# CEP Acceptance - a global achievement (Industry views)

CERTIFIED FOR SUCCESS CONFERENCE
Using the CEP Procedure to elevate quality and drive trust
24. September 2025 | Budapest, Hungary

**Melanie Ramsimmer**, RA Manager, Sandoz Kundl, Austria
APIC member

# Introduction / Agenda

- Advantages of CEPs
- Customer and Change Management
- Limitations and Challenges
- Global Acceptance Overview
- Experience on CEP 2.0
- Conclusion

# Advantages of CEPs from CEP holder's point of view

- ✓Reduces duplication of data
- ✓Speeds up regulatory review
- ✓Confirms compliance with Ph. Eur. standards
- ✓Facilitates lifecycle management
- ✓Simplified process for full and partial recognition areas

# Customer and Change Management

- According to EDQM Guideline “CEP holders' responsibilities towards their customers” it is the responsibility of the CEP holder to provide necessary information:
  - *“In addition to the CEP itself, **CEP holders should provide the MAH with any necessary information** that is needed to guarantee the quality, safety and efficacy of the medicines e.g. information on the route of synthesis of the API, details of risk evaluations for impurities that CEP holders have performed (nitrosamines, elemental impurities, etc.). “*

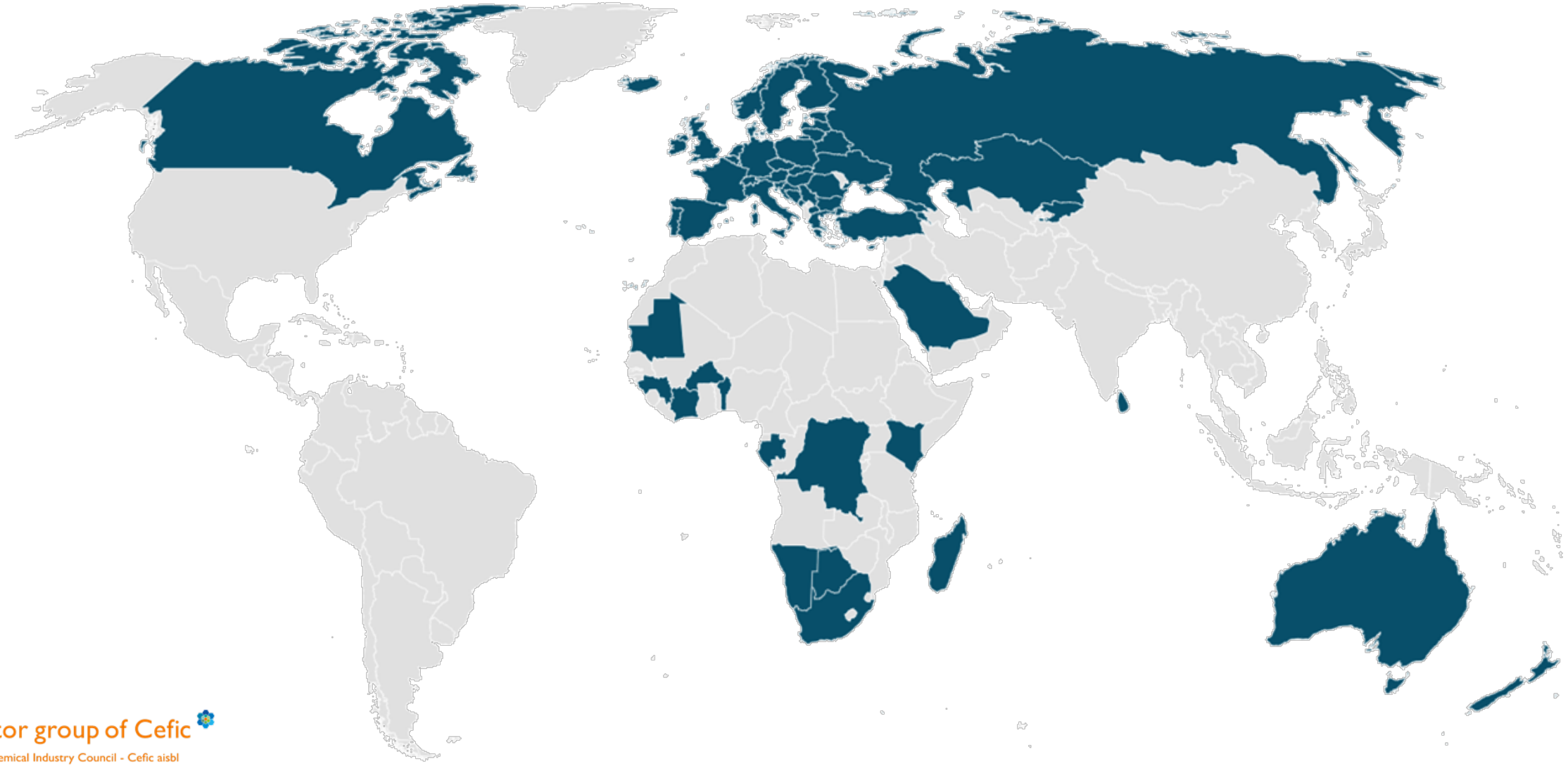
- In case of a variation/CEP revision the CEP holder needs to provide necessary information:
  - “To allow the MAH to evaluate the impact of any change introduced by the API manufacturer/CEP holder, regardless of whether it leads to a revision of the CEP and to update the marketing authorisation information, it is of utmost importance that the **CEP holder provides the necessary information to their customers**.”

