Joint UNICEF–UNFPA–WHO Meeting for Manufacturers and Suppliers

ePQS & eCTD

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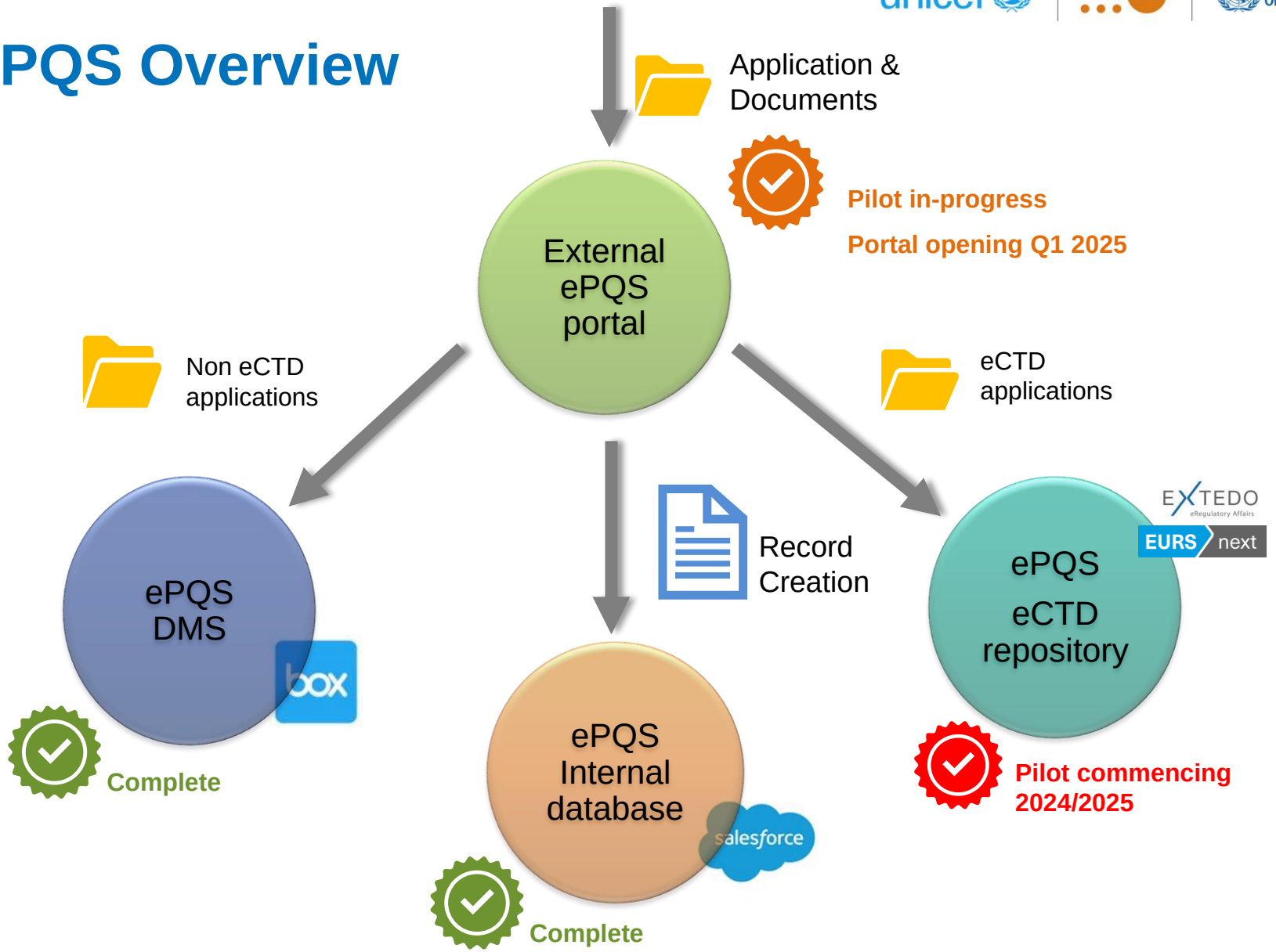
What is ePQS?

