Transfusion medicine in Switzerland

Switzerland, with its about 7.5 Millions inhabitants and 23 political independent districts (“cantons”) is a small country with 13 Regional Blood Transfusion Services (RBTS) ensuring currently the blood supply for the whole population under the umbrella of the national Blood Transfusion Service of the Swiss Red Cross (BTS SRC).

The BTS SRC Ltd is a Non for Profit Organisation managed by a supervisory board and an executive board (director, medical director and financial director). A board of directors of the RBTS advises the executive board in operational decisions.
It is limited by shares allotted to the SRC and to the 13 RBTS in charge of blood supply for the Swiss population. The RBTS perform all the core activities (blood donation, preparation, testing, storage and release of blood components). They are responsible of blood supply in their own region and organise blood donation according to the local conditions: in one or several BTC and mobile drives, for a total of 370'000 blood donations per year for the whole country. The biggest facilities are located in the 5 main cities (Bern, Zurich, Basel, Lausanne and Geneva) with a university and a medical faculty. Switzerland covers currently its own needs and remains in a comfortable situation with a sufficient number of regular and new donors (but still a certain lack of young male donors). Increasing number of deferral reasons in the last few years lead to a diminution of the donor population which is remarkable but still not a threat.

The standards of quality, logistics (national coordination system of planning and interregional exchange of blood components ensuring an adequate supply of all the hospitals even in case of bottleneck situations during the holiday season) and reference activities in immunohematology and serology (these last activities performed in a Reference Laboratory located in the facility of the RBTS Bern) are in charge of the BTS SRC.

Legal background

Since 2002, a federal 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. Furthermore, criterias for donor selection, mandatory tests, traceability and record keeping are defined.

The regulations refer also to the Guide to the preparation, use and quality assurance of blood components published annually by the Council of Europe and to the PIC/S GMP guide for blood establishments published by the Pharmaceutical inspection convention.
The law set up a federal drug regulatory agency (Swissmedic) 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 receive after each inspection an official licence in order to carry out their activity.

The licence is delivered for a limited period of time and is regularly renewed (generally every 2 years) according to inspections results. It covers the following activities: collection, preparation, testing, storage and distribution according to the swiss regulations mentioned above.

The main points to be considered are:

- A designated person in charge of ensuring that blood and blood components meet the specifications and that collection, preparation and distribution of blood and blood components comply with the regulations for Good Manufacturing Practices;
This person must have a medical or scientific degree (MD / PhD) and should have the necessary experience in running blood transfusion services;

- The blood transfusion service must work in accordance with the regulations of Good Manufacturing Practices and maintain a quality management system which fulfils the requirements of Good Manufacturing Practices;
- The blood transfusion service must nominate a person in charge of hemovigilance, who notifies all adverse events to Swissmedic.

From these requirements, preparation of blood components today is obviously standardised so far and the quality is ensured. But the appropriate use of these components is not regulated by law: national transfusion guidelines per se do not exist in Switzerland.