- Link to EDQM Guideline

# Limitations and Challenges

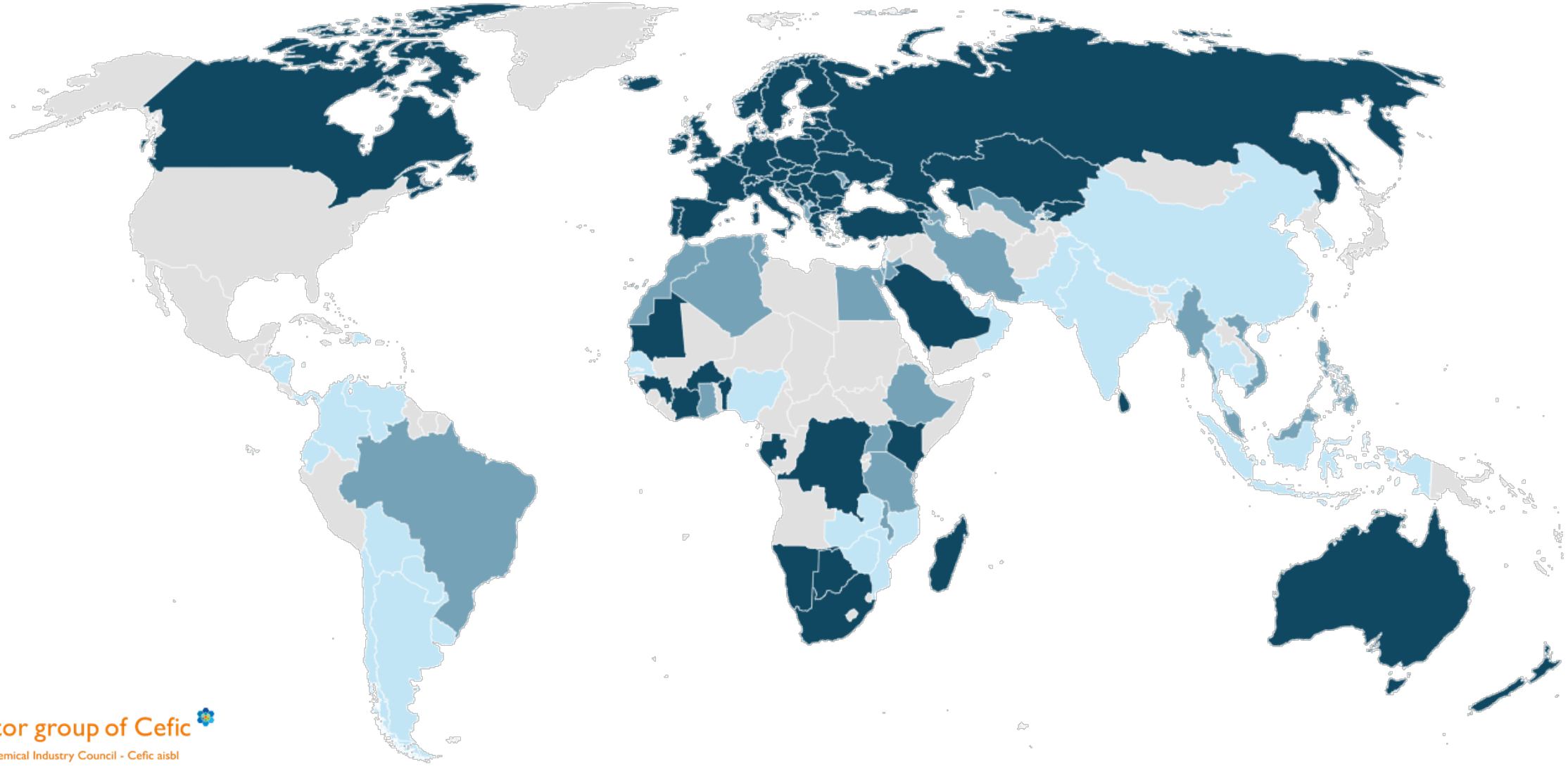
- Information that is not included in CEP (e.g. container closure, storage condition, retest period)
  - Triggers requests for additional information from customer
- Most requests:
  - API specification, analytical methods and method validations -> improvement expected with CEP 2.0
  - Container closure, stability data (in case retest period is not on CEP)
- Open Part shared with customers
  - For the CEP holder it is not always clear whether the information is intended for internal use – where the MAH can ensure the quality, safety, and efficacy of the medicines – or whether it is provided to the Health Authority to support the CEP
  - MAH expect generally more for internal use, as to be provided to Health Authority

