

Unit 4: Vaccines and Blood Products

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4.1 Vaccine regulations: the common frame in India, the US and the EU

Vaccines are the oldest biologics and the most intensively regulated per dose, because they are given to healthy people, very often children, in very large numbers. The three systems of this unit share one architecture, and this section teaches the architecture before Unit 4's remaining sections divide the detail. A vaccine is developed under the clinical trial machinery of its jurisdiction, tested in progressively larger populations with immunogenicity, the measured immune response, standing where possible as the readable endpoint in place of field efficacy. It is authorised on a dossier covering the antigen, the seed and cell substrate history, the manufacturing process and its consistency, and the clinical evidence. Uniquely in this class, authorisation is followed by **official batch release**: because no end product test fully characterises a vaccine, an official laboratory re-examines and releases each batch, or a defined sample of batches, before sale. And because vaccination is a public programme, its safety is watched by dedicated surveillance of adverse events following immunisation, at section 4.3.

4.2 Clinical evaluation, licensing, quality assessment and additional requirements by jurisdiction

India. Vaccines are new drugs under the Drugs and Cosmetics framework, developed under the NDCT Rules 2019 and CDSCO oversight, with clinical trials designed around the vaccine's immunogenicity and safety in the Indian population, including bridging evaluation for vaccines developed abroad. Quality assessment and batch control rest substantially with the **Central Drugs Laboratory, Kasauli**, the national control laboratory for vaccines, which tests batches of vaccines for release in the Indian market; licensure of manufacture follows the Drugs and Cosmetics Rules with CDSCO as the central authority for this class. Additional requirements in the Indian setting are programmatic: vaccines destined for the Universal Immunization Programme must meet the programme's specifications and cold chain discipline, and export vaccines commonly carry WHO prequalification, below. **United States.** Vaccines are CBER products, developed under an IND and licensed by BLA, with the distinctive feature of **lot release under 21 CFR 610.1**: FDA may require submission of samples and protocols of each lot, and no lot subject to that requirement may be distributed until CBER releases it, a power applied lot by lot to vaccines and other designated biologics. Clinical evaluation follows the preventive vaccine pattern of large safety databases, immunogenicity endpoints and, where a disease endpoint trial is impracticable, immunological correlates accepted by agreement with the agency. **European Union.** Vaccines are centrally authorised like other biologics, and batch release is performed by the network of **Official Medicines Control Laboratories** under the Official Control Authority Batch Release (OCABR) system coordinated through EDQM: the manufacturer tests the batch, an official laboratory of one member state reviews the protocol and may test the batch, and the resulting certificate is recognised across the Union, so a batch is officially released once for all of Europe. Behind all three stands the **WHO prequalification** of vaccines, which assesses quality, safety and efficacy and the supplying programme's suitability, and on which United Nations agency procurement depends, making it a fourth, de facto licence for any vaccine aimed at the world's public programmes.

Vaccines: from authorisation to official batch release



WHO prequalification stands behind export supply and United Nations procurement

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Figure: The vaccine route after authorisation: every batch passes consistency testing, and an official laboratory, the Central Drugs Laboratory in India, CDER lot release in the USA, an OMCL under OCABR in the EU, releases it before sale (Unit 4, sections 4.1 and 4.2).

4.3 Pharmacovigilance for vaccines and blood products

Vaccine safety surveillance has its own vocabulary because the events it watches occur against a background of coincidental illness in a recently vaccinated, usually healthy population, and must be separated from reactions the vaccine caused. India runs a dedicated **Adverse Events Following Immunization (AEFI)** surveillance system within the immunisation programme: events are reported upward from the vaccination site, investigated, and causality assessed by expert committees at district, state and national level, distinguishing vaccine product related and quality defect related reactions from immunisation error related events, anxiety related events and coincidence. The United States operates **VAERS**, the Vaccine Adverse Event Reporting System, jointly run by FDA and the Centers for Disease Control and Prevention, an open reporting system for events after licensed vaccines, read together with active follow up systems for signal confirmation. In the EU, vaccine reactions are reported into **EudraVigilance** under the general pharmacovigilance system, with the additional monitoring and risk management machinery of section 3.8. Blood products carry the parallel discipline of **haemovigilance**, treated at section 4.6: the surveillance of the whole transfusion chain, in which the event of interest may be a reaction in the recipient, an incident in processing, or a near miss in identification, and the system's value lies in tracing any unit of blood from donor to recipient and back.

