8.6.2. *Overview of the study protocols for efficacy follow-up*

It is recommended to use the table below to keep consistency with the format of the tables used for safety follow-up in the Pharmacovigilance plan.

Study	Protocol version	Protocol status	Planned date for submission of interim data	Planned date for submission of final data

8.6.3. *Detailed protocols of the efficacy follow-up studies*

All the protocols listed in the overview table above should be included. When protocols are not ready at the time of submission, at least their drafts (outlines) should be incorporated.

In addition to the points listed in 6.2 and 6.3 above, the following should be taken into account when drafting the protocol of post-authorisation efficacy studies:

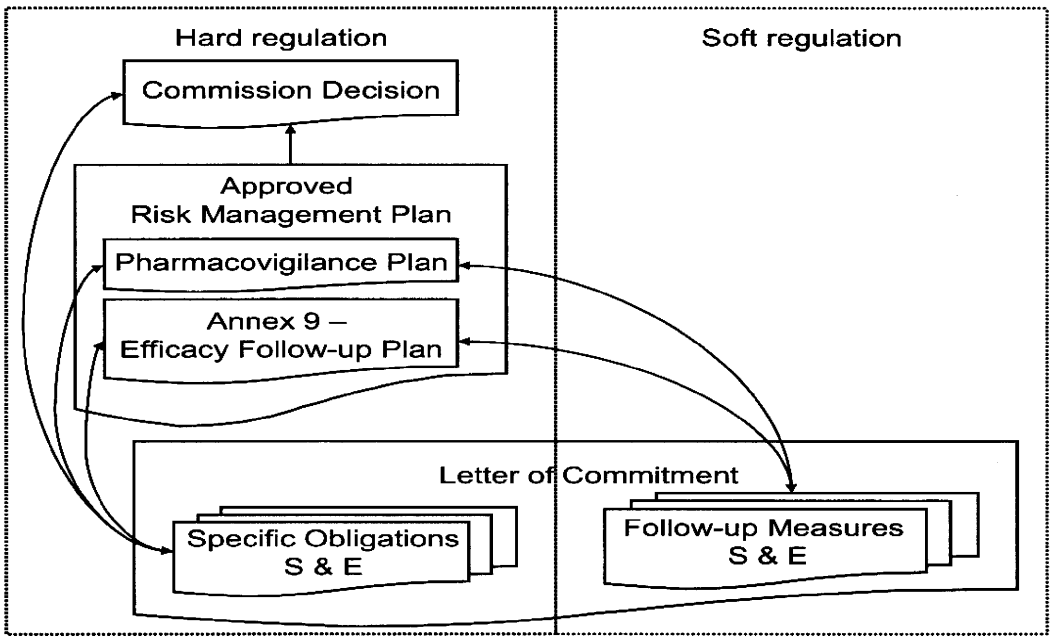
- Existing guidelines on efficacy studies should be followed when applicable.
- Design of any post-authorisation observational study should build on existing or recommended clinical follow-up of patients.
- Wider spectrum of endpoint(s) should be considered reflecting real life effectiveness (clinical monitoring, laboratory monitoring, and biomarkers). Surrogates should not be used unless necessary.
- Reasons for drop outs, and cases of re-administration or re-initiation of therapy should be of particular interest for efficacy follow-up.
- Long-term efficacy (observational) studies should normally be of comparative design. The choice of comparator or lack thereof should be justified. It is acknowledged that changes in the standard of care over time may influence the conduct of such studies. This should be discussed with regulators on regular basis as part of relevant reports (e.g. in PSUR, Annual Safety Reports, updates of the EU-RMP).

9. USE OF REGULATORY TOOLS IN POST-AUTHORISASTION SURVEILLANCE OF THE ADVANCED THERAPY MEDICINAL PRODUCTS

There are number of tools available for management of various post-authorisation commitments for products authorised via centralised procedure. These include letters of commitments; follow-up measures; conditional approvals or approvals under exceptional circumstances with specific obligations and their annual re-assessments; and there are number of reporting obligations too (expedited and periodic reports, EU-RMP updates, various special reports requested by regulators, sunset clause reporting etc.)

Use of these tools is covered by common rules for medicinal products. All of these tools have their appropriate use and their effective combination should ensure high quality post-authorisation benefit-risk management of the product. Both regulators and marketing authorisation holders should ensure consistency in use of these various tools. This consistency between soft and hard (legally enforceable) regulation in the area of post-authorisation surveillance may be illustrated by the following figure:

630 **Figure 3 Illustration of the need for consistency in (parallel) use of various tools in the post-authorisation**
631 **surveillance of ATMPs.**



632

633 # 10. ELECTRONIC EXCHANGE OF PHARMACOVIGILANCE
634 # INFORMATION

635 It is recognised that the length of some data fields set up by the ICH E2B (M) for Individual Case
636 Safety Report, and consequently length of some fields in the EudraVigilance Medicinal Product
637 Dictionary (EVMPD) might not be sufficient for the needs of Advanced Therapy Medicinal Products.
638 At the same time, a need for additional fields needs to be considered. The EMEA will address this
639 issue with EudraVigilance system stakeholders and keep the users informed via the EudraVigilance
640 website.