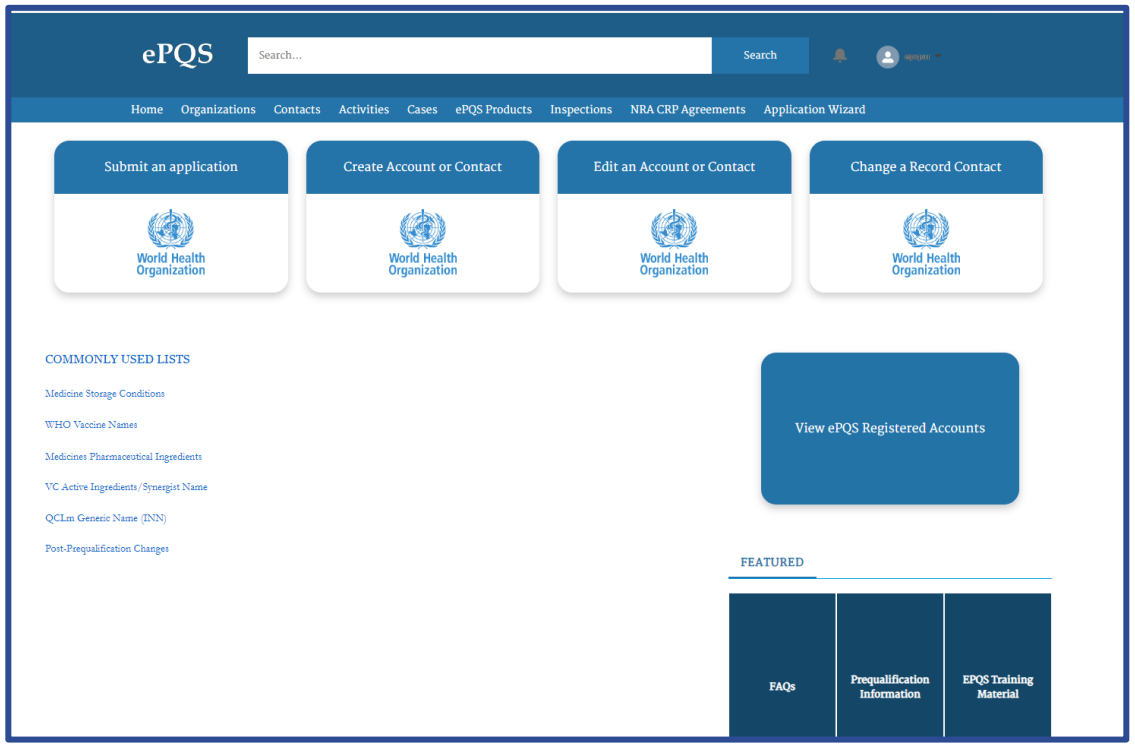
The “**e**lectronic **P**re **Q**ualification **S**ystem” is an IT solution that brings all core areas of WHO PQ Unit into a centralized platform, that will allow the processing of information.

