Development of Assessment Tools For Evaluation of Blood System Regulation

WHO Blood Regulators Network

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BACKGROUND

• As a pillar for safe blood programs globally, WHO has advocated the establishment and sustenance of strong National Regulatory Authorities (NRA) both in developed and developing countries
Ancillary to the existence of NRAs to regulate activities assuring the provision of safe blood, there is currently an unmet need to develop criteria to benchmark NRAs globally as concerns activities related to regulation of blood.
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AN UNMET NEED

For both developed and developing countries, a benchmarking process could serve as a useful means to highlight strengths of NRA programs for regulation of blood and blood products whilst identifying gaps or areas for future development.
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AN UNMET NEED

While it is recognized that there may be regulatory performance frameworks in place for assessment of regulatory oversight for pharmaceutical drugs in many jurisdictions, these assessment tools may have limited applicability to blood.
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HARMONIZATION AS A GOAL

- Industry groups such as the Alliance of Blood Operators (ABO) amongst others have advocated to governments to work toward establishment of greater standardization amongst regulatory bodies globally in the area of regulation of blood and blood products
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PURPOSE & OBJECTIVES

1. To identify essential control functions that should be undertaken by an effective/functional NRA to assure the quality, safety and efficacy of blood and blood products

2. To establish harmonized indicators for these essential functions to allow NRAs to assess their performance in the regulation of
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OVERALL STRUCTURE OF ASSESSMENT TOOL

- Focus on the following general areas:
  - Legal framework/authorities
  - Essential functions
  - Infrastructure
  - Quality elements to be defined under each of these headings.
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PROPOSED ESSENTIAL FUNCTIONS

- National Regulatory System
- National Regulatory Authority
- Licensing of Blood Establishments
- Authorization of Blood and Blood Components (Product/Process authorization)
- IVD Authorization
- Access to an independent laboratory
- Control of clinical trials
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PROPOSED ESSENTIAL FUNCTIONS (Con’t)

- Marketing Authorization
- System for lot release
- Regulatory Inspections and Enforcement activities
- Hemovigilance
- Traceability and Record keeping
- International co-operation and harmonization
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SPECIAL CONSIDERATIONS IN DEVELOPMENT OF ASSESSMENT CRITERIA

- Some essential functions or activities may be applicable regardless of the intended use of blood or blood components (e.g. transfusion or for further manufacturing) while some functions/activities may only specifically apply to blood components.
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SPECIAL CONSIDERATIONS IN DEVELOPMENT OF ASSESSMENT CRITERIA

• For countries which are importing source material (e.g. Plasma), fewer functions may need to be ensured within the authority of the importing country, although it should ensure that the appropriate regulatory activities are being carried out in the country of manufacture (export)
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SPECIAL CONSIDERATIONS IN DEVELOPMENT OF ASSESSMENT CRITERIA

- In some countries, including BRN members, all functions related to blood regulation fall under the purview of a single agency which has the full authority in command and control of these functions. However, in other cases, regulatory functions may be assigned to two or more responsible authorities, at either...
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EVALUATION TEMPLATES USED TO DEVELOP DRAFT CRITERIA

- WHO Pre-Qualification Assessment Criteria for Vaccines
- Benchmarking of European Medicines Agencies (BEMA) tool
- Draft WHO data collection tool for the review of drug regulatory systems
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CURRENT STATUS OF ASSESSMENT TOOL

- Review of assessment tools and template by BRN members (Oct. 2007, March 2008). Newest draft to be considered at ICDRA (September 18, 2008)
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NEXT STEPS

- Finalization of assessment tools
- Planning for pilot phase
- Evaluation exercise with volunteer BRN members (SwissMedic, Health Canada)
- Pilot phase evaluation of volunteer developing countries
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NEXT STEPS (Con’t)

• Review of piloting exercise
• Evaluation of the need for development of a guidance document to support assessment tool
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CONCLUSION

- WHO BRN members feel that development of assessment tools for blood regulatory systems will serve as a useful tool to evaluate gaps or areas for improvement in national blood programs of both developed and developing
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Questions or Comments?