Facilitated Regulatory Pathways through Reliance

Collaborative Registration Procedure for products approved by SRAs (SRA CRP)

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Collaborative Registration Procedure (CRP)

A **reliance mechanism** that **facilitates exchange of information** to **accelerate national registrations** of medical products in countries **through the provision of detailed assessment and inspection reports** from SRAs/PQ to NRAs – **informed reliance**

Applicant

Same product dossier (CTD)

plus

SRA/PQT Product Assessment & Inspection Reports

WHO

To multiple CRP participating countries (NRAs)

WHO

Accelerated assessment and registration of quality-assured products in countries

Faster access to priority quality-assured products by the population

Patients

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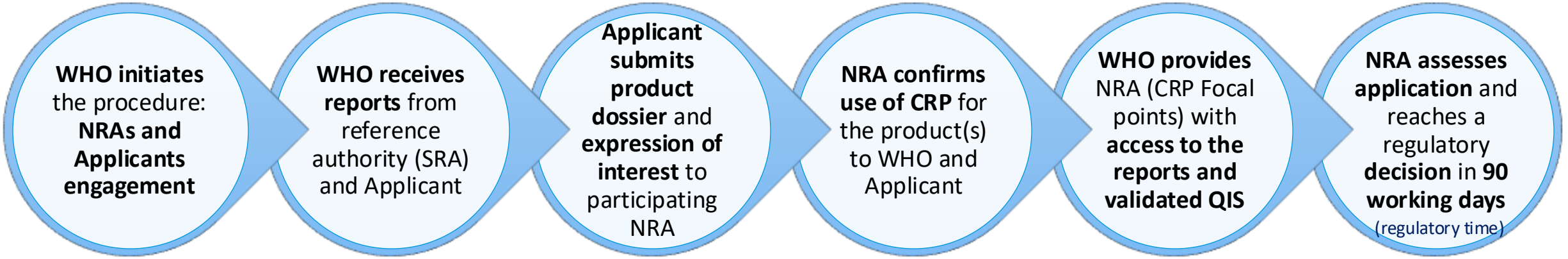
How SRA CRP works

When using CRP, NRAs/countries are able to apply reliance to the following: 1) Product **scientific assessment**/ evaluations; 2) **GMP inspections of** manufacturers, 3) **Testing** prior registration; 4)Post-approval changes such as **variations**



- New Applicant: CDA + training
- NRA: focal points engagement + training (if needed)

- Unredacted Assessment and Inspections reports
- Quality Information Summary (QIS) validated by SRA (WLA)**

- Dossier: ICH CTD format

- Every participating NRA has nominated **focal points** for CRP-related communication
- Reports shared **through secure-web-based platform**

- After approval, NRA uses SRA CRP to apply reliance for **lifecycle management** (PAC) and reaches regulatory decision in **30 working days** (updated QIS updated and validated by SRA)

Product sameness is the underlying principle: **validated QIS to confirm**

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**Completed by applicant and sent to SRA for validation; updated version to be re-validated when there is a PAC affecting the QIS

More information on the procedure available on WHO website: CRP

CRP Product scope

PQ CRP - products prequalified by WHO via full assessment:

- Medicines
- Vaccines
- Biotherapeutics
- IVDs
- Applies to therapeutic areas in the scope of PQ

SRA CRP - any product assessed or approved by an SRA:

- **Innovative and generic products (chemicals or biologicals):** Medicines/Pharmaceuticals, multisource/generics, vaccines, biosimilars, biotherapeutics, etc.
- **Products Prequalified by WHO via Abridged review (**SRA approved)
- **Products approved by special routes or provided with positive scientific opinion: EU M4-all (Article 58), Swissmedic Marketing Authorization for Global Health Products.**
- Applies to any therapeutic area