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 January 2003

setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4], in the light of the joint text approved by the Conciliation Committee on 4 November 2002,

Whereas:

(1) The extent to which human blood is used therapeutically demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of diseases.

(2) The availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate. In order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents.

(3) The quality, safety, and efficacy requirements of proprietary industrially-prepared medicinal products derived from human blood or plasma were ensured through Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [5]. The specific exclusion of whole blood, plasma and blood cells of human origin from that Directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. It is essential, therefore, that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components which are derived from donations in another Member State nonetheless meet the same requirements as those in their own country.

(4) In respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, Directive 2001/83/EC refers to measures to be taken by Member States to prevent the transmission of infectious diseases, comprising the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organisation (WHO) as regards in particular the selection and testing of blood and plasma donors. Furthermore, Member States should take measures to promote Community self-sufficiency in human blood or blood components and to encourage voluntary unpaid donations of blood and blood components.

(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive. Directive 2001/83/EC should be amended accordingly.

(6) The Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency.

(7) In its Resolution of 2 June 1995, on blood safety and self-sufficiency in the Community [6], the Council invited the Commission to submit appropriate proposals in the framework of the development of a blood strategy.

[1] OJ C 154 E, 29.5.2001, p. 141 and OJ C 75 E, 26.3.2002, p. 104.
[2] OJ C 221, 7.8.2001, p. 106.
[3] OJ C 19, 22.1.2002, p. 6.
[4] Opinion of the European Parliament of 6 September 2001 (OJ C 72 E, 21.3.2002, p. 289), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European Parliament of 12 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.
[5] OJ L 311, 28.11.2001, p. 67.
[6] OJ C 164, 30.6.1995, p. 1.

(8) In its Resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community [1], the Council invited the Commission to submit proposals as a matter of urgency with a view to encouraging the development of a coordinated approach to the safety of blood and blood products.

(9) In its Resolutions of 14 September 1993 [2], 18 November 1993 [3], 14 July 1995 [4], and 17 April 1996 [5] on blood safety and self-sufficiency through voluntary unpaid donations in the European Community, the European Parliament stressed the importance of ensuring the highest level of blood safety and has reiterated its continued support for the objective of Community self-sufficiency.

(10) In elaborating the provisions of this Directive account has been taken of the opinion of the Scientific Committee for Medicinal Products and Medical Devices as well as international experience in this field.

(11) The nature of autologous transfusion necessitates a specific consideration in respect of how and when to apply the different provisions of this Directive.

(12) Hospital blood banks are hospital units which perform a limited number of activities, storage, distribution, and compatibility tests. In order to ensure that the quality and safety of blood and blood components are preserved during the whole transfusion chain, while taking account of the specific nature and functions of hospital blood banks, only provisions relevant to these activities should apply to hospital blood banks.

(13) Member States should ensure that an appropriate mechanism for designating, authorising, accrediting or licensing exists to ensure that the activities of blood establishments are performed in accordance with the requirements of this Directive.

(14) Member States should organise inspection and control measures, to be carried out by officials representing the competent authority, to ensure the compliance of the blood establishment with the provisions of this Directive.

(15) Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be appropriately qualified and provided with timely and relevant training, without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers.

(16) Blood establishments should establish and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system, taking into account the principles of good manufacturing practice as well as the EC conformity assessment system.

(17) An adequate system to ensure traceability of whole blood and blood components should be established. Traceability should be enforced through accurate donor, patient, and laboratory identification procedures, through record maintenance, and through an appropriate identification and labelling system. It is desirable that a system is developed in order to enable the unique and unmistakable identification of donations of blood and blood components in the Community. In the case of blood and blood components imported from third countries, it is important that an equivalent level of traceability be ensured by the blood establishments in the stages preceding importation into the Community. The same requirements of traceability which apply to blood and blood components collected in the Community should be ensured in the stages following importation.

(18) It is important to introduce a set of organised surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions resulting from the collection of blood or blood components in order to prevent similar or equivalent events or reactions from occurring thereby improving the security of transfusion by adequate measures. To this end a common system of notification of serious adverse events and reactions linked to the collection, processing, testing, storage, and distribution of blood and blood components should be established in Member States.

