

The ‘Achilles’ project:

A WHO initiative to assure safety and availability of blood products in developing countries

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OUTLINE

- ❑ **Background**
- ❑ **Rational and project goals**
- ❑ **Action plan**
- ❑ **Expected outcomes**



WHO Model List of Essential Medicines

□ Human blood derived medicinal products

– Plasma for Fractionation

- Blood Coagulation Factors: FVIII, PCC
- Human Normal Immunoglobulin (IV and IM)
- Anti-D immunoglobulin
- Anti-tetanus immunoglobulin

Blood-derived medicinal products for the treatment of haemophilia and immune diseases are included in the *WHO Model List of Essential Medicines*



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Rational (I)

- ❑ Plasma derivatives often unavailable in developing countries
- ❑ The global need exceeds by far available supply
- ❑ No realistic possibility of generating surplus products in developed countries to meet developing countries needs and, even when available, would be unaffordable



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Rational (II)

- ❑ Considering that plasma for fractionation available in industrialized countries meets their needs
- ❑ "Developing countries will only be able to create an affordable and sustainable supply of blood derived products by using blood plasma collected in their own blood establishments and from their own populations"
- ❑ Plasma fractionation can be performed through plasma contract fractionation programs with fractionators even if abroad



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Main Goals

To increase the availability of essential plasma derived products for developing countries by supporting their implementation of national validated quality and safety standards for plasma for fractionation:

- ✓ Raising quality standards for production activities in blood establishments
- ✓ Providing a framework to make use of, otherwise destroyed plasma, for the fractionation of plasma derivatives
- ✓ Using expertise and experience from developed countries

The project includes elements of quality, safety and economical benefits



Plasma safety and availability: highly regulated countries

- ❑ Commitment of health politicians, strong regulation and continuous surveillance in place
- ❑ Commitment of blood services and plasma fractionators
- ❑ GMP implementation in manufacture of all blood plasma derived products, including plasma for fractionation
- ➔ No documented blood-borne pathogen transmission by plasma products licensed within this regulatory framework > 10 years
- ➔ Patients needs are generally met



Specific issues in developing countries

1. Availability and affordability of products
2. Wastage of plasma
3. Risk of transfusion-transmitted diseases
4. Poor regulation of blood products
5. Lack of reporting systems



Wastage of blood plasma

A significant volumen of plasma collected in developing countries is discarded because of:

- ❑ Lack of appropriate technology
- ❑ Lack of controls: unmet quality criteria for fractionation
- ❑ Lack of GMP implementation in blood establishments
- ❑ Need to strengthen experience on production, control & regulation of plasma for fractionation



Poor regulation of blood products

- ❑ The situation probably parallels the experience of "developed countries" up until the 90's where blood establishments were largely unregulated.
- ❑ Requirement of regulatory authorities to demonstrate effective control and traceability of plasma for fractionation led to substantial improvement of all activities in blood establishments