SRA CRP Participating Countries

- Angola
- Armenia
- Azerbaijan
- Bangladesh
- Benin
- Botswana
- Burkina Faso
- Burundi
- Bhutan
- Brunei Darussalam
- CARICOM**
- Cameroon
- Cabo Verde
- Central African Republic
- Chad
- Comoros
- Cote d'Ivoire
- Democratic Republic of the Congo
- El Salvador
- Eritrea
- Ethiopia
- Gabon
- The Gambia
- Georgia
- Ghana
- Guinea (Republic of)
- Honduras
- Jordan
- Kazakhstan
- Kenya
- Jordan
- Lao PDR
- Lesotho
- Liberia
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Mauritania
- Montenegro
- Mozambique
- Namibia
- Nepal
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Paraguay
- The Philippines
- Qatar
- Republic of Congo
- Rwanda
- Sao Tome and Principe
- Senegal
- Serbia
- Sierra Leone
- South Africa
- Sri Lanka
- United Republic of Tanzania (Mainland and Zanzibar)
- Thailand
- Timor Leste
- Togo
- Türkiye
- Tunisia
- Uganda
- Ukraine
- Yemen (Sana'a)
- Yemen (Aden)
- Zambia
- Zimbabwe

Signed Agreements (Appendix 1)*

SRA CRP: 68 agreements for 65 countries & 1 REC

*as of November 2025

** Caribbean Community, CARICOM
15 Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

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SRA CRP - Stringent Regulatory Authorities (SRA)

Based on the above interim definition, the following is the list of the countries whose NRAs are designated as SRAs.

Australia	Germany	Netherlands
Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Iceland	Romania
Canada	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Japan	Spain
Czech Republic	Latvia	Sweden
Denmark	Liechtenstein	Switzerland
Estonia	Lithuania	United Kingdom
Finland	Luxembourg	United States of America
France	Malta	Norway

Plus

European Medicines Agency (EMA)

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- As defined in WHO Technical Report Series 1003
- **Participating "SRAs"** as of today:
  - EMA
  - FIMEA (Finland)
  - MEB (The Netherlands)
  - MHRA (UK)
  - MPA (Sweden)
  - Swissmedic (Switzerland)
  - TGA (Australia)
  - Paul-Ehrlich-Institut (Germany)
- **No restrictions to participation** - any SRA that can share reports can participate
- Procedure is **being updated to incorporate WHO-Listed Authorities (WLAs)**

Relevant Tools and Resources

SRA CRP

Annex 11

Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

TRS 1010 - Annex 11: Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

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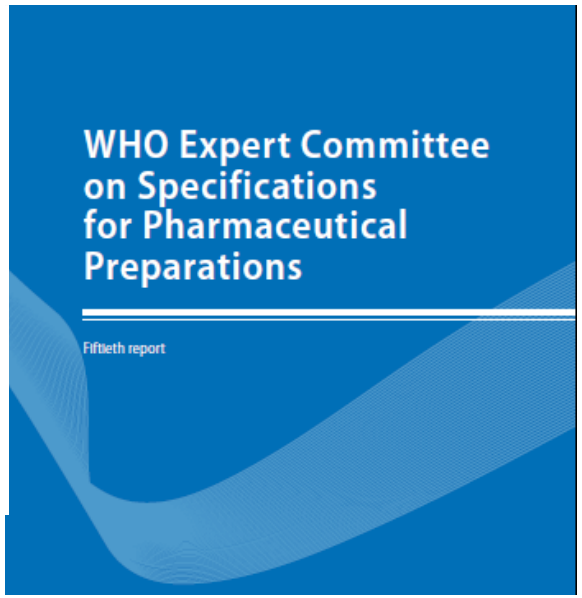
PQ CRP