(19) It is important that when abnormal findings are reported to the donor, relevant counselling is also provided.

(20) Modern blood-transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services.

(21) All necessary measures need to be taken in order to provide prospective donors of blood or blood components with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of the tests on their donations as well as any future traceability of their donation.

[1] OJ C 374, 11.12.1996, p. 1.
[2] OJ C 268, 4.10.1993, p. 29.
[3] OJ C 329, 6.12.1993, p. 268.
[4] OJ C 249, 25.9.1995, p. 231.
[5] OJ C 141, 13.5.1996, p. 131.

(22) According to Article 152(5) of the Treaty, the provisions of this Directive cannot affect national provisions on the donations of blood. Article 152(4)(a) of the Treaty states that Member States cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components.

(23) Voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health. The efforts of the Council of Europe in this area should be supported and all necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account.

(24) Blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised; each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of individuals who are the recipients of blood and blood components.

(25) Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data [1] requires that data related to the health of an individual be subject to reinforced protection. However, it covers only personal data and not that rendered anonymous. This Directive should therefore introduce additional safeguards to prevent any unauthorised changes to donation registries, or processing records, or the unauthorised disclosure of information.

(26) The Commission should be empowered to establish technical requirements and adopt any necessary changes thereto and to the Annexes in order to take into account scientific and technical progress.

(27) Setting of technical requirements and adaptation to progress should take into account the Council recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the EC [2], relevant recommendations of the Council of Europe and the WHO as well as indications of relevant European institutions and organisations such as the monographs of the European Pharmacopoeia.

(28) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of blood and blood components, in particular as regards adapting the provisions of this Directive to scientific and technical progress.

(29) Tests should be carried out in conformity with the latest scientific and technical procedures that reflect current best practice as defined by, and regularly reviewed and updated through, an appropriate expert consultation process. This review process should also take due account of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion.

(30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(31) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States.

(32) Since the objectives of this Directive, namely to contribute to general confidence both in the quality of donated blood and blood components and in the health protection of donors, to attain self-sufficiency at a Community level and to enhance confidence in the safety of the transfusion chain among the Member States, cannot be sufficiently achieved by the Member States and can therefore by reason of its scale and effects be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

(33) Responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Objectives

This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 184, 17.7.1999, p. 23.

Article 2

Scope

1. This Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.

2. Where blood and blood components are collected and tested for the sole purpose and exclusive use in autologous transfusion and are clearly identified as such, the requirements to be complied with in respect thereof shall be in accordance with those referred to in Article 29(g).

3. This Directive shall apply without prejudice to Directives 93/42/EEC [1], 95/46/EC or 98/79/EC [2].

4. This Directive does not apply to blood stem cells.

Article 3

Definitions

For the purposes of this Directive:

(a) 'blood' shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing;

(b) 'blood component' shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

(c) 'blood product' shall mean any therapeutic product derived from human blood or plasma;

(d) 'autologous transfusion' shall mean transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

(e) 'blood establishment' shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks;

(f) 'hospital blood bank' shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

(g) 'serious adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

(h) 'serious adverse reaction' shall mean an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

(i) 'blood component release' shall mean a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

(j) 'deferral' shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary;

(k) 'distribution' shall mean the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.

(l) 'haemovigilance' shall mean a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

(m) 'inspection' shall mean formal and objective control according to adopted standards to assess compliance with this Directive and other relevant legislation and to identify problems.

Article 4

Implementation

1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

2. This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.

3. In carrying out the activities covered by this Directive the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Directive as last amended by Directive 2001/104/EC of the European Parliament and of the Council (OJ L 6, 10.1.2002, p. 50).

[2] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

CHAPTER II

OBLIGATIONS ON MEMBER STATES AUTHORITIES

Article 5

Designation, authorisation, accreditation or licensing of blood establishments

1. Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.

2. For the purpose of paragraph 1, the blood establishment shall submit the information listed in Annex I to the competent authority.

3. The competent authority, having verified whether the blood establishment complies with the requirements set out in this Directive, shall indicate to the blood establishment which activities it may undertake and which conditions apply.

4. No substantial change in activities shall be undertaken by the blood establishment without prior written approval by the competent authority.

5. The competent authority may suspend or revoke the designation, authorisation, accreditation or licence of a blood establishment if inspection or control measures demonstrate that the blood establishment does not comply with the requirements of this Directive.

Article 6

Hospital blood banks

Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 shall apply to hospital blood banks.

Article 7

Provisions for existing establishments

Member States may decide to maintain national provisions for nine months after the date laid down in Article 32 so as to enable blood establishments operating under their legislation to comply with the requirements of this Directive.