ePQS Overview



ePQS Portal

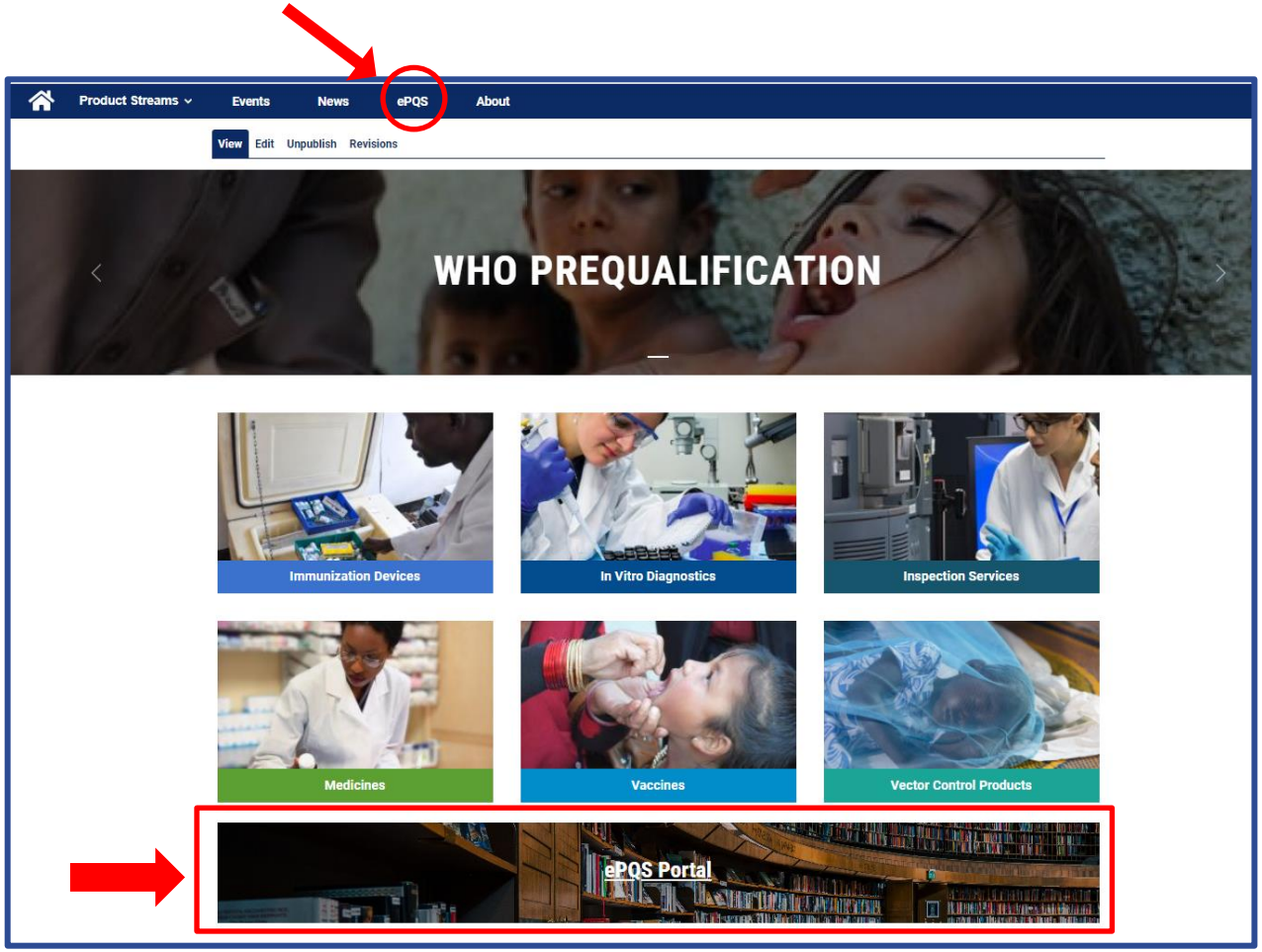
- ✓ A secure platform for external users that uses WHO's Microsoft Azure Active Directory.
- ✓ Submit, manage & track applications:
  - PQ and EUL application,
  - post-PQ changes,
  - annual reports and
  - reassessments.
- ✓ Upload and download documents in a secured environment
- ✓ View and monitor notifications for pending activities.
- ✓ Applicants, NRAs, External experts each have different visibility of records.



The use of the portal will not be mandatory immediately. A transition period is therefore envisaged of 2 to 3 months

Please check portal webpage for more information.
https://extranet.who.int/prequal/epqs-portal

Access to the ePQS portal



https://extranet.who.int/prequal/

eCTD – electronic Common Technical Document

- Integration is being developed to allow submission of eCTD formatted documents via the portal into an eCTD repository.
- The purpose is to reduce burden of document lifecycle and facilitate document review by the assessors