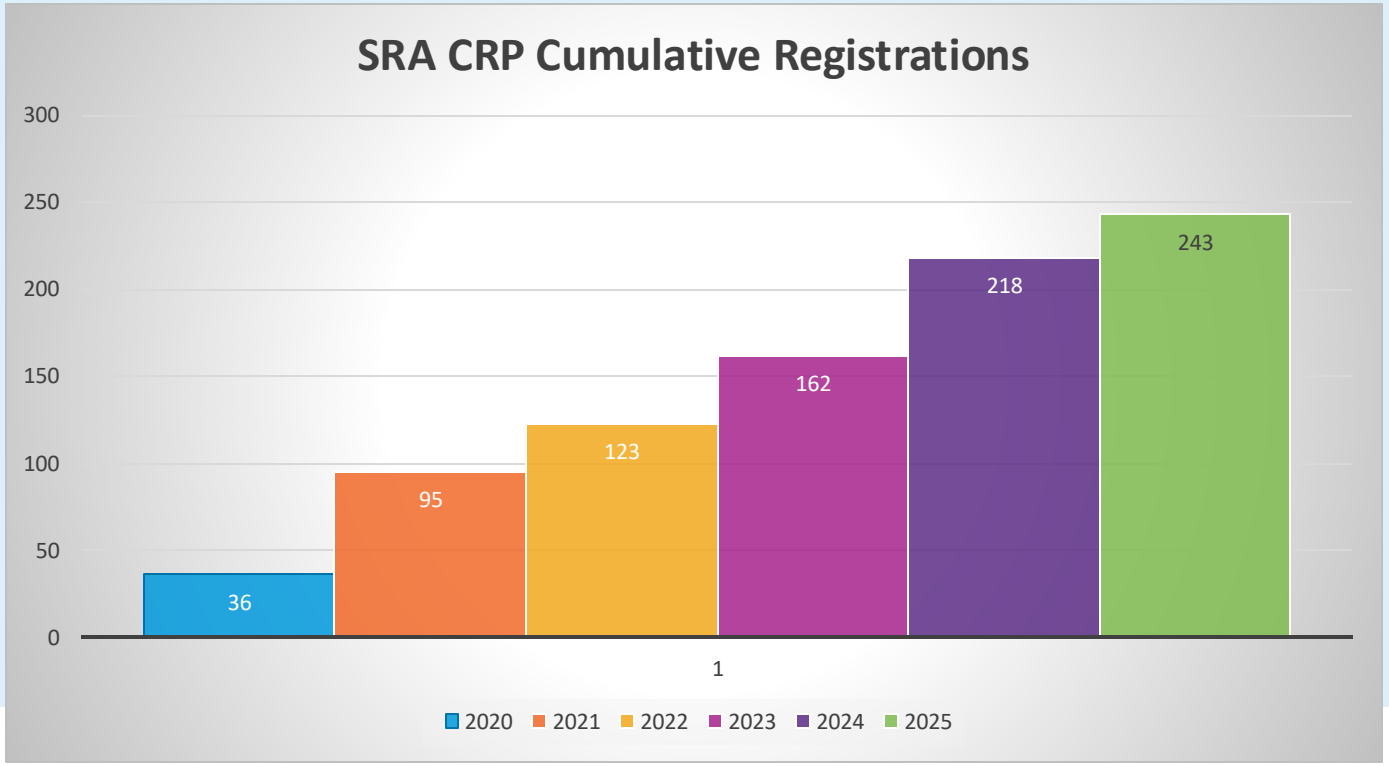
Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

TRS 966 - Annex 8: WHO collaborative procedure between the WHO prequalification team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

SRA CRP data and progress in 2025

- Number of Product Submissions and Registrations in 2025



Number of prod. submissions in 2025:

368

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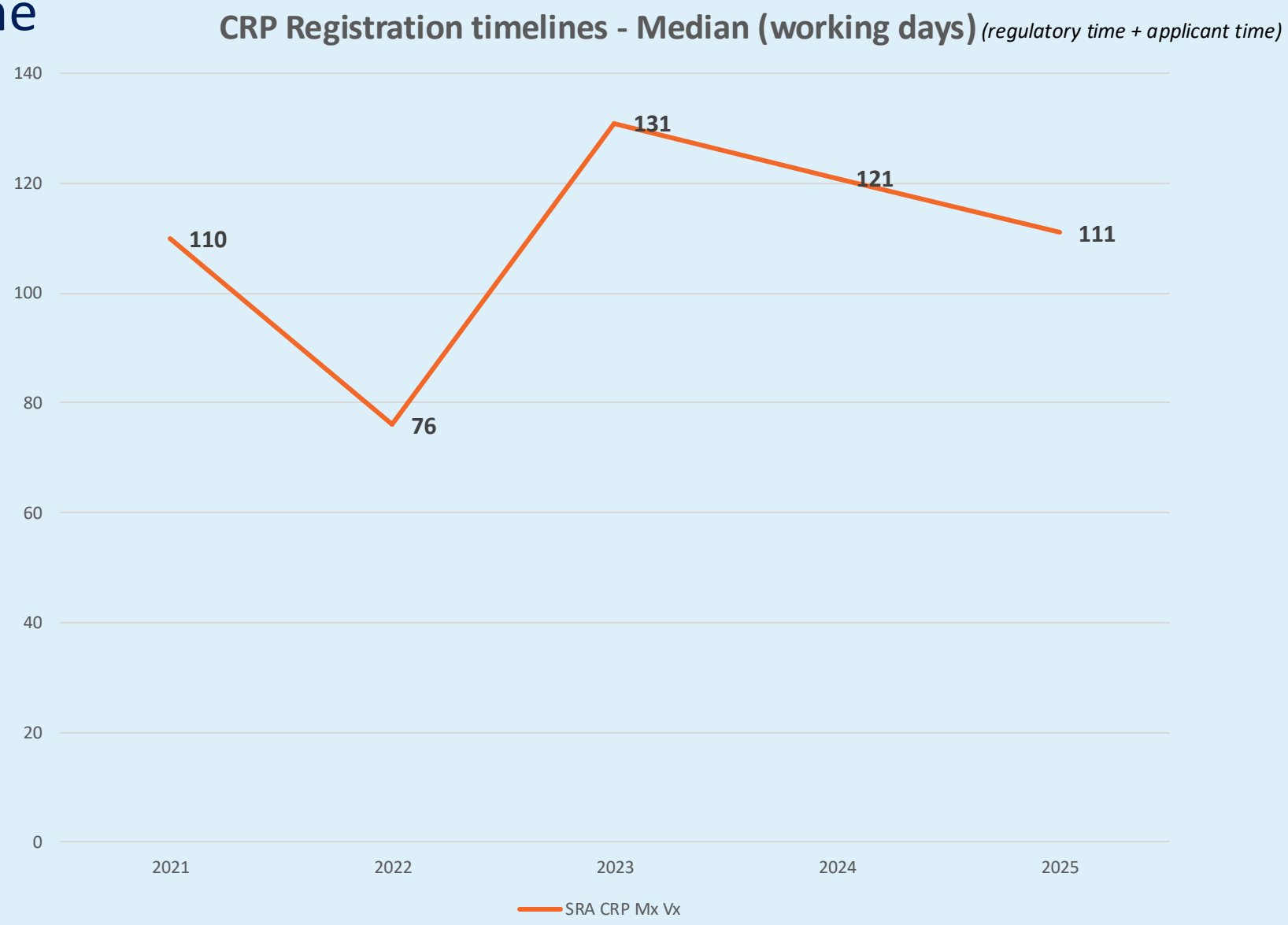