Article 8

Inspection and control measures

1. Member States shall ensure that the competent authority organise inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with.

2. Inspection and control measures shall be organised by the competent authority on a regular basis. The interval between two inspections and control measures shall not exceed two years.

3. Such inspection and control measures shall be carried out by officials representing the competent authority who must be empowered to:

(a) inspect blood establishments as well as facilities of any third parties on its own territory entrusted by the holder of the designation, authorisation, accreditation or licence referred to in Article 5 with the task of carrying out evaluation and testing procedures pursuant to Article 18;

(b) take samples for examination and analysis;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States at the time of the entry into force of this Directive and which place restrictions on these powers with regard to the descriptions of the method of preparation.

4. The competent authority shall organise inspection and other control measures as appropriate in the event of any serious adverse event or reaction or suspicion thereof in accordance with Article 15.

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

Article 9

Responsible person

1. Blood establishments shall designate a person (responsible person), responsible for:

— ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,

— providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,

— the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

2. The responsible person shall fulfil the following minimum conditions of qualification:

(a) he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

(b) he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution.

3. The tasks specified in paragraph 1 may be delegated to other persons who shall be qualified by training and experience to perform such tasks.

4. Blood establishments shall notify the competent authority of the name of the responsible person referred to in paragraph 1 and other persons referred to in paragraph 3 together with information on the specific tasks for which they are responsible.

5. Where the responsible person or such other persons referred to in paragraph 3 are permanently or temporarily replaced, the blood establishment shall provide immediately the name of the new responsible person and his or her date of commencement to the competent authority.

Article 10

Personnel

Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.

CHAPTER IV

QUALITY MANAGEMENT

Article 11

Quality system for blood establishments

1. Member States shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice.

2. The Commission shall establish the Community standards and specifications referred to in Article 29(h) for the activities relating to a quality system to be carried out by a blood establishment.

Article 12

Documentation

1. Member States shall take all necessary measures in order to ensure that blood establishments maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms.

2. Member States shall take all necessary measures in order to ensure that access is provided to these documents for officials entrusted with inspection and control measures referred to in Article 8.

Article 13

Record keeping

1. Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d). The records shall be kept for a minimum of 15 years.

2. The competent authority shall keep records of the data received from the blood establishments according to Articles 5, 7, 8, 9 and 15.

CHAPTER V

HAEMOVIGILANCE

Article 14

Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a).

With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

Article 15

Notification of serious adverse events and reactions

1. Member States shall ensure that:

— any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority,

— blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

2. These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in Article 29(i).

CHAPTER VI

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

Article 16

Provision of information to prospective donors

Member States shall ensure that all prospective donors of blood or blood components in the Community are provided with information referred to in Article 29(b).

Article 17

Information required from donors

Member States shall take all necessary measures to ensure that, upon agreement of a willingness to commence the donation of blood or blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment.

Article 18

Eligibility of donors

1. Blood establishments shall ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met.

2. The results of the donor evaluation and testing procedures shall be documented and any relevant abnormal findings shall be reported to the donor.

Article 19

Examination of donors

An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.

Article 20

Voluntary and unpaid blood donation

1. Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.

2. Member States shall submit reports to the Commission on these measures two years after the entry into force of this Directive, and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measure it intends to take at Community level.

Article 21

Testing of donations

Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV.

Member States shall ensure that blood and blood components imported into the Community are tested in conformity with requirements listed in Annex IV.

Article 22

Storage, transport and distribution conditions

Blood establishments shall ensure that the storage, transport and distribution conditions of blood and blood components comply with the requirements referred to in Article 29(e).

Article 23

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that quality and safety requirements for blood and blood components meet the high standards in compliance with the requirements referred to in Article 29(f).

CHAPTER VII

DATA PROTECTION

Article 24

Data protection and confidentiality

Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive to which third parties have access have been rendered anonymous so that the donor is no longer identifiable.

For that purpose, they shall ensure:

(a) that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) that procedures are in place to resolve data discrepancies;

(c) that no unauthorised disclosure of such information occurs, whilst guaranteeing the traceability of donations.

CHAPTER VIII

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 25

Information exchange

The Commission shall hold regular meetings with the competent authorities designated by the Member States, delegations of experts from blood establishments and other relevant parties to exchange information on the experience acquired with regard to the implementation of this Directive.

Article 26

Reports

1. Member States shall send to the Commission, commencing on 31 December 2003 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

2. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, the reports submitted by the Member States on the experience gained in implementing this Directive.

3. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, commencing on 1 July 2004 and every three years thereafter, a report on the implementation of the requirements in this Directive, and in particular those relating to inspection and control.