# Global Acceptance Overview
# Full recognition



APIC
ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

# Global Acceptance Overview
# Partial recognition / Helpful



A sector group of Cefic
European Chemical Industry Council - Cefic aisbl

# Global Acceptance Overview Europe

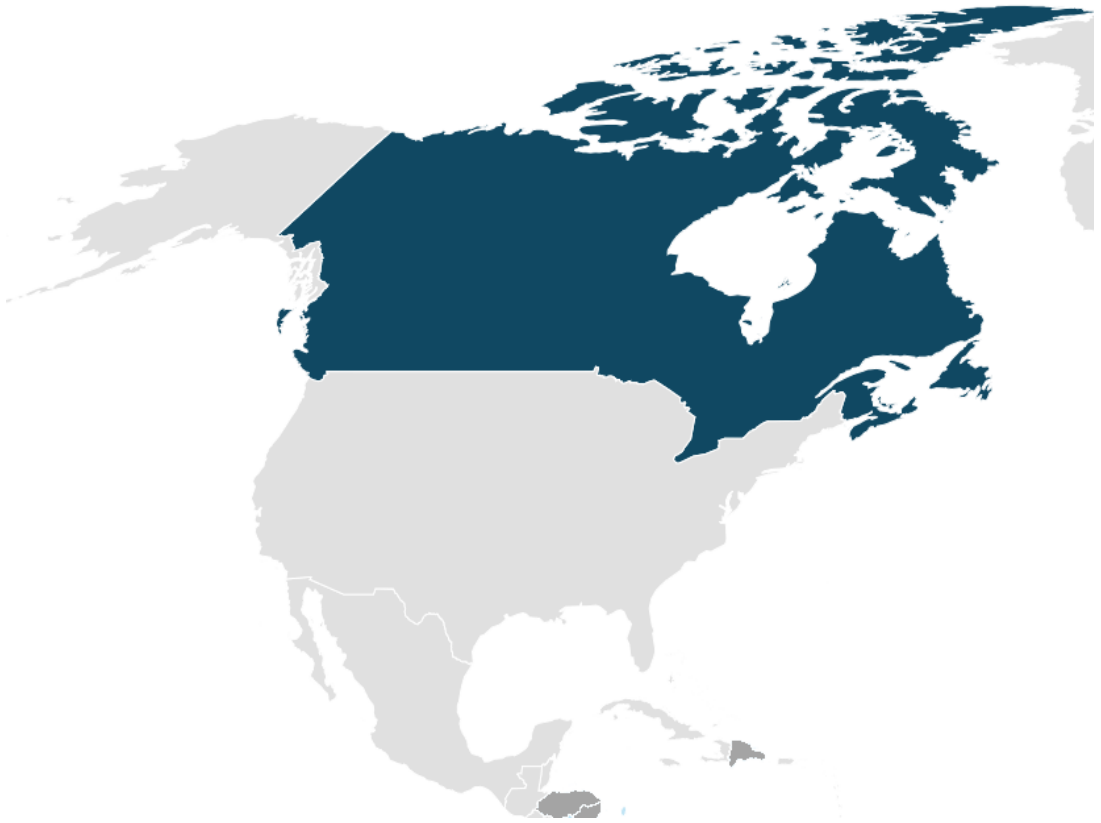
- Full recognition
- Good experience
- Some exceptions:
  - Albania
  - Greece
  - Kosovo
  - Moldova
  - Netherlands
    - signed sections needed
  - Poland
  - Serbia
  - Turkey
    - additional documents needed, signed sections

