



IX PAN-RUSSIAN
GMP CONFERENCE



MINISTRY OF INDUSTRY
AND TRADE OF RUSSIA



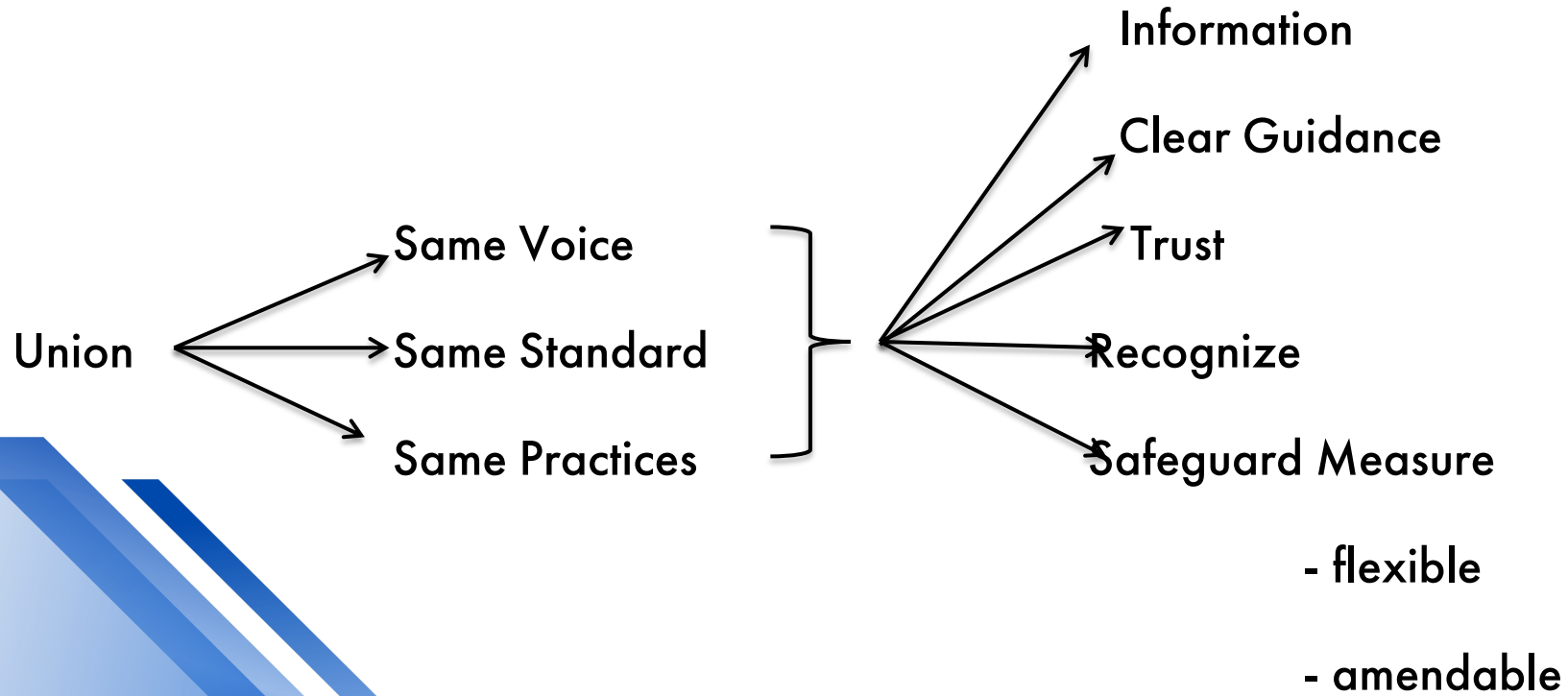
“Regional Unions – Advantages and disadvantages Manufacturers of Medical Products”

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- Myanmar is one of the member of ASEAN Pharmaceutical Products Working Group.
So Food and Drug Administration Drug Control official as focal of Pharmaceutical Products Working Group (PPWG).
- Pharmaceutical Products Working Group is actively participate the Role of Regulation, Standard, Guideline, Safety alert, Capacity building of regulators. There is implementing Working Group; Task Force on BA/ BE, GMP, APRF.



Malaysia is Chair, Myanmar is Co-chair of Pharmaceutical Products Working Group in 2024.

Regional Unions Advantages

1. Harmonization and implementation of ASEAN Common Technical Dossier, ASEAN Common Technical Requirement for Marketing Authorization
2. Lead countries of technical task force **discuss** the technical matters and also **ask** opinion of other for implementation. (e. g Listed Inspection Services on GMP, BE)
3. Regional Unions that make **one voice** to other international development partner for Cooperation of future development.

Disadvantages - 1. Myanmar Experience: Among ASEAN Some countries are developed but some are developing. So different level of developing status, need the time for negotiation esp: Standard/ Mutual Recognition

Arrangement (GMP, BABE) etc.

2. Each NRA has own national law and regulation, So MRA process need to review and revised more time Regulatory frame work

Agreement. (Some countries protect their own safeguard.)

3. There is a country specific requirement and other trade related issue matters, So full in implementation will be difficult and face challenges. Difficult to take the action immediately.



THANK YOU
ကျေးဇူးတင်ပါသည်။ (Спасибо)

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