**TRACEABILITY ISSUES in the EUROPEAN UNION**

**(case study of blood transfusion sector)**

Legal regime

The legal and administrative regime in this area in the European Union is defined by a number of European directives, namely by a basic and overwhelming directive 2002-98 which will be analyzed in detail further down.

A number of directives covering specific issues were also adopted to facilitate implementation of the directive 2002/83. Among them: COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 on certain technical requirements for blood and blood components; COMMISSION DIRECTIVE 2005/61/EC of 30 September 2005 on traceability requirements and notification of serious adverse reactions and events; COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 on Community standards and specifications relating to a quality system for blood establishments.

Among related directives one can mention Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 2001/104/EC of the European Parliament and of the Council, as well as Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

As mentioned above the basic Directive in this area is: the directive 2002/98/EC of the European Parliament and of the council - "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 Directive notes that 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. Thus, the Directive states that when human blood is used therapeutically it demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of infectious diseases and to protect health and safety of donors and of patients.

The scope of the Directive (as specified in article 2, Chapter I) applies to the collection and testing of human blood and blood components, and to their processing, storage, and distribution when intended for transfusion.

The Directive requires (article 4, Chapter I) thatMember States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

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| This document contains information (compiled from open sources) on approaches used by regulators in Europe in the area of blood traceability.It is provided for information of the delegates. |

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 (article 5, Chapter II). And relevant controls to this end shall be organized (article 8, Chapter II).

The activities under the Directive are seen as a part of the general quality management process and article 11 of chapter IV calls on member states to "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". As a part of this process record keeping shall be organized and blood establishments shall keep them for a minimum of 15 years (article 13, chapter IV).

The major emphasis of the Directive is on haemovigilance (article 14,chapter V) which says that
"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".

"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."

The directive requires that "Member States shall take all necessary measures in order to ensure that the system used for the labeling 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 labeling requirements listed in Annex III. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years."

The Directive calls on the Member States to take necessary measures to ensure data protection and confidentiality (chapter VII) .

The Directive also requires that member states introduce system of notification of serious adverse events (accidents and errors) and reactions*.( Article 15 ,Chapter V,)* and system of penalties *(article 27, Chapter VIII)* or infringements of national laws relating to this Directive.

The Directive contains annexes on information which shall be submitted by blood establishments for the purpose of their designation, accreditation or licensing; information to be included in annual reports by blood establishments; labeling requirements for donor blood components, and basic testing requirements to me in respect of blood donations.

Reporting requirements under the Directive.

The Directive requires (article 15) that 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.

Some of the definitions that are provided to this end in the Directive (article 3):

(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;

(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.

The definitions were later further elaborated and précised in the framework of the EU project “EU Optimal use” but nevertheless there is still difference between definitions used in countries.

For example, in the Netherlands a term “serious transfusion reaction” (an incident that results in death or is life threaten to a patient) is used, at UK and Ireland - “near miss” (an error that might have harmed a patient but did not). In Denmark “near miss” is considered almost “incident” (which is a deviation from a standard operating procedure during transfusion)..

Besides difference in definitions, national reporting requirements differ from the point of scope of information. Thus in the Netherlands hospitals are required to report all cases of transfusion of an incorrect blood component, but reporting of “near miss” is optional. UK and Ireland concentrate on ‘serious hazards’ of transfusion (as defined in their reporting schemes) but do not require reports of transfusion reactions that are considered be less serious for patients. On the other extreme, in France data is collected on all reactions regardless of their severity.

These differences are important to remember when comparing haemovigilance results among the different schemes.

Blood transfusion traceability standards

There are no harmonized European standards in this area. But there are standards prepared by medical/business associations and such two standards are currently used in the European countries: one is EUROCODE (primarily used in Germany) and another one is ISBT 128, which has a wider application in Europe. These standards are encoding information and allow for its transfer through various electronic means. Both standards are aimed at identification, labeling and information transfer based on bar code technology, namely by assigning specific bar codes. For example, under ISBT 128 an unique 13 number bar code (so called DIN or Donation Identification Number) is assigned to every particular blood donation which allows to identify and to trace it, including the facility where such donation took place.

The ISBT standard was prepared in the 90-s by a number of European and American associations and organizations with participation of health authorities. The implementation of the standard was entrusted to a specially established organization [International Council for Commonality in Blood Banking Automation (ICCBBA)](http://iccbba.org/) which charges fees for the use of this standard and for registration of its user in the common database.