# Global Acceptance Overview Australia and New Zealand

- Full recognition
- Good experience with CEP and supportive forms
- Letter of Access to EDQM evaluation report

# Global Acceptance Overview North America

- Canada
  - Good experience with full recognition
  - Special case: sterile APIs
- Mexico:
  - CEP is not acceptable since HA requires specific information mentioned in DMF open part
- US:
  - Full US DMF to be filed

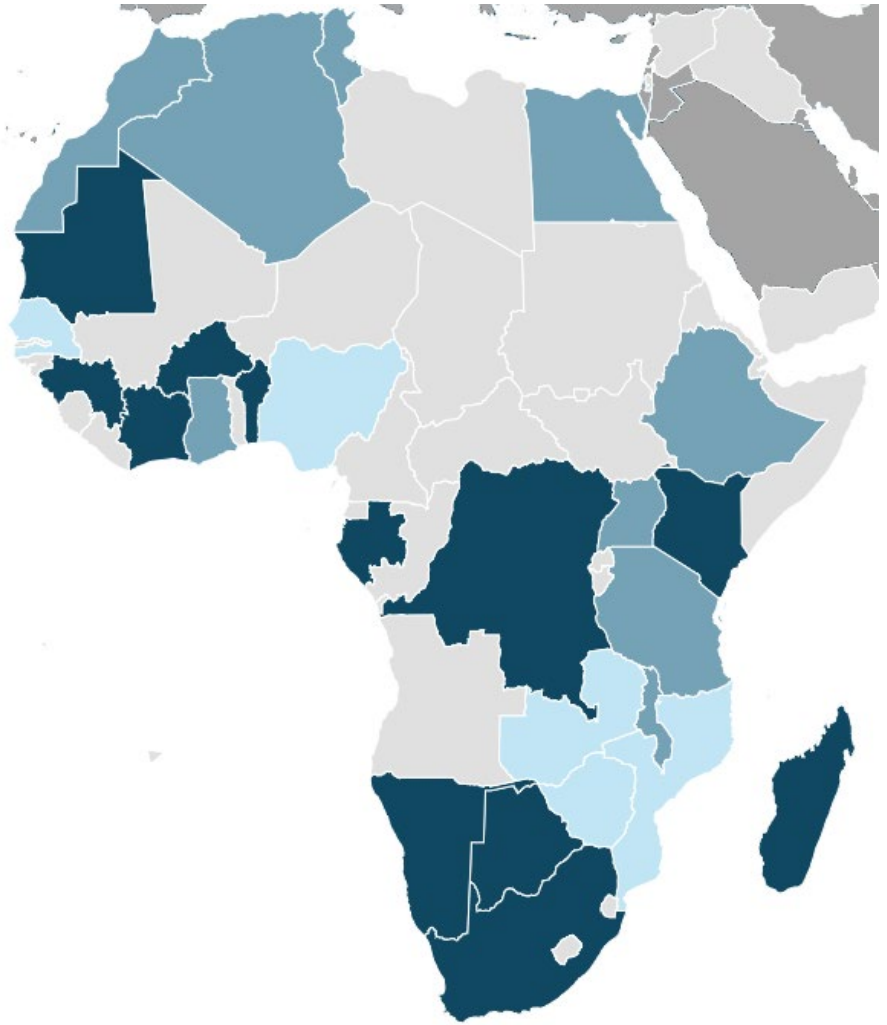


# Global Acceptance Overview Middle and South America

- Partial recognition
  - Brazil
    - CEP is partially recognized; for CADIFA and not CADIFA procedures
  - Uruguay
    - CEP is very useful to complete validation process of a new supplier