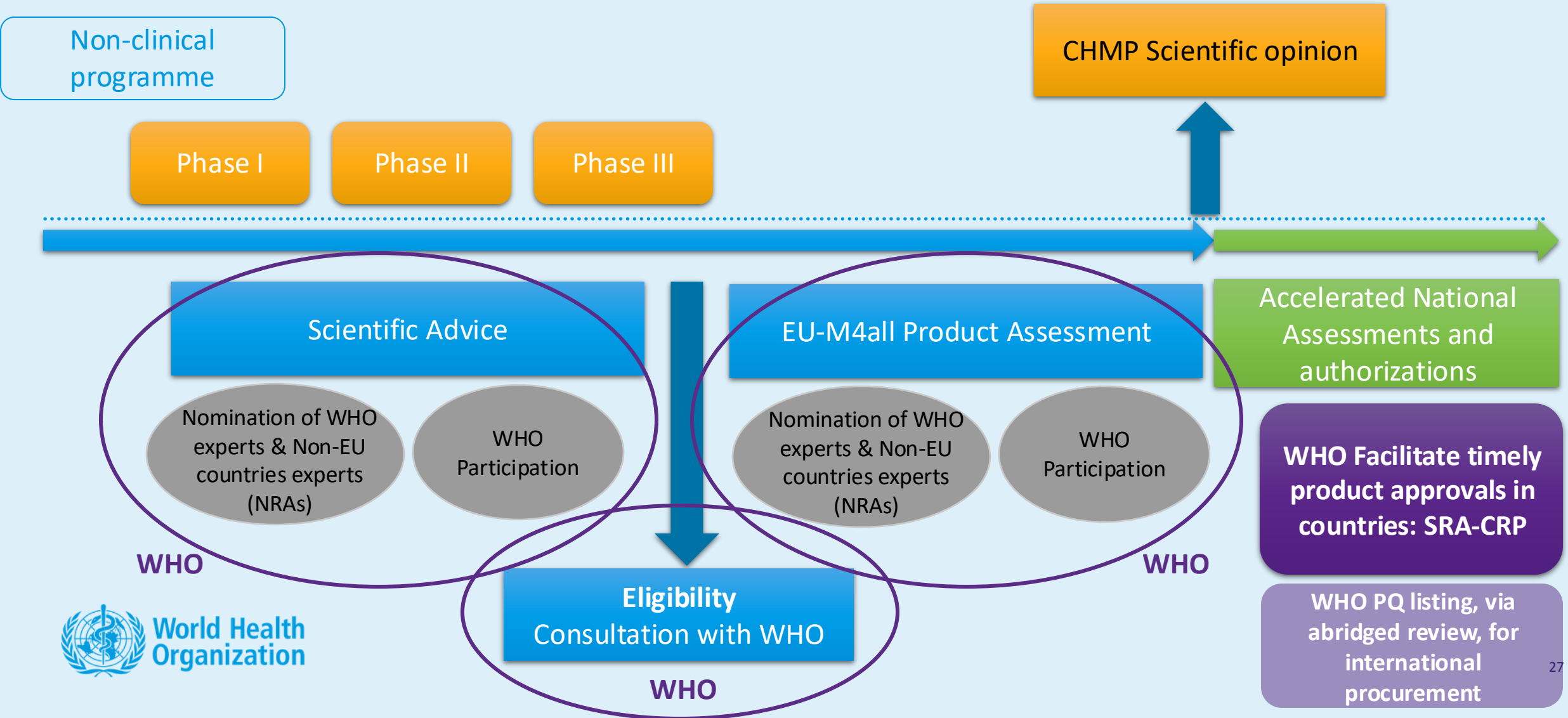
SRA CRP Data – Median time