4.4 Blood and blood products: regulatory requirements in India, the US and the EU

Blood regulation governs two different things that share a supply chain: **components** prepared from donations, whole blood separated into red cells, plasma, platelets and cryoprecipitate for transfusion; and **plasma derived medicinal products**, the fractionated albumin, immunoglobulins and clotting factors manufactured industrially from pooled plasma, which are licensed as medicines. **India** regulates blood banks under the Drugs and Cosmetics Rules: a blood bank requires a licence, granted for premises that meet the prescribed conditions of accommodation, equipment, staffing and testing, operates under the technical standards of the national blood policy framework with the National AIDS Control Organisation's standards for blood safety, and must test every donation for the prescribed transfusion transmitted infections, including HIV, hepatitis B and C, syphilis and malaria, with the component separation and storage conditions the Rules prescribe; the Central Drugs Laboratory and state laboratories stand behind the system for biological testing functions. **United States**. Blood establishments register with FDA and operate under the biologics regulations and the cGMP of Parts 606 and following of Title 21: donor eligibility is determined under Part 630, each donation is tested for the required infectious disease markers under Part 610.40, and components are labelled and released under a quality system whose errors and accidents must be reported to CDER; source plasma collection centres feed the fractionation industry under the same

discipline. **European Union.** The Blood Directive 2002/98/EC sets the quality and safety standards for the collection and testing of human blood and components across the member states: designated competent authorities license and inspect blood establishments, every donation is tested for the Directive's marker panel, traceability from donor to recipient must be maintained for 30 years, and haemovigilance reporting of serious adverse reactions and events is mandatory, while the fractionated products themselves are authorised as medicines under the pharmaceutical legislation, with the plasma master file of section 3.4 carrying their starting material data.

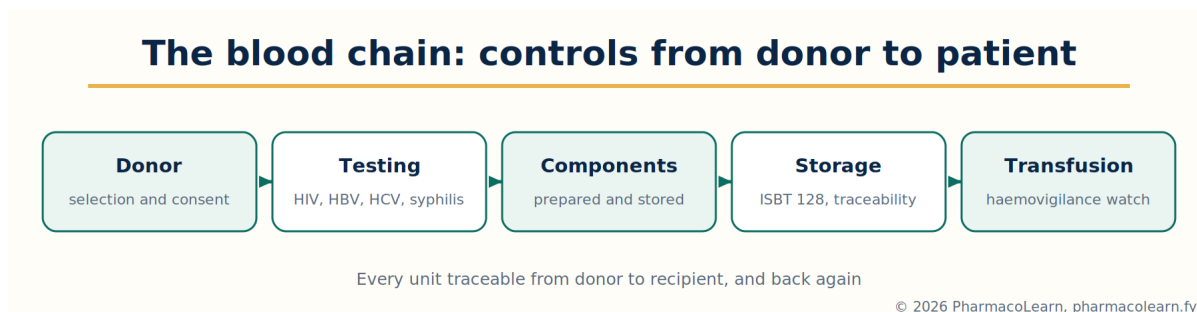


Figure: The chain every system in section 4.4 controls: donor selection, donation testing for transfusion transmitted infections, component preparation, labelled storage under traceability, and transfusion watched by haemovigilance (Unit 4, section 4.4).

4.5 Label requirements for blood and its components

A blood component label is an identification instrument before it is anything else: an error in matching unit to patient kills faster than any quality defect, so the label must state, unambiguously and durably, the identity of the component, its unique donation identification number, the blood group, the expiry date and time, the storage conditions, and the identity of the collecting and processing establishment. The three systems prescribe these contents through their blood regulations, and all require the label to connect the unit to its full record: donor, tests, processing and destination, the traceability chain of section 4.4. The modern carrier of this identity is the ISBT 128 standard of the next section, in which the label's information is encoded in barcodes and data structures read identically by blood services worldwide, so that a unit's group, product code and donation number survive every border it crosses.

4.6 ISBT labelling and the International Haemovigilance Network

The **International Society of Blood Transfusion (ISBT)** maintains **ISBT 128**, the global standard for the identification, labelling and information transfer of medical products of human origin, administered internationally by ICCBBA. Its donation identification number, built from a facility code, a year and a serial number, is unique worldwide and for all time; its product codes describe the component in standard terms; and its barcoded and electronic formats carry blood group, expiry and special attributes in a form any compliant system can read, which is why ISBT 128 labelling appears in the syllabus beside the label contents of section 4.5: it is how the content requirements are made machine true in practice. The **International Haemovigilance Network (IHN)** is the professional network of national haemovigilance systems: it harmonises the definitions of adverse reactions and events in donors and recipients, shares alerts and annual data between countries, and develops the standards by which a transfusion service learns from another's incident. India's own haemovigilance programme, the Haemovigilance Programme of India run under the National Institute of Biologicals with PvPI, applies the same logic domestically: transfusion reactions are reported on standard forms into a national database, so that the safety of the blood chain, like the safety of a vaccine programme, is a measured quantity rather than an assumption.

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