Both Eurocode and ISBT 128 are voluntary standards but some organizations promote the use of a particular standard. Thus, one of the associations which participated in the elaboration of the ISBT 128 standard was ABBB (current name -Advancing Transfusion and Cellular Therapies Worldwide; initially an association of American blood banks which later expanded its activities). AABB requires that its accredited blood banks implement ISBT 128 standard.

On a practical level there a number of products on the market that allow medical institutions to implement bar code based traceability systems by using specific tools, for example, by combining into one traceability chain wrist labels for patients, fridges for blood storage, codes on blood donations, etc...and by allowing for their checking at each stage of blood components movement (example- software and related tools - "BLOODTRACK").

On the basis of information received from national authorities (see below under countries) one could conclude that bar coded technologies used in the region allow to ensure required traceability and to reduce significantly the number of potential mistakes.

National implementation at EU

The basic 2002/98 Directive (and other related EU directives) was implemented (transposed into national legislation) by all EU member states plus by other European countries (for example, by Switzerland).

As a part of national implementation in most cases a two stage institutional system was introduced: with ministries or specially designated agencies which are setting rules for activities of blood establishments (and for their accreditation, if required) and with controlling agencies (usually) on a regional level (“Laender” in Germany).

It could be noted that there are certain differences in national implementation in the EU blood transfusion traceability requirements; very often it relates to how EU requirements are interpreted on a national level .

For example, there exist different understanding of what is a “blood establishment”. Thus, in Italy there is no distinction between "Blood Establishment" and "Hospital Blood Bank". Blood Transfusion Services (BTSs) are by law can be only public hospital-based services.

The reporting issues also vary from country to country. In some cases there are different interpretations of the definitions provided in the Directive (se above under "reporting", for example the Netherlands dedicate a big part of the report to “error transfusion in the ward” like patient identification problems. It can be noted that in general , each country focuses on where it has encountered most difficulties.

The reporting scope can be different as well. In France it is mandatory to report all events caused in the transfusion chain while in Germany “incorrect blood transfused” is a voluntary report (making it sometimes poorly documented.)

The issue of penalties varies also with the most severe sanctions foreseen at UK (up to prison term) to rather light penalties namely fines in most European countries.

The annex below provides information on the Directive transposition in selected European countries plus some related statistical data on blood transfusion facilities and details of national reporting (information is based on the latest available EU and national statistics from various sources) .

France

Germany

Italy

Netherlands

Switzerland

**Annex**

**FRANCE**

Abbreviations:

SAE: Serious Adverse Event

SAR: Serious Adverse Reaction

RAR: Recipient Adverse Reaction

DSAR/DSARF: Donor serious adverse effect/donor serious adverse effect form

PDI: Post Donation Information

RHC: Regional Haemovigilance Coordinator

LBP: Labile Blood Products

**Summary information**

1. **Legal framework**

The legal framework is composed of the EU directives (Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC) that have transposed into the national law.

1. **Control and implementation institutional framework**
2. Direction générale de la santé (DGS) – policy authority
3. Controlling and implementing agency
4. **Haemovigilance system**
5. Afssaps is responsible for the compilation of the haemovigilance data. The data was submitted in paper form but from March 2010 a new system of electronic declarations was put in place.
6. This system shall offer the haemovigilance network the possibility of immediate responsiveness, via the simultaneous communication of information to all the participants.
7. **Summary of key statistics on blood transfusion facilities**

There are around 800 registered facilities in the country.

1. Blood establishments: 17 regional establishments performing 158 collection activities, 17 processing activities, 17 testing activities and 152 distribution activities
2. 705 Hospital Blood Banks are in activity
3. **Reporting of blood transfusion related “adverse events”**

In 2009, 440 SAEs ("serious adverse reactions") were declared, i.e.:

- 176 incidents with transfusion of LBP( labile blood products) without SAE (ratio of 5.9 per 100,000 distributed LBPs)

- 33 incidents with transfusion of LBP ("Labile Blood Products") that caused an SAE of a grade higher than or equal to 1 (ratio of 1.1 per 100,000 distributed LBPs)

- 231 serious incidents with transfusion (ratio of 7.8 per 100,000 distributed LBPs)

In 2009, the number of RAR ("Recipient Adverse Reaction") declarations, including all grades, levels of imputability and enquiries, stood at 7,808, i.e. a frequency of 2.6 per 1,000 distributed LBPs.