- Median time to registration **includes both applicant time and regulatory** (NRA) time
- Longer timelines due to innovative nature of products (versus generics for other CRP streams)
- Registration within 6 months: **Significantly less than NRA timelines**
- **Shortest time** to registration observed is **5 working days**
- Full list of registrations is published on the website: FPI SRA CRP Webpage



Data as at October 2025

Role of WHO in EU-M4all procedures



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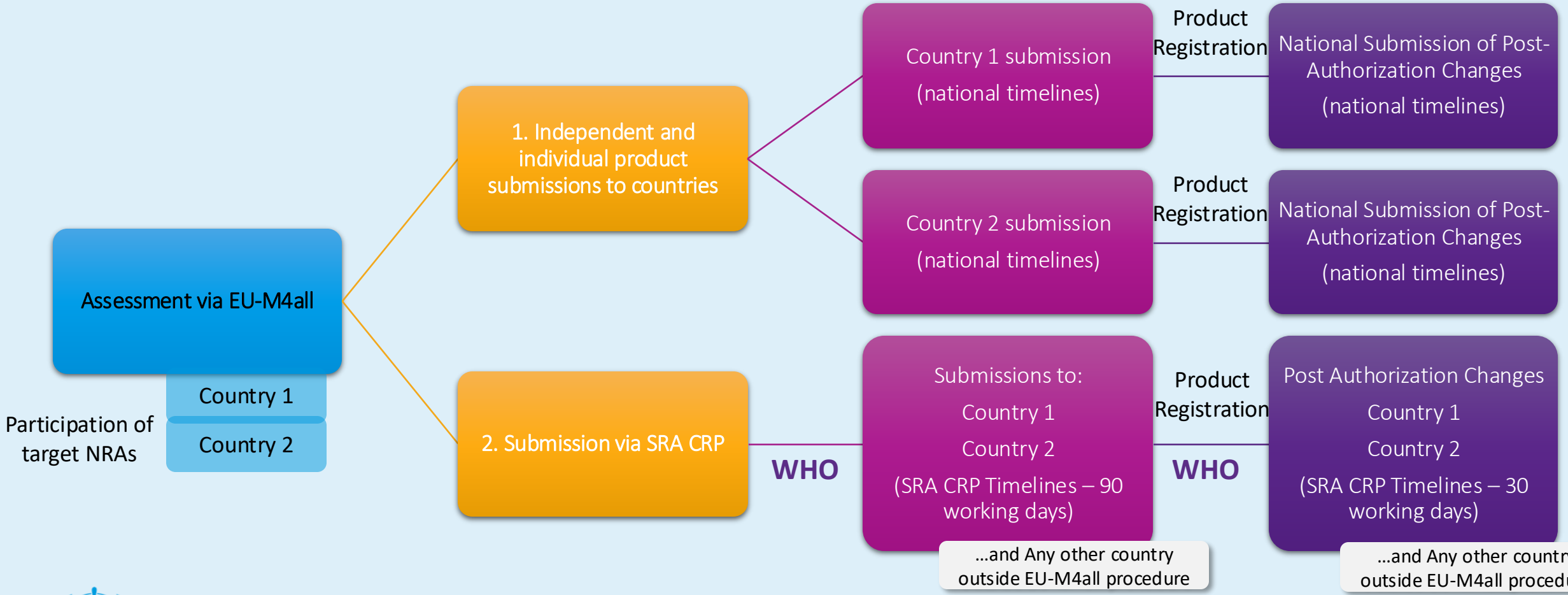
Accelerated in-country Registration

Two Product Introduction Pathways following EU-M4all



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Lenacapavir Case

Lenacapavir Gilead 300 mg film-coated tablet
Lenacapavir Gilead 464mg solution for injection

1. Q2-Q4 2024: Engagement between EMA, WHO and applicant to plan EU-M4all and SRA CRP

Assessment via EU-M4all

2. Q1-Q3 2025: EU-M4all Assessment and positive scientific opinion
3. Q4 2025: SRA CRP was initiated for an accelerated product approval in countries

1. Independent and individual product submissions to countries

1. South Africa: submitted in March 2025 in parallel with EUMed4all

South Africa NRA submission

(national timelines)

1. SA approval End of October 2025

National Submission of Post-Authorization Changes

(national timelines)

2. Submission via SRA CRP

Q4 2025

1. Malawi
2. Zambia
3. Zimbabwe
4. Kenya
5. Uganda
6. Botswana
7. Rwanda
8. Tanzania
9. Namibia
10. Nigeria
11. Ethiopia

SRA CRP procedure

(approval Timelines – 90 working days)

1. Malawi:
2. Zambia: 4 November 2025 (approval in 12 working days)
3. Zimbabwe: 19 November 2025 (approval in 18 working days)
4. Kenya:
5. Uganda:
6. Botswana:
7. Rwanda:
8. Tanzania:
9. Namibia:
10. Nigeria
11. Ethiopia:

Post Authorization Changes

(SRA CRP approval Timelines – 30 working days)

Case of Lenacapavir submissions as an example of substantial efficiencies when applying reliance through SRA CRP, following SRA assessment (EU Med4all)