Article 27

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. Member States shall notify those provisions to the Commission by the date specified in Article 32 at the latest and shall notify it without delay of any subsequent amendments affecting them.

CHAPTER IX

COMMITTEES

Article 28

Regulatory procedure

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 29

Technical requirements and their adaptation to technical and scientific progress

The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2).

The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):

(a) traceability requirements;

(b) information to be provided to donors;

(c) information to be obtained from donors including the identification, health history, and the signature of the donor;

(d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including

— permanent deferral criteria and possible exemption thereto

— temporary deferral criteria;

(e) storage, transport and distribution requirements;

(f) quality and safety requirements for blood and blood components;

(g) requirements applicable to autologous transfusions;

(h) Community standards and specifications relating to a quality system for blood establishments;

(i) Community procedure for notifying serious adverse reactions and events and notification format.

Article 30

Consultation of scientific committee(s)

The Commission may consult the relevant scientific committee(s) when establishing the technical requirements referred to in Article 29 and when adapting the technical requirements set out in Annexes I to IV to scientific and technical progress, in particular with a view to ensuring an equivalent level of quality and safety of blood and blood components used for transfusion and blood and blood components used as a starting material for the manufacture of medicinal products.

CHAPTER X

FINAL PROVISIONS

Article 31

Amendment of Directive 2001/83/EC

Article 109 of Directive 2001/83/EC shall be replaced by the following:

'*Article 109*

For the collection and testing of human blood and human plasma, Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (*) shall apply.

(*) OJ L 33, 8.2.2003, p. 30.'

Article 32

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 8 February 2005. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 33

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 34

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 27 January 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	G. DRYS

ANNEX I

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING IN ACCORDANCE WITH ARTICLE 5(2)

Part A: General information:

— identification of the blood establishment

— name, qualification and contact details of responsible persons

— a list of hospital blood banks which it supplies.

Part B: A description of the quality system, to include:

— documentation, such as an organisation chart, including responsibilities of responsible persons and reporting relationships

— documentation such as site master file or quality manual describing the quality system in accordance with Article 11(1)

— number and qualifications of personnel

— hygiene provisions

— premises and equipment

— list of standard operating procedures for recruitment, retention and assessment of donors, for processing and testing, distribution and recall of blood and blood components and for the reporting and recording of serious adverse reactions and events.

ANNEX II

REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

This annual report will include:

— total number of donors who give blood and blood components

— total number of donations

— an updated list of the hospital blood banks which it supplies

— total number of whole donations not used

— number of each component produced and distributed

— incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components

— number of product recalls

— number of serious adverse events and reactions reported.

ANNEX III

LABELLING REQUIREMENTS

The label on the component must contain the following information:

— the official name of the component

— the volume or weight or number of cells in the component (as appropriate)

— the unique numeric or alphanumeric donation identification

— the name of producing blood establishment

— the ABO Group (not required for plasma intended only for fractionation)

— the Rh D Group, either Rh D positive or Rh D negative (not required for plasma intended only for fractionation)

— the date or time of expiry (as appropriate)

— the temperature of storage

— the name, composition and volume of anticoagulant and/or additive solution (if any).

ANNEX IV

BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and apheresis donations, including autologous predeposit donations:

— ABO Group (not required for plasma intended only for fractionation)

— Rh D Group (not required for plasma intended only for fractionation)

— testing for the following infections in the donors:

  — Hepatitis B (HBs-Ag)

  — Hepatitis C (Anti-HCV)

  — HIV 1/2 (Anti-HIV 1/2)

Additional tests may be required for specific components or donors or epidemiological situations.

►B 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

(OJ L 281, 23.11.1995, p. 31)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003

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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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure referred to in Article 189b of the Treaty (3),

(1) Whereas the objectives of the Community, as laid down in the Treaty, as amended by the Treaty on European Union, include creating an ever closer union among the peoples of Europe, fostering closer relations between the States belonging to the Community, ensuring economic and social progress by common action to eliminate the barriers which divide Europe, encouraging the constant improvement of the living conditions of its peoples, preserving and strengthening peace and liberty and promoting democracy on the basis of the fundamental rights recognized in the constitution and laws of the Member States and in the European Convention for the Protection of Human Rights and Fundamental Freedoms;

(2) Whereas data-processing systems are designed to serve man; whereas they must, whatever the nationality or residence of natural persons, respect their fundamental rights and freedoms, notably the right to privacy, and contribute to economic and social progress, trade expansion and the well-being of individuals;

(3) Whereas the establishment and functioning of an internal market in which, in accordance with Article 7a of the Treaty, the free movement of goods, persons, services and capital is ensured require not only that personal data should be able to flow freely from one Member State to another, but also that the fundamental rights of individuals should be safeguarded;