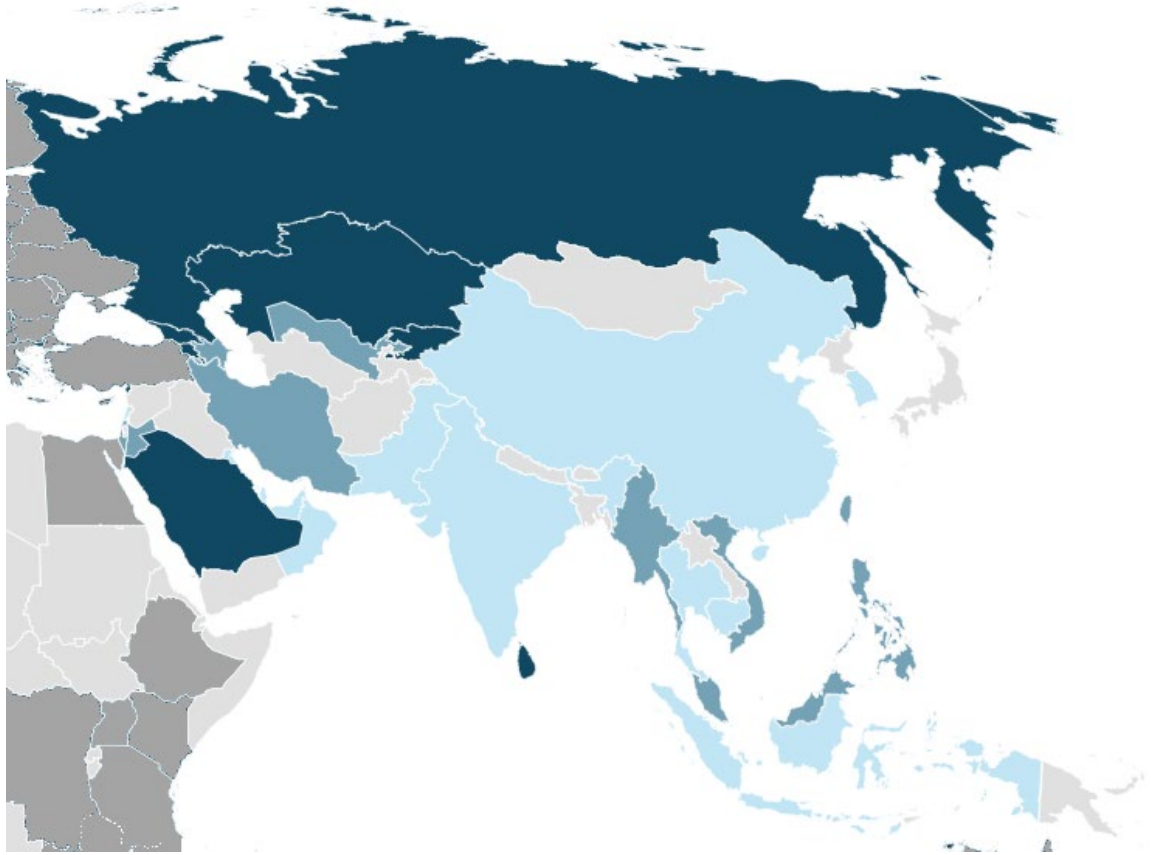
# Global Acceptance Overview Africa

- Full recognition
  no additional documentation required
  - Benin, Botswana, Burkina Faso, Congo, Gabon, Guinea, Ivory Coast, Kenya, Madagascar, Mauritania
  - recent experience: Algeria, Egypt, Malawi Morocco, Namibia, South Africa (different experiences, signed sections), Tanzania
- Partial recognition / Helpful
  - e.g. Ethiopia, Ghana
  - Nigeria
    - CEP is helpful for faster review