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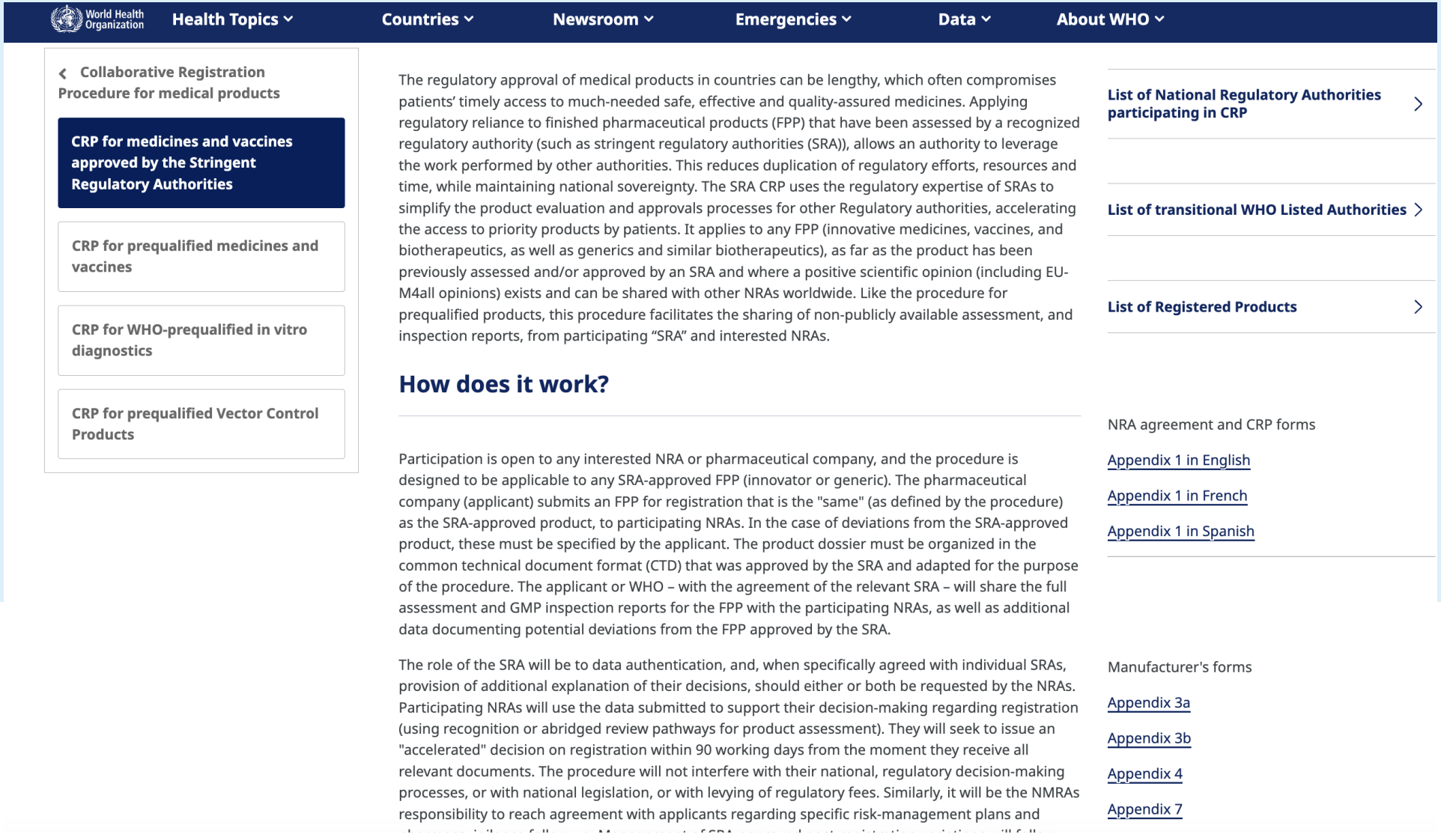
Information Resources

Additional information, relevant guidelines, forms and statistics available on the Facilitated Product Information website



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Collaborative Registration Procedure for medical products

- **CRP for medicines and vaccines approved by the Stringent Regulatory Authorities**
- CRP for prequalified medicines and vaccines
- CRP for WHO-prequalified in vitro diagnostics
- CRP for prequalified Vector Control Products

The regulatory approval of medical products in countries can be lengthy, which often compromises patients' timely access to much-needed safe, effective and quality-assured medicines. Applying regulatory reliance to finished pharmaceutical products (FPP) that have been assessed by a recognized regulatory authority (such as stringent regulatory authorities (SRA)), allows an authority to leverage the work performed by other authorities. This reduces duplication of regulatory efforts, resources and time, while maintaining national sovereignty. The SRA CRP uses the regulatory expertise of SRAs to simplify the product evaluation and approvals processes for other Regulatory authorities, accelerating the access to priority products by patients. It applies to any FPP (innovative medicines, vaccines, and biotherapeutics, as well as generics and similar biotherapeutics), as far as the product has been previously assessed and/or approved by an SRA and where a positive scientific opinion (including EU-M4all opinions) exists and can be shared with other NRAs worldwide. Like the procedure for prequalified products, this procedure facilitates the sharing of non-publicly available assessment, and inspection reports, from participating "SRA" and interested NRAs.