(4) Whereas increasingly frequent recourse is being had in the Community to the processing of personal data in the various spheres of economic and social activity; whereas the progress made in information technology is making the processing and exchange of such data considerably easier;

(5) Whereas the economic and social integration resulting from the establishment and functioning of the internal market within the meaning of Article 7a of the Treaty will necessarily lead to a substantial increase in cross-border flows of personal data between all those involved in a private or public capacity in economic and social activity in the Member States; whereas the exchange of personal data between undertakings in different Member States is set to increase; whereas the national authorities in the various Member States are being called upon by virtue of Community law to collaborate and exchange personal data so as

(1) OJ No C 277, 5. 11. 1990, p. 3 and OJ No C 311, 27. 11. 1992, p. 30.
(2) OJ No C 159, 17. 6. 1991, p 38.
(3) Opinion of the European Parliament of 11 March 1992 (OJ No C 94, 13. 4. 1992, p. 198), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993, p. 30); Council common position of 20 February 1995 (OJ No C 93, 13. 4. 1995, p. 1) and Decision of the European Parliament of 15 June 1995 (OJ No C 166, 3. 7. 1995).

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to be able to perform their duties or carry out tasks on behalf of an authority in another Member State within the context of the area without internal frontiers as constituted by the internal market;

(6) Whereas, furthermore, the increase in scientific and technical cooperation and the coordinated introduction of new telecommunications networks in the Community necessitate and facilitate cross-border flows of personal data;

(7) Whereas the difference in levels of protection of the rights and freedoms of individuals, notably the right to privacy, with regard to the processing of personal data afforded in the Member States may prevent the transmission of such data from the territory of one Member State to that of another Member State; whereas this difference may therefore constitute an obstacle to the pursuit of a number of economic activities at Community level, distort competition and impede authorities in the discharge of their responsibilities under Community law; whereas this difference in levels of protection is due to the existence of a wide variety of national laws, regulations and administrative provisions;

(8) Whereas, in order to remove the obstacles to flows of personal data, the level of protection of the rights and freedoms of individuals with regard to the processing of such data must be equivalent in all Member States; whereas this objective is vital to the internal market but cannot be achieved by the Member States alone, especially in view of the scale of the divergences which currently exist between the relevant laws in the Member States and the need to coordinate the laws of the Member States so as to ensure that the cross-border flow of personal data is regulated in a consistent manner that is in keeping with the objective of the internal market as provided for in Article 7a of the Treaty; whereas Community action to approximate those laws is therefore needed;

(9) Whereas, given the equivalent protection resulting from the approximation of national laws, the Member States will no longer be able to inhibit the free movement between them of personal data on grounds relating to protection of the rights and freedoms of individuals, and in particular the right to privacy; whereas Member States will be left a margin for manoeuvre, which may, in the context of implementation of the Directive, also be exercised by the business and social partners; whereas Member States will therefore be able to specify in their national law the general conditions governing the lawfulness of data processing; whereas in doing so the Member States shall strive to improve the protection currently provided by their legislation; whereas, within the limits of this margin for manoeuvre and in accordance with Community law, disparities could arise in the implementation of the Directive, and this could have an effect on the movement of data within a Member State as well as within the Community;

(10) Whereas the object of the national laws on the processing of personal data is to protect fundamental rights and freedoms, notably the right to privacy, which is recognized both in Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and in the general principles of Community law; whereas, for that reason, the approximation of those laws must not result in any lessening of the protection they afford but must, on the contrary, seek to ensure a high level of protection in the Community;

(11) Whereas the principles of the protection of the rights and freedoms of individuals, notably the right to privacy, which are contained in this Directive, give substance to and amplify those contained in the Council of Europe Convention of 28 January 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data;

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(12) Whereas the protection principles must apply to all processing of personal data by any person whose activities are governed by Community law; whereas there should be excluded the processing of data carried out by a natural person in the exercise of activities which are exclusively personal or domestic, such as correspondence and the holding of records of addresses;

(13) Whereas the acitivities referred to in Titles V and VI of the Treaty on European Union regarding public safety, defence, State security or the acitivities of the State in the area of criminal laws fall outside the scope of Community law, without prejudice to the obligations incumbent upon Member States under Article 56 (2), Article 57 or Article 100a of the Treaty establishing the European Community; whereas the processing of personal data that is necessary to safeguard the economic well-being of the State does not fall within the scope of this Directive where such processing relates to State security matters;

(14) Whereas, given the importance of the developments under way, in the framework of the information society, of the techniques used to capture, transmit, manipulate, record, store or communicate sound and image data relating to natural persons, this Directive should be applicable to processing involving such data;

