (see section 3.10 below).

3.5. Data retention

Article 4(1)(e) of Regulation (EC) No 45/2001 lays down the principle that data must be "kept in a

³ Certain national legislative systems make a distinction between the two.

form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed".

Medical file

As has been pointed out, in the case in point personal data are kept for 30 years after the data subjects have left the service; three specific cases are mentioned in section 2.5 above. Files are archived when data subjects leave the service. They are never destroyed. There are plans to digitise medical files. Storage for historical, statistical or scientific purposes has been excluded.

All medical certificates, supporting medical reports and opinions of the medical officer are added to the data subject's medical file. Some opinions are inserted in the personal file.

We must therefore consider to what extent and for what purposes it is necessary to keep, throughout an official's career, the contents of a medical file which includes data such as the results of medical examinations and medical certificates.

The EDPS acknowledges the significance of keeping the data, even after the death or retirement of the data subject, for those data can in certain cases contribute to the discovery of information relating to the cause of death or illness (exposure to asbestos, for instance). However, it would appear, in the light of Regulation (EC) No 45/2001 that the institution must set a time-limit (which is still being discussed by the institutions). Under the principles governing data protection, data should be kept only for as long as the official or his or her heirs have rights which must be safeguarded.

There is also the question of the storage of results of medical examinations performed on candidates who, after having undergone the medical examination, have not been recruited, be it for medical or other reasons. Data relating to these candidates which are obtained in the context of the medical examination provided for under Article 33 of the Staff Regulations should not be kept indefinitely. The EDPS considers that such data should be kept for only a certain period of time; this could be the same length of time as that during which the data, or a decision taken on the basis of such data, can be contested

Long-term retention of data must be accompanied by appropriate safeguards. The data that are being kept are sensitive. The fact that they are archived for long-term retention does not make them any less sensitive. Accordingly, even where long-term retention is concerned, appropriate transmission and storage measures must be applied when handling those data, as is the case for all sensitive information.

Clinic daybook

Daybooks are kept for 15 years. The EDPS considers that the time-limit for storing such data appears to exceed what is needed for the purposes of establishing a daily register of medical diagnoses and of care and treatment administered at the dispensaries. Accordingly, the EDPS feels a reasonable time-limit should be set, for example 10 years.

The EDPS recommends that a reasonable time-limit for storing daybooks should be set – e.g. 10 years – which should be proportionate to the purposes for which the data have been collected.

3.6. Change of purpose/Compatible use

Data are retrieved from or entered into the staff databases. The processing operation being reviewed involves no general change of the specified purpose of staff databases and is not incompatible with

that purpose. Accordingly, Article 6(1) of Regulation (EC) No 45/2001 does not apply in this instance and the conditions of Article 4(1)(b) of the Regulation are fulfilled.

3.7. Transfer of data

The processing operation should also be scrutinised in the light of Article 7(1) of Regulation (EC) No 45/2001. The processing covered by Article 7(1) is the transfer of personal data within or to other Community institutions or bodies "if the data are necessary for the legitimate performance of tasks covered by the competence of the recipient".

The case in point concerns transfers within the same institution (to the Appointing Authority, Welfare Office, Leave Department and Salaries Department, or from the dispensary daybook). It also concerns transfers between institutions since the personal data are transferred not only to the Invalidity Committee, which is the ad hoc committee provided for by the Staff Regulations of Officials of the European Communities, but also to the other Community institutions and bodies in the event of a change or transfer of post.

Care should therefore be taken to ensure that the conditions of Article 7(1) are fulfilled; that is the case since the data collected are necessary for carrying out the processing and, furthermore, are "necessary for the legitimate performance of tasks covered by the competence of the recipient". In this case, the task is the responsibility of the various departments of the Council, the Invalidity Committee and the other institutions. As regards transfers, only relevant data must be transferred. Such transfers are therefore indeed lawful insofar as the purpose is covered by the competences of the recipients. Article 7(1) is therefore duly complied with.

Article 7(3) of Regulation (EC) No 45/2001 provides that "the recipient shall process the personal data only for the purposes for which they were transmitted". There should be explicit assurance that any member of the Council's Medical Department receiving and processing data may not use them for other purposes. Accordingly, the EDPS recommends that, in the case in point, the Council should specify that the persons responsible for processing Clinic daybooks may not use those data for any other purpose.