How does it work?

Participation is open to any interested NRA or pharmaceutical company, and the procedure is designed to be applicable to any SRA-approved FPP (innovator or generic). The pharmaceutical company (applicant) submits an FPP for registration that is the "same" (as defined by the procedure) as the SRA-approved product, to participating NRAs. In the case of deviations from the SRA-approved product, these must be specified by the applicant. The product dossier must be organized in the common technical document format (CTD) that was approved by the SRA and adapted for the purpose of the procedure. The applicant or WHO – with the agreement of the relevant SRA – will share the full assessment and GMP inspection reports for the FPP with the participating NRAs, as well as additional data documenting potential deviations from the FPP approved by the SRA.

The role of the SRA will be to data authentication, and, when specifically agreed with individual SRAs, provision of additional explanation of their decisions, should either or both be requested by the NRAs. Participating NRAs will use the data submitted to support their decision-making regarding registration (using recognition or abridged review pathways for product assessment). They will seek to issue an "accelerated" decision on registration within 90 working days from the moment they receive all relevant documents. The procedure will not interfere with their national, regulatory decision-making processes, or with national legislation, or with levying of regulatory fees. Similarly, it will be the NMRAs responsibility to reach agreement with applicants regarding specific risk-management plans and

List of National Regulatory Authorities participating in CRP

List of transitional WHO Listed Authorities

List of Registered Products

NRA agreement and CRP forms

Appendix 1 in English

Appendix 1 in French

Appendix 1 in Spanish

Manufacturer's forms

Appendix 3a

Appendix 3b

Appendix 4

Appendix 7

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Thank you

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WHO collaborative registration procedure using stringent regulatory authorities' medicine evaluation: reliance in action?

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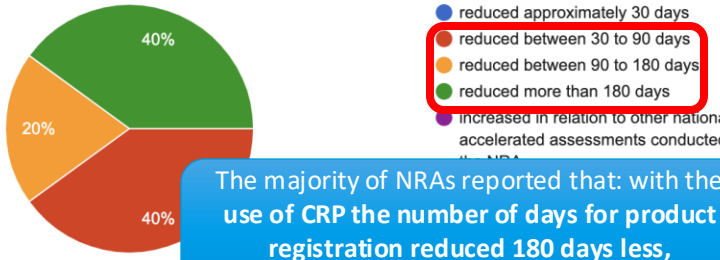
INTRODUCTION The regulatory approval of medical products in countries with limited regulatory resources can be lengthy, which often compromises patients' timely access to much-needed medicines. To improve the efficiency of regulatory systems, reliance is being used. Reliance allows an authority to leverage the work performed by other authorities, such as scientific evaluations, to decide on medical products approval within their jurisdiction. This reduces duplication of regulatory efforts, resources and time, while maintaining national sovereignty.

AREAS COVERED This article analyzes the outcomes and stakeholders' experience of using medicines assessments performed by Stringent Regulatory Authorities (SRA) in the Collaborative Registration Procedures (CRP). Since its establishment in 2015, 59 approvals were granted to 16 medicines in 23 countries through SRA CRP. Results show that the procedure is delivering on the intended benefits of access and speed, with long-term positive impact for resource-limited countries. The article concludes with recommendations on the need for guidance on management of post-approval changes, wider promotion of the procedure, and increased collaboration between authorities.

37. In comparison to your fastest national procedure for assessment and registration of new products outside CRP, through the use of CRP procedure the estimated total number of days needed to evaluate and register a new product at your NRA:

5 responses



The majority of NRAs reported that: with the **use of CRP the number of days for product registration reduced 180 days less,** compared to national procedure outside CRP