Specialized technical assistance for medicines

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Specialized technical assistance

WHO provides Specialized Technical Assistance (TA) to help recipients achieve compliance with international regulatory norms and standards, so that they can attain WHO prequalification (PQ) for priority products or services, or emergency use listing (EUL) for unlicensed products to be used in the context of a public health emergency.

- Medicines
- In Vitro Diagnostics
- Vaccines

Unique service by Local Production & Assistance Unit

- Across all stages of development and life cycle
- Continuous nature
- Pre-data collection / pre-production
- Knowledge construction

Across all stages of development and lifecycle

LPA Unit provides guidance and directions **at any stage** of a medicine's development, i.e. for **new generic products** but also for **locally marketed** products.

- Fermentation, semi-synthetic and chemically synthesized generics, as well as (similar) biotherapeutic products (e.g. insulin and monoclonal antibodies).
- Oral dosage forms, parenteral products, transdermal patches, vaginal ring etc.

Examples

- Priority of products within portfolio
- Presentation of API data in the dossier (use of prequalified API, CEP-procedure, APIMF)
- Assistance with a specific aspect at a late development stage, e.g. requirements for compatibility and in-use stability studies for parenteral products.

LPA Unit: Local production & Assistance Unit
EOI: Expression of Interest
API: Active Pharmaceutical Ingredient

Continuous nature

Manufacturers have the ability to provide data and pose inquiries to LPA Unit's experts **on a rolling basis**.

- Queries can be raised at **any moment** and of **any scope**.
  - ✓ GAP analysis on an API Master File (APIMF)
  - ✓ Has the polymorphism of the API been sufficiently addressed?
  - ✓ How to proceed when issues arise with the identification of impurities?
  - ✓ What are the requirements for validation of test methods for excipients?
  - ✓ Is the deviation in the composition of our product compared to that of the reference product sufficiently justified?
  - ✓ Suitability of the batch for bioequivalence and/or comparative dissolution testing (biobatch).

LPA Unit: Local production & Assistance Unit

Pre-production / pre-data collection

To help ensure that the appropriate experiments and studies are conducted, manufacturers can ask the LPA Unit for assistance beforehand.

- ✓ Characterization of the API
- ✓ How to adequately justify a control strategy for impurities or solvents
- ✓ Aspects that need to be addressed for a specific API or dosage form, e.g. stability of the polymorph, suitability of a break mark, compatibility with diluents.

Feedback on protocols before start of production or testing.

- ✓ Validation of analytical procedures
- ✓ Process validation
- ✓ Comparative dissolution testing
- ✓ Stability testing (e.g. storage conditions, parameters, test intervals)

Construction of knowledge

Experts from LPA Unit offer additional clarification to **build understanding of the rationale** behind policies and guidances.

This unique assistance aims to **help addressing queries** raised by assessors and may also **prevent their recurrence** in future applications.

Dedicated training can be provided to manufacturers on specific topics.

LPA Unit: Local production & Assistance Unit

Take home messages

✓ Specialized technical assistance by LPA Unit saves manufacturers time and efforts by diminishing the risk that new experiments and studies need to be conducted after submission and/or of a major dossier revision.

✓ Gained knowledge to be used to address deficiencies raised by assessors as well diminish their recurrence.

LPA Unit: Local production & Assistance Unit

Thank you for your attention