Furthermore, data may be transferred to external doctors appointed by the data subject. If these doctors are nationals of countries whose national law was adopted pursuant to Directive 95/46/EC, the processing will come under Article 8 of Regulation (EC) No 45/2001 as regards the transfer of data. The transfer is covered by Article 8(b), which stipulates that data may be transferred if "the recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subject's legitimate interests might be prejudiced".

If health-related data are transferred to third parties other than the Medical Department, compliance with Article 10 must also be ensured. Medical files may also be transferred to external doctors appointed by the data subject, or to other Community institutions or bodies in the event of a change or transfer of post. As the data are transferred to comply with labour-law obligations arising from the Staff Regulations, Article 10(2) of the Regulation is fully complied with. As regards the last hypothesis (other institutions), however, it would seem necessary to specify that the data should be transmitted only to persons authorised to have access to them – i.e. persons who are subject to professional secrecy.

The EDPS recommends that, in the context of transfers to other institutions, only persons authorised to have access to data relating to health, and who are subject to professional secrecy, receive medical files.

Lastly, transfers to recipients who do not come within the scope of 95/46/EC (if the external doctors are citizens of a country with national legislation not based on Directive 95/46/EC) need to be examined in the light of Article 9 of Regulation 45/2001. Article 9 states: "personal data shall only be transferred to recipients, other than Community institutions and bodies, which are not subject to national law adopted pursuant to Directive 95/46/EC, if an adequate level of protection is ensured in the country of the recipient or within the recipient international organisation and the data are transferred solely to allow tasks covered by the competence of the controller to be carried out."

If the country of the recipient does not ensure an adequate level of protection, the exceptions provided for in Article 9(6) and (7) may apply. In the case under examination, Article 9(6)(a) and (e) would be particularly relevant: "By way of derogation from paragraphs 1 and 2, the Community institution or body may transfer personal data if: (a) the data subject has given his or her consent unambiguously to the proposed transfer; or (...) (e) the transfer is necessary in order to protect the vital interests of the data subject; or (...)."

3.8. Processing including the personal or identifying number

The Council very probably uses the personal number in the context of social medicine (family leave, aid for the disabled, family allowances) and in procedures involving the Invalidity Committee. While the use of an identifier is, in itself, no more than a means (and a legitimate one in this case) of facilitating the task of the personal data controller, its effects may nevertheless be significant. This was why the European legislator decided to regulate the use of identifying numbers under Article 10(6) of the Regulation, which makes provision for action by the European Data Protection Supervisor. In the case in point, use of the personnel number may allow the linkage of data processed in different contexts. Here, it is not a case of establishing the conditions under which the Council may process the personal number, but rather of drawing attention to this point in the Regulation. In this instance, the Council's use of the personal number is reasonable because it is a means of facilitating the processing of data, in particular in social medicine procedures.

3.9 Right of access and rectification

Article 13 of Regulation (EC) No 45/2001 establishes a right of access – and the arrangements for exercising it – upon request by the data subject. Under Article 13 of the Regulation, the data subject has the right to obtain, without constraint, from the controller, communication in an intelligible form of the data undergoing processing and any available information as to its source.

Article 20 of the Regulation provides for certain restrictions on this right, notably where such a restriction constitutes a necessary measure to safeguard the protection of the data subject or the rights and freedoms of others.

Rectification, blocking, erasure and objection rights are dealt with in Section 5 of the Council Decision of 13 September 2004 adopting implementing rules concerning Regulation (EC) No 45/2001 of the European Parliament and of the Council 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. Section 5 of that document sets out the procedures for enabling data subjects to exercise their rights.

The EDPS wishes to draw attention to the fact that the rule provided for in the Regulation is intended to enable the data subject to have access to his personal data. Accordingly, this right may not be subject to limitations, except under strict conditions.

With regard to point 2 of Staff Note No 31/04 of 19 March 2004, supplementing Article 26a of the Staff Regulations on access to medical files, the limitation on access to psychiatric/psychological

reports arising from the fact that the right of access must be exercised "through the intermediary of a doctor" confers on the latter the right not to communicate certain information to the data subject. However, the EDPS would emphasise that any limitation on the right of access must be based on Article 20(1)(c) of the Regulation. It must aim to protect the data subject.