1. **Standards used**

ISBT 128 for labeling, coding and identification of blood, blood components, tissues and cells

1. **Sources/references**

European commission public health and risk assessment questionnaire 2008 and 2010, French annual haemovigilance report 2009

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**GERMANY**

Abbreviations:

AMG: German medicinal products act

PEI: Paul-Ehrlich-Institut

GMP: Good manufacturing practices

SAE: Serious Adverse Event

SAR: Serious Adverse Reaction

RAR: Recipient Adverse Reaction

**Summary information**

1. **Legal framework**

The legal framework is composed of the EU directives (Directive 2002/98/EC 2004/33/EC 2005/61/EC 2005/62/EC) and have been transposed into the national law.

In the German law blood components have been defined as medicinal products and therefore require a marketing authorization pursuant to the German medicinal products act (AMG)

1. **Control and implementation institutional framework**
2. Paul-Ehrlich-Institut (PEI)
3. 32 regional GMP( Good manufacturing practices) inspection services of the “Laender”

PEI is an independent highest federal authority within the framework of the German Federal Ministry of Health.

Regional GMP inspection services are competent authorities of the federal states (“Laender”). Blood establishments/facilities obtain GMP license from the regional GMP inspection services. Marketing authorization for blood products is given by the PEI.

PEI and GMP have linked responsibilities and are working closely together. Inspections of blood establishments are in the responsibility of the regional GMP inspection services, according to the German Medicinal Products Act (Art. 64), and are in general performed together with authorized experts from PEI.

Vigilance inspections (Medicinal Products Act Art. 63b para. 5a and Art. 63c para. 5) and inspections prior to marketing authorization (Medicinal Products Act Art. 25 para. 5, and 8) have to be organized by authorized experts from PEI and are performed in consultations with inspectors of the regional GMP inspection services.

1. **Haemovigilance system**

 Blood establishments as marketing authorization holders of blood components are legally obligated to notify any suspicion of SAE ("Serious Adverse Event") or SAR ("Serious Adverse Reaction") with a possible impact on quality and safety of the blood component to the PEI within 15 days. In case of blood components without marketing authorization like autologous blood establishments, they have to notify to the regional GMP inspection services (Medicinal Products Act Art. 63c). Physicians are legally obligated to notify without delay any suspicion of a transfusion transmitted SAR to the PEI and to the blood establishment (German Transfusion Act Art. 16 para. 2).

Requirements for an efficient haemovgilance system are based on precise documentation of the adverse events and reactions of the reporting physician and the blood establishment which is evaluated and standardized by the PEI.

The management of medication errors is managed at the local level whereas product errors are managed at the state or national level.

1. **Summary of key statistics on blood transfusion facilities**

There are around 120 registered facilities in the country

84 blood establishments with 140 production sites

5 private organisations which exclusively collect plasma for fractionation with several collection centers each 22 hospital blood banks are in activity

1. **Reporting of blood transfusion related “adverse events”**

 Germany gives a rather detailed information on the transfusion reactions, but it is not always comparable with other countries which do not use the same classification. Overall in 2009 there were 498 “suspected cases” reported which are considered as serious transfusion reactions
( varying from incorrect blood transfused, to bacteria, and incompatibility and 66 mortal cases for the period 1997-2009)

1. **Standards used**

ISBT 128 and EUROCODE for labeling, coding and identification of blood, blood components, tissues and cells

1. **Sources/references**

Documents used: European commission public health and risk assessment questionnaire 2008 and 2010, Paul –Ehrlich-Institute report 2008/2009

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**ITALY**

Abbreviations:

CRCC: Regional Centres of Coordination and Compensation [Centri Regionali di Coordinamento and Compensazione – CRCC].

 ISS: National Institute of Health [Istituto Superiore di Sanità - ISS]

 PETRA: National form proposed for notifying adverse reactions

BTS: Blood Transfusion Services

TS: Transfusion Structures

SAE: Serious Adverse Event

SAR: Serious Adverse Reaction

RAR: Recipient Adverse Reaction

**Summary information**

**1) Legal framework**

The legal framework is composed of the EU directives (Directives 2002/98/EC, 2004/33/EC 2005/61/EC and 2005/62/EC) that have been transposed into the national law.

