



QUALITY ASSURANCE IN RECONSTITUTION

- **Medication error:** any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to: professional practice, health care products, procedures and systems, including prescribing; order communication; **product labelling, packaging, and nomenclature; compounding; dispensing; distribution;** administration; education and monitoring of patients; and use.

Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care of Council of Europe



IMPLEMENTATION MEDICINES AND HEALTHCARE POLICY

- Only standards (justified scientifically) are providing high level of assurance that the process will consistently comply with predetermined expectations
- Policy makers (Ministry of Health) are not able to guarantee safety, quality and efficacy in healthcare establishment (GXPractices)



COUNCIL OF EUROPE RESOLUTION

- Standard elaboration needs resources
- High level of quality assurance (excepting mix-ups and contamination)
- Harmonization between Council of Europe members



DRAFT LICENSING PROCEDURE RA GOVERNMENT DECREE 1936-N

- Designated person (DP)
 - Each healthcare establishment having DP
 - Responsibility
 - Authority (DP or unit)
 - Parenteral manual
 - Preferable to be a pharmacist, otherwise undergo specific training



LONG TERM ACTIONS TO BE TAKEN

- Changes in the Law on Medicines
 - Licensing condition
 - Healthcare establishment must conduct reconstitution according to established standards
 - It is intended to establish Council of Europe Good Reconstitution Practice resolution as a standard

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The SCDMTE

THANK YOU FOR COLLABORATION

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