Good Manufacturing Practices (GMP): an essential tool for improvement of safety

GMP implementation in Blood/Plasma Establishments: a key element to

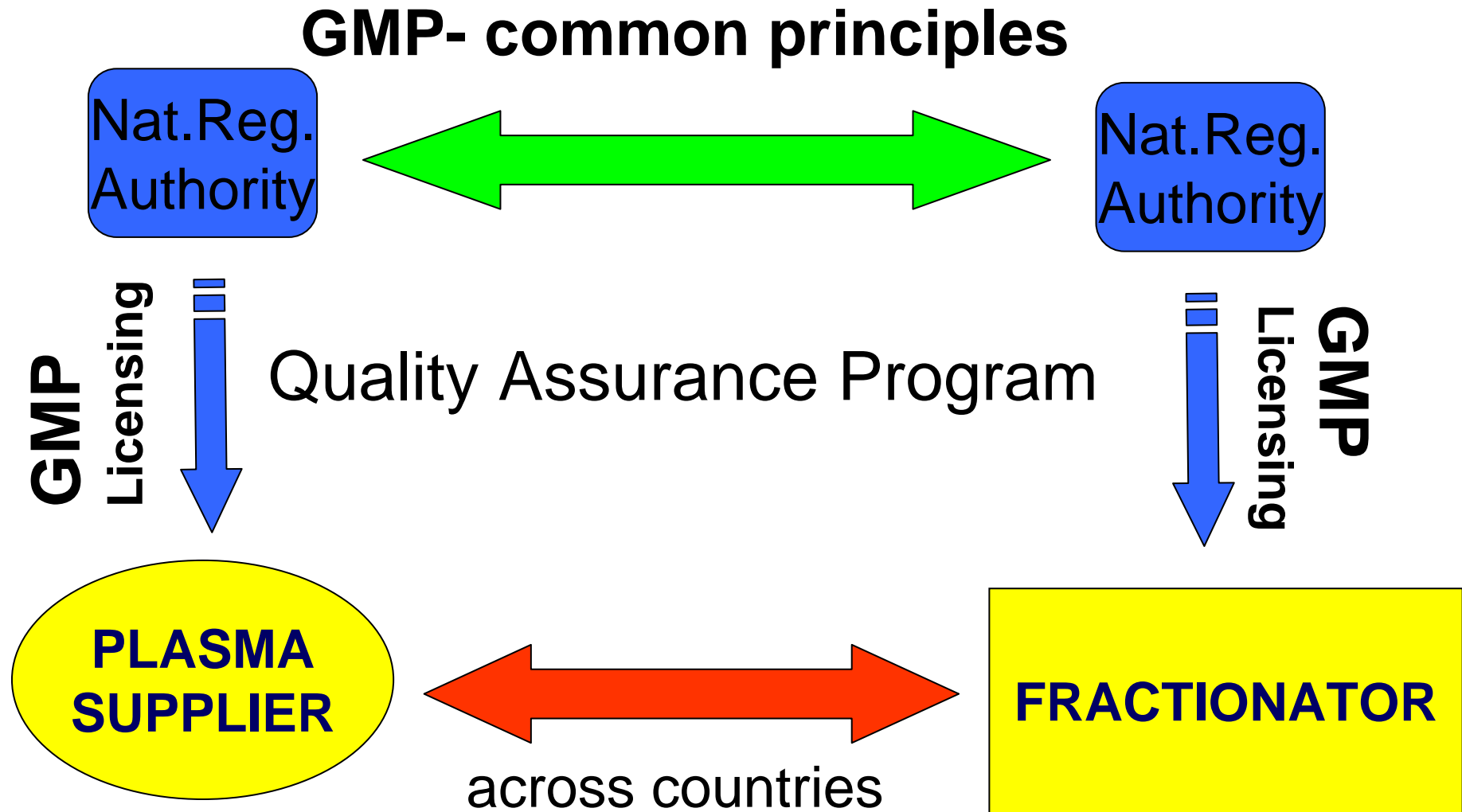
Quality and safety of plasma for fractionation
Plasma contract fractionation programs

Supporting access to blood plasma products



Plasma Contract Fractionation Programs

- Need for GMP implementation in BE -



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Benefits

- ❑ Build-up technical expertise of National Regulatory Authorities (NRA) and plasma suppliers (BE), a need
- ❑ Common GMP standards, a basis for mutual recognition of quality standards and inspections results between NRA's
- ❑ Compliance with GMP, a key tool for successful plasma contract fractionation programs



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What do we have?

- ❑ **Materials and mechanisms on which training and technical capacity can be provided to BE and regulatory authorities:**
 - ❑ WHO Guidelines: Production, control and regulation of plasma for fractionation; Viral Inactivation and Removal procedures
 - ❑ Biological reference materials: quality control of blood products and of blood safety related IVDs
 - ❑ Practical workshops supporting implementation
 - ❑ Regional networks: regulatory authorities and BE
 - ❑ Coordination of international expertise: ECBS, BRN, WHOCC.....
 - ❑ Expertise from other quality assurance programs in WHO
 - ❑ Support from WHO Regional Offices and Country Offices



The “Achilles” project Action Plan

- ❑ Development of comprehensive GMP guidelines to support training and inspection activities: **WHO GMP Guidelines for Blood Establishments are being developed (high priority)**
- ❑ Development of country Work Plans aiming to upgrade quality assurance systems and regulatory expertise (**demonstration project**)



The “Achilles” project Work Plans^()*

- ❑ Work Plans imply development of specific and measurable indicators to monitor success and progress with the pilot countries. Examples are:
 - ❑ Blood products regulations updated;
 - ❑ BE GMP compliance;
 - ❑ Decrease of GMP failures
 - ❑ Quality assurance officers trained;
 - ❑ Increase in plasma volume accepted for fractionation;
 - ❑ Reduction of infectious disease markers in blood donors;
 - ❑ Economic benefit

(*) Demonstration project



The “Achilles” project: Expected Outcomes

- ❑ Use of local plasma to improve supply of blood derived medicinal products
- ❑ Sustainable and affordable blood plasma derived essential medicines
- ❑ Increased quality and safety of all blood products in blood establishments
- ❑ Optimal use and benefit from donated blood and plasma
- ❑ Independent regulatory systems for blood products established
- ❑ Potential application of QA and GMP principles to other medical disciplines
- ❑ Substantial contribution to public health programs



Relevant Web site addresses

www.who.int/bloodproducts

www.who.int/biologicals

www.who.int/medicines