The principal law is the law of 21 October 2005 (on new regulations for blood transfusion activities and national productions of blood derivatives).

Legal challenges

Although the general framework was harmonized at EU, there are still some national provisions which are different from basic EU directives.

Among such challenges is harmonization of the transposition 2002/98/EC with the 21st Oct 2005 national blood law as, for example, national organizational model of BTSs (“blood transfusion services”; see below) do not correspond to the organizational models proposed by the Directive2002/98/EC.

Due to the essentiality of safety requirements for blood and blood components established by the Directive 2002/98/EC problems were encountered regarding revising national requirements of import plasma for fractionation and in harmonizing them with the provisions derived from the transposition of the Directive 2001/83/EC.

**2) Control and implementation institutional framework**

The institutional framework includes:

1. the Ministry of Welfare
2. National blood center
3. regional health authorities and regional blood centers and also
4. National Institute of Health.

The Ministry of Welfare has legislative and general planning tasks.

The National Blood Centre is the technical body of the Ministry of Welfare responsible for co-ordination and technical and scientific control of all transfusion medicine issues ruled by national laws and European provisions; it also co-ordinates the Regional Blood Centers which work as a national network.

Regional health authorities participate in controls in their areas of competence.

National Institute of Health is involved in reporting process.

**3) Haemovigilance system**

The collection of haemovigilance data is the responsibility of the 326 Italian TSs (“transfusion structures”) distributed throughout the country and located within hospitals. Inside the TS, blood is donated, tested and processed to produce the blood components that are then sent to the wards; the TS must then receive, from the doctor who uses the transfusion therapy, documentation on every transfusion and any adverse reactions.

The TS store and manage the information, filling in the computerised PETRA form for every case identified. The records are periodically sent to the CRCC, which then transmit the regional data to the ISS. The data collected can be used at local, regional, national and international levels.

The national haemovigilance system has been created to be fully complying with the Directive 2005/61/EC; it is being implemented within the framework of the national blood information system instituted under the national blood law of 21st Oct 2005

The haemovigilance system calls for the registration of immediate transfusion reactions (haemolysis, TRALI, bacterial contamination, anaphylactic shock, etc.), late effects [haemolysis, graft-versus-host disease (GvHD), post-transfusional purpura, etc.] and transfusion of wrong blood components.

The notification of severe unwanted reactions and incidents is mandatory

The national form proposed for notifying adverse reactions (PETRA) was prepared by the National Institute of Health and distributed to all Transfusion Structures(TS)

The PETRA forms sent by the Region of Piemonte are filled in electronically, interfacing the

PETRA software with that of the “Form for recording adverse events of transfusion therapy”, used by this region which is implementing electronic reporting on a pilot basis.

In Italy, the surveillance of adverse events in recipients was activated at the end of 2004 by the

National Institute of Health [Istituto Superiore di Sanità - ISS][5](http://www.ncbi.nlm.nih.gov/pubmed/16507025). There were already systems for monitoring adverse reactions in some Regions[6](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2535888/#b6-blt5_2p066); at a national level, efforts were made to guarantee the homogeneity of the data collected by using the same forms. The proposed form for national suveillance was designed by Transfusion Medicine specialists and agreed upon through consultatory meetings with representatives of the Regional Centres of Coordination

and Compensation [Centri Regionali di Coordinamento and Compensazione – CRCC]. Subsequently, dedicated software was developed, based on the paper form.

This software, called PETRA (Programma degli Errori Transfusionali e delle Reazioni Avverse – Programme for Transfusion Errors and Adverse Reactions), was distributed by the ISS to all TS.

Participation in the haemovigilance system was not obligatory, but was strongly recommended by the institutions (ISS and CRCC).

**4) Summary of key statistics on blood transfusion facilities .**

There are around 330 registered facilities in the country.

In Italy there no distinction is made between "Blood Establishment" and "Hospital Blood Bank". Blood Transfusion Services (BTSs) are by law only public hospital-based services. The overall number of BTSs is 326 (2005 survey, latest available).

The number of blood components distributed in 2005 (1,834,474)

**5) Reporting on blood transfusion related “adverse events”**

In 2005 (latest full data available) , the percentage of the 326 Italian TS that participated in the haemovigilance survey was 38.4%, which was almost double that in 2004 (21.0%). This percentage also includes the TS that did not use PETRA (electronic data submission) and those that stated the absence of adverse reactions.