In relation to point 3 of that Communication (personal notes by the doctor), the limitation based on the "rights and freedoms of others" ("others" cannot mean the controller) refers to the fact that the rights and freedoms of an identified third party take precedence over the right of access of the data subject to the information. The EDPS welcomes the fact that this is subject to examination on a case-by-case basis in accordance with the principle of proportionality. The above limitation must not be allowed to result in a general refusal of access to the personal notes of doctors in the medical file.

Article 14 of Regulation (EC) No 45/2001 allows the data subject the right of rectification. In addition to being given access to their personal data, data subjects may also have the data amended if necessary. This right is somewhat limited as regards medical data, in that it is difficult to guarantee the accuracy or completeness of medical data. It may, however, apply to other types of data contained in medical files (administrative data, for example). Furthermore, as mentioned above (under section 3.4 "Quality of data"), the data subject may request that his medical file be complete in the sense that he may request that information such as counter opinions by another doctor or a Council decision on an element of the medical file be placed in his file so as to ensure it contains upto-date information.

With regard to the dispensary register, the data subject does not have the right of access to the daybooks, but rather is entitled to request a certificate – a reasonable solution designed to protect the right of other persons on the list. The right of rectification in this case is limited, since the personal data are data resulting from an assessment of the data subject's state of health at the time the medical care and treatment are given. Accordingly, the consultation form is added to the medical file.

3.10 Information to be given to the data subject

Regulation (EC) No 45/2001 provides that the data subject must be informed where his or her personal data are processed and lists a series of specific items of information that must be provided. In the present case, some of the data are collected directly from the data subject and other data from other persons.

Article 11 (*Information to be supplied where the data have been obtained from the data subject*) on the information to be given to the data subject applies in this case insofar as officials themselves provide the information during medical visits or by means of the certificates to be submitted in the context of the different social medicine procedures.

The provisions of Article 12 (*Information to be supplied where the data have not been obtained from the data subject*) on information to be given to the data subject also apply in this case because information is obtained from the various parties involved in the process (external doctors, Invalidity Committee).

As mentioned above, information is communicated to data subjects in accordance with Article 26a of the Staff Regulations of Officials of the European Communities. Implementation of that article of the Staff Regulations is complemented by Staff Note No 31/04 of 19 March 2004, which sets out the principles already mentioned in section 3.9 above. Furthermore, the different procedures relating to family leave, special leave, aid for the disabled, family allowances, etc. are described in Staff Notes sent out to all Council staff.

For the fairness of the processing to be fully compliant, Articles 11(f) and 12(f) should also be mentioned. It refers to the following points: *legal basis of the processing operation, time-limits for storing the data, the right to have recourse at any time to the European Data Protection Supervisor.*

As regards the medical examination on recruitment, information is collected initially from the data subject during the medical examination prior to entry into service. The data subject should be provided with adequate information on that occasion, at any rate concerning the processing of medical data relating to the medical examination.

As regards information on the purpose of the data processing, pursuant to Article 1 of Annex VIII to the Staff Regulations and Article 32 of the Conditions of Employment of other servants, where the medical examination carried out before an official takes up his duties shows that he is suffering from sickness or invalidity, the Appointing Authority, insofar as risks arising from such sickness of invalidity are concerned, may decide to admit that official to guaranteed benefits in respect of invalidity or death only after a period of five years. Given that the official or servant does not have that information at the time of the pre-recruitment medical examination, it should be provided to him when data are collected.

The data subject should also be informed of the potential recipients of the data.

The medical questionnaire should moreover stipulate whether the replies to the questions are obligatory or voluntary, and what the possible consequences of not replying are. The data subject should also be informed of the data-retention period. The data subject should be expressly informed that there is no specific data-retention period.

Candidates are also required to take blood tests. However, the questionnaire does not give any information on the types of analysis performed or on their purpose. New staff members should be informed of the right of access to the results of analyses and the right to rectify data concerning them.

As regards the processing of data subsequent to the pre-recruitment medical examination, the Council considers that, in principle, no additional information needs to be supplied, since provision for the information is made in the Staff Regulations. The EDPS considers that this information should also appear in the questionnaire on medical fitness and should be the subject of a staff note.

Finally, all the information specified in Articles 11(f) and 12(f) must be notified to the data subjects.