(15) Whereas the processing of such data is covered by this Directive only if it is automated or if the data processed are contained or are intended to be contained in a filing system structured according to specific criteria relating to individuals, so as to permit easy access to the personal data in question;

(16) Whereas the processing of sound and image data, such as in cases of video surveillance, does not come within the scope of this Directive if it is carried out for the purposes of public security, defence, national security or in the course of State activities relating to the area of criminal law or of other activities which do not come within the scope of Community law;

(17) Whereas, as far as the processing of sound and image data carried out for purposes of journalism or the purposes of literary or artistic expression is concerned, in particular in the audiovisual field, the principles of the Directive are to apply in a restricted manner according to the provisions laid down in Article 9;

(18) Whereas, in order to ensure that individuals are not deprived of the protection to which they are entitled under this Directive, any processing of personal data in the Community must be carried out in accordance with the law of one of the Member States; whereas, in this connection, processing carried out under the responsibility of a controller who is established in a Member State should be governed by the law of that State;

(19) Whereas establishment on the territory of a Member State implies the effective and real exercise of activity through stable arrangements; whereas the legal form of such an establishment, whether simply branch or a subsidiary with a legal personality, is not the determining factor in this respect; whereas, when a single controller is established on the territory of several Member States, particularly by means of subsidiaries, he must ensure, in order to avoid any circumvention of national rules, that each of the establishments fulfils the obligations imposed by the national law applicable to its activities;

(20) Whereas the fact that the processing of data is carried out by a person established in a third country must not stand in the way of the protection of individuals provided for in this Directive; whereas in these cases, the processing should be governed by the law of the Member State in which the means used are located, and there should be guarantees to ensure that the rights and obligations provided for in this Directive are respected in practice;

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(21) Whereas this Directive is without prejudice to the rules of territoriality applicable in criminal matters;

(22) Whereas Member States shall more precisely define in the laws they enact or when bringing into force the measures taken under this Directive the general circumstances in which processing is lawful; whereas in particular Article 5, in conjunction with Articles 7 and 8, allows Member States, independently of general rules, to provide for special processing conditions for specific sectors and for the various categories of data covered by Article 8;

(23) Whereas Member States are empowered to ensure the implementation of the protection of individuals both by means of a general law on the protection of individuals as regards the processing of personal data and by sectorial laws such as those relating, for example, to statistical institutes;

(24) Whereas the legislation concerning the protection of legal persons with regard to the processing data which concerns them is not affected by this Directive;

(25) Whereas the principles of protection must be reflected, on the one hand, in the obligations imposed on persons, public authorities, enterprises, agencies or other bodies responsible for processing, in particular regarding data quality, technical security, notification to the supervisory authority, and the circumstances under which processing can be carried out, and, on the other hand, in the right conferred on individuals, the data on whom are the subject of processing, to be informed that processing is taking place, to consult the data, to request corrections and even to object to processing in certain circumstances;

(26) Whereas the principles of protection must apply to any information concerning an identified or identifiable person; whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person; whereas the principles of protection shall not apply to data rendered anonymous in such a way that the data subject is no longer identifiable; whereas codes of conduct within the meaning of Article 27 may be a useful instrument for providing guidance as to the ways in which data may be rendered anonymous and retained in a form in which identification of the data subject is no longer possible;

(27) Whereas the protection of individuals must apply as much to automatic processing of data as to manual processing; whereas the scope of this protection must not in effect depend on the techniques used, otherwise this would create a serious risk of circumvention; whereas, nonetheless, as regards manual processing, this Directive covers only filing systems, not unstructured files; whereas, in particular, the content of a filing system must be structured according to specific criteria relating to individuals allowing easy access to the personal data; whereas, in line with the definition in Article 2 (c), the different criteria for determining the constituents of a structured set of personal data, and the different criteria governing access to such a set, may be laid down by each Member State; whereas files or sets of files as well as their cover pages, which are not structured according to specific criteria, shall under no circumstances fall within the scope of this Directive;

(28) Whereas any processing of personal data must be lawful and fair to the individuals concerned; whereas, in particular, the data must be adequate, relevant and not excessive in relation to the purposes for which they are processed; whereas such purposes must be explicit and legitimate and must be determined at the time of collection of the data; whereas the purposes of processing further to collection shall not be incompatible with the purposes as they were originally specified;

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(29) Whereas the further processing of personal data for historical, statistical or scientific purposes is not generally to be considered incompatible with the purposes for which the data have previously been collected provided that Member States furnish suitable safeguards; whereas these safeguards must in particular rule out the use of the data in support of measures or decisions regarding any particular individual;