 In 2005, there were reports of 1,495 adverse reactions, 823 of which were reported using a summary data-sheet other than PETRA, such that, in most cases of events notified, a description of the causative role of the transfusion in the adverse reaction was not given.

 Overall, 0.8 reactions were reported every 1,000 units of blood components distributed.

Almost all the adverse events reported were acute: 46.9% of the reactions were febrile type reactions and 38.7% were of an allergic nature.

 Overall, 986 forms were returned, of which 871 reported adverse reactions and 63 reported near miss errors or errors; 52 forms could not be evaluated

**6) Standards used**

ISBT 128 for labeling, coding and identification of blood, blood components, tissues and cells

**7) Sources/references**

Documents used: European commission public health and risk assessment questionnaire 2008 and 2010, The haemovigilance system in Italy 2007

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**Netherlands**

Abbreviations:

SAE: Serious Adverse Event

SAR: Serious Adverse Reaction

RAR: Recipient Adverse Reaction

**Summary information**

**1) Legal framework**

The legal framework is provided by the EU directives (Directives 2002/98/EC, 2004/33/EC 2005/61/EC and 2005/62/EC) that have been transposed into the national law.

**2) Control and implementation institutional framework**

 a) Ministry of Health, Welfare and Sport

 b) Healthcare Inspectorate (Inspectie voor de Gezondheidszorg, IGZ).

The Ministry is a competent authority which is granting permissions and inspecting agency is the Healthcare Inspectorate.

**3) Haemovigilance system**

Hospitals and the Blood Establishment are obliged to report serious adverse events and serious adverse reactions to the competent authority (CA) and on a voluntarily basis to an independent foundation "TRIP" (“Transfusion reactions in patients”). TRIP is responsible for haemovigilance. The CA cooperates cordially with this organization and has above that,its own database mainly to trace quickly donor-related products. TRIP participates in the European Haemovigilance Network.

The registration (reporting) concerns both serious and non serious adverse effects and incidents. These are reported by the permanent contact person (hemovigilance officer), a special position which exists in the Dutch hospitals for this purpose.

TRIP National Hemovigilance Office has managed the national reporting system for transfusion reactions in collaboration with contact persons in the hospitals and the blood supply service Sanquin.

 Implementation controls

Four blood banks (big establishments) are responsible for the collection of blood/plasma. The blood banks have central management and central storage/testing facilities. The blood banks have more than one location where blood/plasma is actually donated. Every two years each blood bank and all fixed blood establishments are inspected. The mobile blood collection sites are excluded from this obligatory inspection. The inspections of mobile sites are organized at random.

**4) Summary of key statistics on blood transfusion facilities**

 Around 120 registered facilities engaged in blood transfusion.

1. 1 blood establishment
2. 4 big blood banks (responsible for the collection of blood)
3. In total, approximately 115 Hospital Blood Banks are in activity (including 4 big banks mentioned above)
4. In 2009, Sanquin supplied a total of 699,720 blood components to hospitals.

**5) Reporting on blood transfusion related “adverse events.”**

The reports from participating facilities contain various, rather detailed information.

A lot of information is attributed to incorrect blood transfused or blood that has become unsuitable for transfusion.

Imputability which is a measure of probability that the reaction resulted from the transfusion, is highly used and various from events considered “serious” ( 2 to 4 on a scale) and non “serious” (0 to 2).

There were 2134 transfusion reactions reported in 2009 and 330 were considered certainly related to the transfusion.

For example, out of the 2134 transfusion reactions reported in 2009, the imputability was listed for 2093 cases (98.1 %).

Of these, 330 reports (15.8 %) were considered certainly related to the transfusion, 623 (29.8 %) were probable, 975 (46.6 %) were possible, 145 (6.9 %) were unlikely and 20 (1.0 %) were excluded.