The same considerations apply to the annual medical examination. With respect to the additional examinations requested by the Medical Department, staff must be notified of their right of access to and right to rectify the data concerning them. Finally, this same information must be notified in the supporting documentation relating to the different social medicine procedures and the Invalidity Committee procedure already referred to.

In the case of treatment at the dispensary, all the information contained in Articles 11 and 12 of Regulation (EC) 45/2001 must be furnished by the Council Medical Department in order to enable the data subject to exercise his or her rights.

Security measures

In accordance with Article 22 of Regulation (EC) No 45/2001 on the security of processing, the controller implements "appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to

be protected".

The entire procedure is confidential. Appropriate security measures are provided for with respect to consultation of the file by the data subject and retention of such files or with respect to guaranteeing the confidentiality of communications when information is transferred to and from the Medical Department. Article 22 of the Regulation is therefore duly complied with.

Conclusion:

The proposed processing does not appear to involve any infringement of the provisions of Regulation (EC) No 45/2001 provided that the comments made above are taken into account. This implies, in particular, that the Council should:

- remind all the administrative departments responsible, within the framework of social medicine, for processing files containing certificates issued by medical staff of their obligation of professional secrecy;
- take steps to ensure that all data placed in the medical files comply with the principle of data quality. This could take the form of a general recommendation to the persons handling the files asking them to ensure that this rule is observed;
- take great care during processing to ensure that non-authorised persons are not sent or given access to purely medical data;
- assess the data in the questionnaire on medical fitness in the light of data protection principles; bear in mind that only data which are relevant in terms of medical fitness to carry out his duties may be requested from the candidate;
- consider whether requiring that the diagnosis be included with the medical certificate in the procedure relating to serious illness of a spouse or relative in the ascending line might not be excessive and whether a detailed medical report would not be sufficient;
- delete the data contained in the prescriptions table relating to the purpose of the prescriptions;
- examine, in the context of annual medical check-ups carried out by a medical practitioner chosen by the official (Article 59(6) of the Staff Regulations), whether it is necessary for the Medical Department to receive the medical report and copies of complementary examinations performed;
- take all reasonable measures to ensure that data is up to date and relevant;
- establish a specific period for keeping data after the death or retirement of the data subject;
- retain for only a certain period of time the data on candidates not ultimately recruited (this could be the period during which the data or a decision taken on the basis of such data, can be contested);
- establish, in the case of long-term retention, appropriate data transmission and storage measures, as for all sensitive information;
- set a reasonable time-limit for storing daybooks, i.e. 10 years, which should be proportionate to the purposes for which the data have been collected;

- specify that the persons responsible for processing may not use the related data for any other purpose;
- in the context of transfers to other institutions, only persons authorised to have access to data relating to health, and who are subject to professional secrecy, should receive medical files;
- provide the data subject with adequate information, at the very least concerning the processing of medical data relating to the medical examination, on the occasion of the pre-recruitment medical check-up;
- inform the official or agent, at the pre-recruitment medical examination, of the purpose of the data processing, and in particular of Article 1 of Annexe VIII to the Staff Regulations and Article 32 of the Conditions of Employment of other servants;
- inform the data subject of the potential recipients of the data;
- stipulate in the medical questionnaire whether the replies to the questions are obligatory or voluntary, and what the possible consequences of not replying are;
- inform the data subject of the data-retention period and expressly inform the data subject that there is no specific data-retention period in this case;
- inform new staff members of their right of access to and right to rectify data concerning them in the case of blood tests;
- mention, in the questionnaire on medical fitness and in a specific decision communicated to staff, the processing of data after the medical examination;
- notify the data subjects of all the information specified in Articles 11(f) and 12(f) of Regulation (EC) No 45/2001;
- with respect the additional examinations requested by the Medical Department as part of the annual medical check-up, inform staff of their right of access to and right to rectify the data concerning them;
- mention the information concerning the recipients of the data, the existence of a right of
 access and rectification and the information referred to in Articles 11(f) and 12(f) of
 Regulation (EC) No 45/2001, in the supporting documentation relating to the different social
 medicine procedures and the Invalidity Committee procedure;
- via the Medical Department provide data subjects with all the information contained in Articles 11 and 12 of Regulation (EC) No 45/2001, through an internal note or statement which specifically mentions the processing operation in question, in order to enable the data subject to exercise his or her rights.

Done at Brussels, 29 May 2006

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