(30) Whereas, in order to be lawful, the processing of personal data must in addition be carried out with the consent of the data subject or be necessary for the conclusion or performance of a contract binding on the data subject, or as a legal requirement, or for the performance of a task carried out in the public interest or in the exercise of official authority, or in the legitimate interests of a natural or legal person, provided that the interests or the rights and freedoms of the data subject are not overriding; whereas, in particular, in order to maintain a balance between the interests involved while guaranteeing effective competition, Member States may determine the circumstances in which personal data may be used or disclosed to a third party in the context of the legitimate ordinary business activities of companies and other bodies; whereas Member States may similarly specify the conditions under which personal data may be disclosed to a third party for the purposes of marketing whether carried out commercially or by a charitable organization or by any other association or foundation, of a political nature for example, subject to the provisions allowing a data subject to object to the processing of data regarding him, at no cost and without having to state his reasons;

(31) Whereas the processing of personal data must equally be regarded as lawful where it is carried out in order to protect an interest which is essential for the data subject's life;

(32) Whereas it is for national legislation to determine whether the controller performing a task carried out in the public interest or in the exercise of official authority should be a public administration or another natural or legal person governed by public law, or by private law such as a professional association;

(33) Whereas data which are capable by their nature of infringing fundamental freedoms or privacy should not be processed unless the data subject gives his explicit consent; whereas, however, derogations from this prohibition must be explicitly provided for in respect of specific needs, in particular where the processing of these data is carried out for certain health-related purposes by persons subject to a legal obligation of professional secrecy or in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms;

(34) Whereas Member States must also be authorized, when justified by grounds of important public interest, to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest so justify in areas such as public health and social protection - especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system - scientific research and government statistics; whereas it is incumbent on them, however, to provide specific and suitable safeguards so as to protect the fundamental rights and the privacy of individuals;

(35) Whereas, moreover, the processing of personal data by official authorities for achieving aims, laid down in constitutional law or international public law, of officially recognized religious associations is carried out on important grounds of public interest;

(36) Whereas where, in the course of electoral activities, the operation of the democratic system requires in certain Member States that political parties compile data on people's political opinion,

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the processing of such data may be permitted for reasons of important public interest, provided that appropriate safeguards are established;

(37) Whereas the processing of personal data for purposes of journalism or for purposes of literary of artistic expression, in particular in the audiovisual field, should qualify for exemption from the requirements of certain provisions of this Directive in so far as this is necessary to reconcile the fundamental rights of individuals with freedom of information and notably the right to receive and impart information, as guaranteed in particular in Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms; whereas Member States should therefore lay down exemptions and derogations necessary for the purpose of balance between fundamental rights as regards general measures on the legitimacy of data processing, measures on the transfer of data to third countries and the power of the supervisory authority; whereas this should not, however, lead Member States to lay down exemptions from the measures to ensure security of processing; whereas at least the supervisory authority responsible for this sector should also be provided with certain ex-post powers, e.g. to publish a regular report or to refer matters to the judicial authorities;

(38) Whereas, if the processing of data is to be fair, the data subject must be in a position to learn of the existence of a processing operation and, where data are collected from him, must be given accurate and full information, bearing in mind the circumstances of the collection;

(39) Whereas certain processing operations involve data which the controller has not collected directly from the data subject; whereas, furthermore, data can be legitimately disclosed to a third party, even if the disclosure was not anticipated at the time the data were collected from the data subject; whereas, in all these cases, the data subject should be informed when the data are recorded or at the latest when the data are first disclosed to a third party;

(40) Whereas, however, it is not necessary to impose this obligation of the data subject already has the information; whereas, moreover, there will be no such obligation if the recording or disclosure are expressly provided for by law or if the provision of information to the data subject proves impossible or would involve disproportionate efforts, which could be the case where processing is for historical, statistical or scientific purposes; whereas, in this regard, the number of data subjects, the age of the data, and any compensatory measures adopted may be taken into consideration;

(41) Whereas any person must be able to exercise the right of access to data relating to him which are being processed, in order to verify in particular the accuracy of the data and the lawfulness of the processing; whereas, for the same reasons, every data subject must also have the right to know the logic involved in the automatic processing of data concerning him, at least in the case of the automated decisions referred to in Article 15 (1); whereas this right must not adversely affect trade secrets or intellectual property and in particular the copyright protecting the software; whereas these considerations must not, however, result in the data subject being refused all information;

(42) Whereas Member States may, in the interest of the data subject or so as to protect the rights and freedoms of others, restrict rights of access and information; whereas they may, for example, specify that access to medical data may be obtained only through a health professional;

(43) Whereas restrictions on the rights of access and information and on certain obligations of the controller may similarly be imposed by Member States in so far as they are necessary to safeguard, for example, national security, defence, public safety, or impor-