



# EU4Health

## Joint Action Quality of Medicines/ cooperation between Member States and EU / Third countries

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# EU4Health Sub-action: quality of medicines and implementation of the pharmaceutical legislation/strategy

## Scope and Activities

- Support the cooperation between competent authorities by **organizing trainings, joined audits, reassessments and inspections on GMP, and GDP** in the EU and in third countries
- Preparatory work of a **joined audit programme training, planning of joined audits and reassessment planning** in the EU and third countries including for implementation of the MRAs with the US, Switzerland, Japan, New Zealand and Canada, Australia, Israel, UK in consultation with the Compliance Group of the GMDP Inspection working Group
- In the framework of preparation for **future cooperation on the quality of active substances with third countries** - preparation of fact finding missions with inspectors from the Member States.

# EU4Health Sub-action: quality of medicines and implementation of the pharmaceutical legislation/strategy

Total budget: ~ 2,15 M EUR - 2021 WP for 3 years

## Expected results

- 1. Capacity strengthening of EU/EEA inspectors/auditors to ensure compliance with GMP and GDP in inspections and audits**
- 2. Improve compliance with the EU pharma acquis and alignment with the pharma strategy**
- 3. Ensure the quality of the active pharmaceutical ingredients (API) imported from non-EU countries**

# EU4Health - sub action on shortages and quality of medicines

- Quality of medicines and implementation of the pharmaceutical legislation/strategy Total budget ~ 2,15 M EUR for 3 years
- Support cooperation between competent authorities by organizing trainings, joined audits (JAP), reassessments and GMP/GDP inspections in EU (MRA implementation) & third countries
- Discussed with NCAs in June and in September GMDP IWG

# EU4Health - sub action on shortages and quality of medicines

- 2 countries expressed interest in coordinating (AT and FR), high interest to participate in Joint Action
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