Panel C: MEDICAL PRODUCTS OF HUMAN ORIGIN AND OTHER BIOLOGICALS

Participation of different actors in the regulation of some health technologies: *Blood and blood products - The regulatory plurality*.

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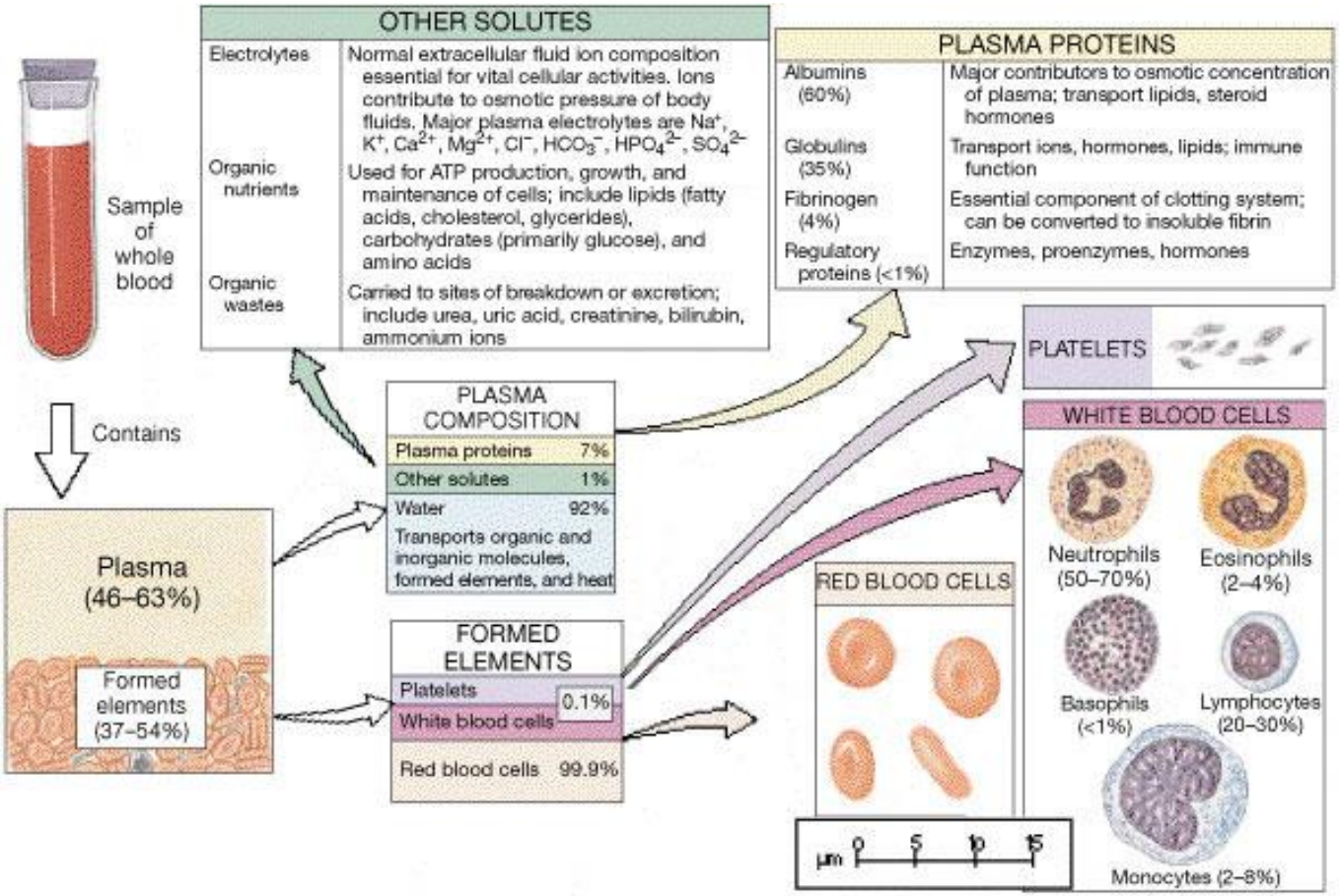
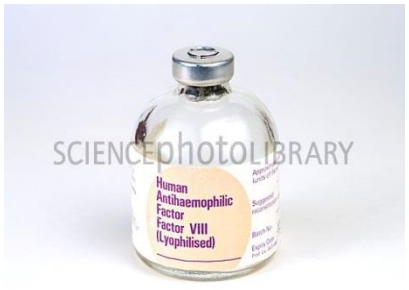
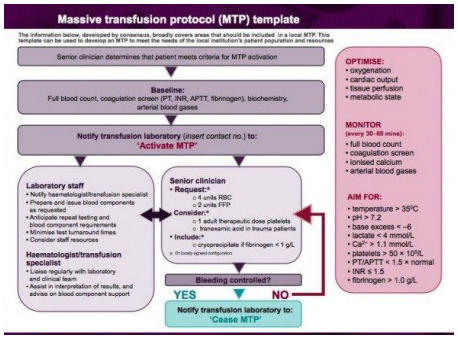
Blood is not a single therapeutic product



Effects of blood therapies depend on multiple factors





Blood - Relevant Regulatory Frameworks

Drug – *Food & Drugs Act*

- Blood Derived Products
  - *Food & Drug Regulations*

- Blood Components
  - *Blood Regulations*
  - *Medical Device Regulations*
  - *Cell, Tissues and Organs Regulations*

Others

- Federal vs Provincial Authorities
- Practice of Medicine
- Research - *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*.
- National Standards

Federal

- *Food and Drugs Act* and relevant *Regulations*
- National Surveillance (Regulatory and Public Health)
- Compliance & Enforcement

Provincial / Territorial

- Health Professionals
- Hospitals & Health Authorities
- Public Health

SAFETY

Manufacturers

- Private Companies
- Blood Establishments (Cell & Stem Cell Banks)
- Public & Private Organizations
- Processors

Other Players

- Donors & Recipients
- NGOs
- Standard Associations
- International Authorities and Organizations
- Academic Institutions

- There are several key stakeholders involved in blood therapies
- A single regulatory framework is most probably highly impractical
- Useful regulatory frameworks need to take into account the role of the different players and the scope of the authority

THE END … ?

Muchas Gracias !

Merci beaucoup!

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