eCTD Current status

✓ The eCTD development is completed

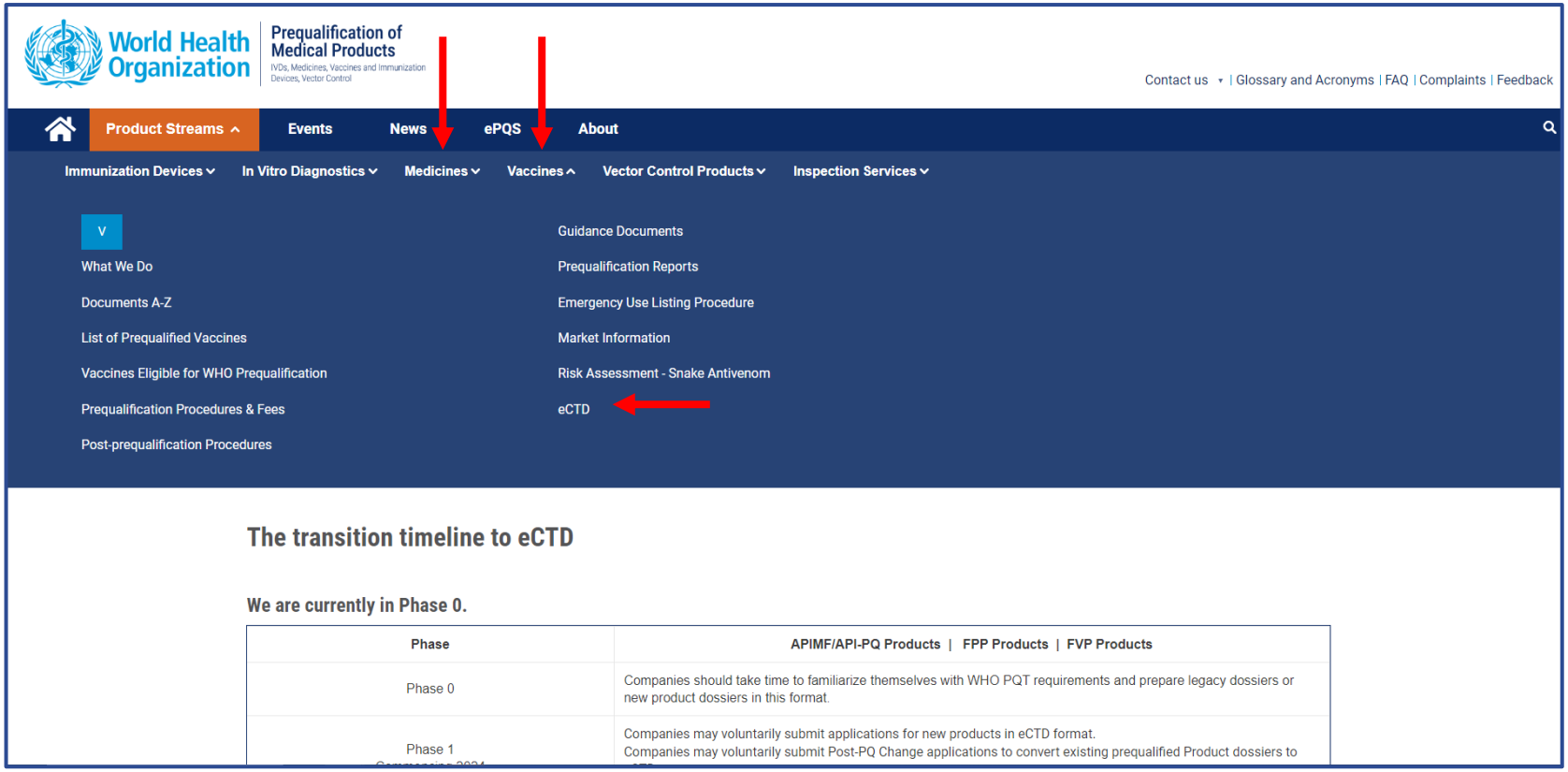
✓ Pilot commencing late 2024/early 2025

✓ Submissions in eCTD format for APIs, FPPS and FVPs will not be compulsory immediately.

eCTD Transition phases

Phase	APIMF/API-PQ Products | FPP Products | FVP Products
Phase 0	eCTD submissions are not possible. Companies should take time to familiarize themselves with WHO PQT requirements and prepare legacy dossiers or new product dossiers in this format.
Phase 1 Commencing 2025	Companies may **voluntarily submit** applications for **new products in eCTD format**. Companies may voluntarily submit Post-PQ Change applications to convert existing prequalified Product dossiers to eCTD.
Phase 2 (+ 1 year) Commencing 2026	Companies **must submit** applications **for new products in eCTD format**. Companies **should submit** Post-PQ Change applications **to convert existing prequalified Product dossiers to eCTD.**
Phase 3 (+ 2 years) Commencing 2027	Both **new and legacy product dossiers must be in eCTD format** for APIMFs, API-PQs and **FVPs**.

eCTD Portal


World Health Organization
Prequalification of Medical Products
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Vaccines Eligible for WHO Prequalification
Prequalification Procedures & Fees
Post-prequalification Procedures
Guidance Documents
Prequalification Reports
Emergency Use Listing Procedure
Market Information
Risk Assessment - Snake Antivenom
eCTD
The transition timeline to eCTD
We are currently in Phase 0.
Phase
APIMF/API-PQ Products | FPP Products | FVP Products
Phase 0
Companies should take time to familiarize themselves with WHO PQT requirements and prepare legacy dossiers or new product dossiers in this format.
Phase 1
Companies may voluntarily submit applications for new products in eCTD format.
Companies may voluntarily submit Post-PQ Change applications to convert existing prequalified Product dossiers to

eCTD Portal – Useful links

https://extranet.who.int/prequal/ectd-portal

eCTD - WHO eCTD guidance for Industry

eCTD - WHOPQT eCTD M1 Specification (Files-Elements-Folders)

THANK YOU