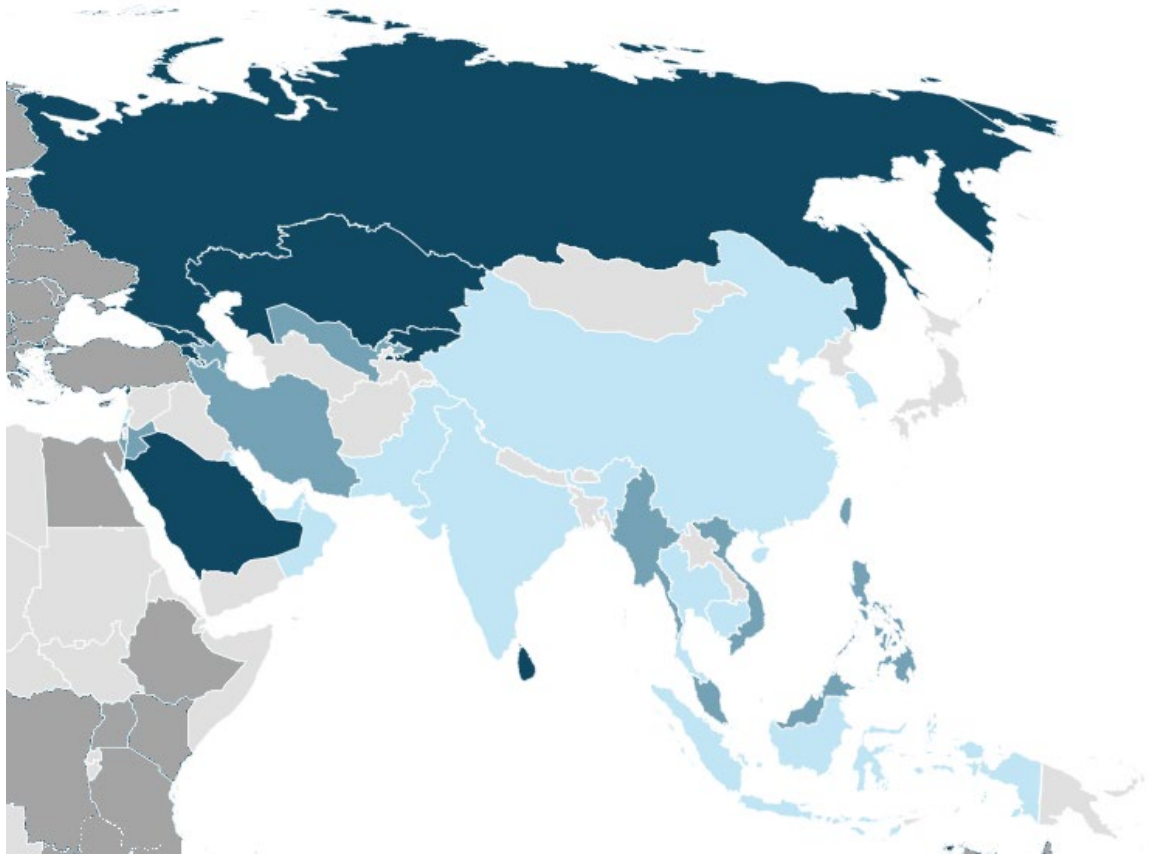
# Global Acceptance Overview Asia – Part I

- Full recognition
  - for members of EAEU
    - Kazakhstan exception (DMF part is also required even if supplier is providing the CEP)
  - recent experience: Bahrain, Georgia, Hong Kong, Indonesia (different experiences), Israel, Jordan, Malaysia, Philippines, Saudi Arabia (according to HA presentation), Singapore, Vietnam (different experiences, needs to be legalized)



# Global Acceptance Overview Asia – Part II

- Partial recognition / Helpful
  - e.g. Myanmar, Pakistan
  - Helpful in India
  - Taiwan
    - Simplified procedure
    - Special case: fermentation-derived APIs
  - China
    - CEP is requested for registration, but full DMF needed
    - CEP is not helpful for the speed (could be used as a FSC)
- Recent experience:
  - some countries (e.g. South Korea, Vietnam) do not accept statement that API complies with "EP" (while using **equivalent alternative methods** for testing – even though these methods are approved as equivalent by the EDQM)



# Experience on CEP 2.0

- Good acceptance
- Some clarification requests from customers at the beginning e.g. ask for LoA – good training from EDQM
- For customer items at the beginning clarifications needed
- More experience to be gained

# Conclusions

- CEP is widely accepted globally
- Often provides advantage for submission
- Sometimes additional sections of the DMF are requested in addition to the CEP by customers
- Additional documentation might be requested by HA
  - often in case of CEP only AP needed, not RP
- Different industry experiences for same country scope
  - assumption is made as this depends on molecule / manufacturing process
- Legalizations / stamped and signed DMF sections still exist
- CEP 2.0 – positive first experiences, more practice to be gained

# Conclusions

APIC
ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

# Thank you!

# APIC Contact Information

Home - APIC

Contact - APIC

Pieter van der Hoeven

Anaïs Fantasia