1. **Standards used**

ISBT 128 for labeling, coding and identification of blood, blood components, tissues and cells

1. **Sources / references**

Documents used: European commission public health and risk assessment questionnaire 2008, TRIP annual haemovigilance report 2009

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**SWITZERLAND**

Abbreviations:

LTP: Law on Therapeutic Products

BTC: Blood Transfusion Center

BTS SRC: Blood Transfusion Service of the Swiss Red Cross

SAE: Serious Adverse Event

SAR: Serious Adverse Reaction

RAR: Recipient Adverse Reaction

**Summary information**

1. **Legal framework**

Switzerland is not a Member State of the European Union. But the existing regulations on blood transfusion in Switzerland are equivalent to the requirements set in Directives 2002/98/EC. 2004/33/EC, 2005/61/EC and 2005/62/EC. It should be noted that in Switzerland national transfusion regulations are not mandatory,

Law on Therapeutic Products (LTP) applies to synthetic human drugs, biotechnology, vaccines, medical devices, implants, diagnostic agents and blood products. Special dispositions concern blood and blood components whose preparation must comply with the requirements in place for drugs.

The Law provides for setting of a federal drug regulatory authority (Swismedic; see below) with powers for the whole country.

1. **Control and implementation institutional framework**

a) Swissmedic (Swiss Agency for Therapeutic Products)

b) Federal Office of Public Health

Swissmedic is the central Swiss supervisory authority for therapeutic products (human and veterinary medicines together with medical devices). It is linked to the Federal Department of Home Affairs (FDHA). Swissmedic's administrates practical implementation of the Swiss Law on Therapeutic Products (LTP).

The Federal Office of Public Health (FOPH), as the national authority in health matters, is a part of the Federal Department of Home Affairs and represents Switzerland in international organisations and in dealings with other countries. It is responsible - together with the cantons - for public health and the development of national health policy including monitoring transmissible diseases, radiological protection, regulations governing the basic and advanced training of doctors, dentists, pharmacists and veterinary surgeons and for legislation on biological safety, research on humans, stem cell research and transplantation medicine. It is drafting the laws and regulations and supervises the implementation.

The status of Swissmedic is defined by the law (LTP) as a federal regulatory body whose decisions are mandatory all over the country, which guarantees quality, safety and efficiency of drugs and performs consequently regular inspections of all BTC preparing and releasing blood components. BTC (blood transfusion center) receive after each inspection an official license in order to carry out their activity.

Currently, there are no formal mandatory national transfusion regulations or guidelines in Switzerland. The Blood Transfusion Service of the Swiss Red Cross Ltd (BTS SRC), a non-profit organisation, is in charge of the reference activities in immunohaemotology and serology, and issues the national recommendations and guidelines that regulate the standards of quality and logistics for blood donations.

But the appropriate use of these components is not yet regulated by law: national transfusion guidelines per se do not exist in Switzerland

1. **Haemovigilance system**

 In Switzerland, all transfusion related adverse events and reactions, irrespective of their grade of severity, are eligible for reporting. The reports are reviewed by the haemovigilance team at Swissmedic and evaluated.

 Reporting to Swissmedic (the Swiss agency for therapeutic products) of all suspected adverse transfusion events in a standardized format is mandatory.

 Hospital blood banks are required to have a cantonal establishment license. Some basic requirements (e.g. archiving of documents) which are comparable to the EU provisions are laid down in the national Law on Therapeutic Products. In addition, additional cantonal regulations exist for hospital blood banks.

 The Division Inspectorates of Swissmedic conducts these inspections and has a quality management system and accreditation according to ISO 17020 for their activities.

1. **Summary of key statistics on blood transfusion facilities**

There are around 200 registered facilities in the country.

Licensing process distinguishes between those establishments which collect blood and those which perform serology testing.

In Switzerland, 54 Establishments have licenses as blood establishments which perform collection and/or processing activities, and 50 Establishments - licenses for establishments which perform serology testing. These establishment’s licenses may cover multiple sites (e.g. for collection)

Approximately 100 blood banks are in activity, Authorisation for the storage of blood components (only if there are no other activities regarding blood) are issued by a cantonal authority.

There is no open official statistics neither on a federal nor cantonal levels on the exact number of establishments holding an authorisation issued by the cantonal authorities.

1. **Reporting on blood transfusion related “adverse events”**

In Switzerland, all transfusion related adverse events and reactions, irrespective of their grade of severity, are eligible for reporting.

In 2009, according to Swiss sources 538 “serious events” were reported: No details were provided but it is highly probable that they are linked to a transfusion.

1. **Standards used**

ISBT 128 for labeling, coding and identification of blood, blood components, tissues and cells.

1. **Sources/references**

European commission public health and risk assessment questionnaire 2008 and 2010, Swissmedic annual haemovigilance report 2009.

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