COLLABORATIVE REGISTRATION PROCEDURE

SMALL COUNTRY EXPERIENCE

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Scientific Center of Drug and Medical Technology Expertise

MOH ARMENIA



REPUBLIC OF ARMENIA

Territory	29 800 km^2
Population	2 963 000 (2020)
Pharm market	130 mln US $

REGULATION OF MEDICINAL PRODUCTS

GOAL

to implement national medicines policy and ensure the

EFFICACY

SAFETY

QUALITY

ACCESS

of medicinal products



PRODUCT REGULATION REQUIRES, ABOVE ALL, A BALANCE

Protecting public health through an extensive evaluation of a particular product

Promoting public health by making needed products available without undue delay

Implementing flexible approaches to enhancing quicker access of medicinal products, without compromising on stringent standards for safety, quality and efficacy



MODIFICATION OF THE EXISTING LEGAL FRAMEWORK IN ORDER TO ENSURE ACCESS TO ESSENTIAL MEDICINAL PRODUCTS

Goal

Avoiding

- long unpredictable assessment timelines
- duplication of regulatory efforts

Minimizing

- country specific requirements

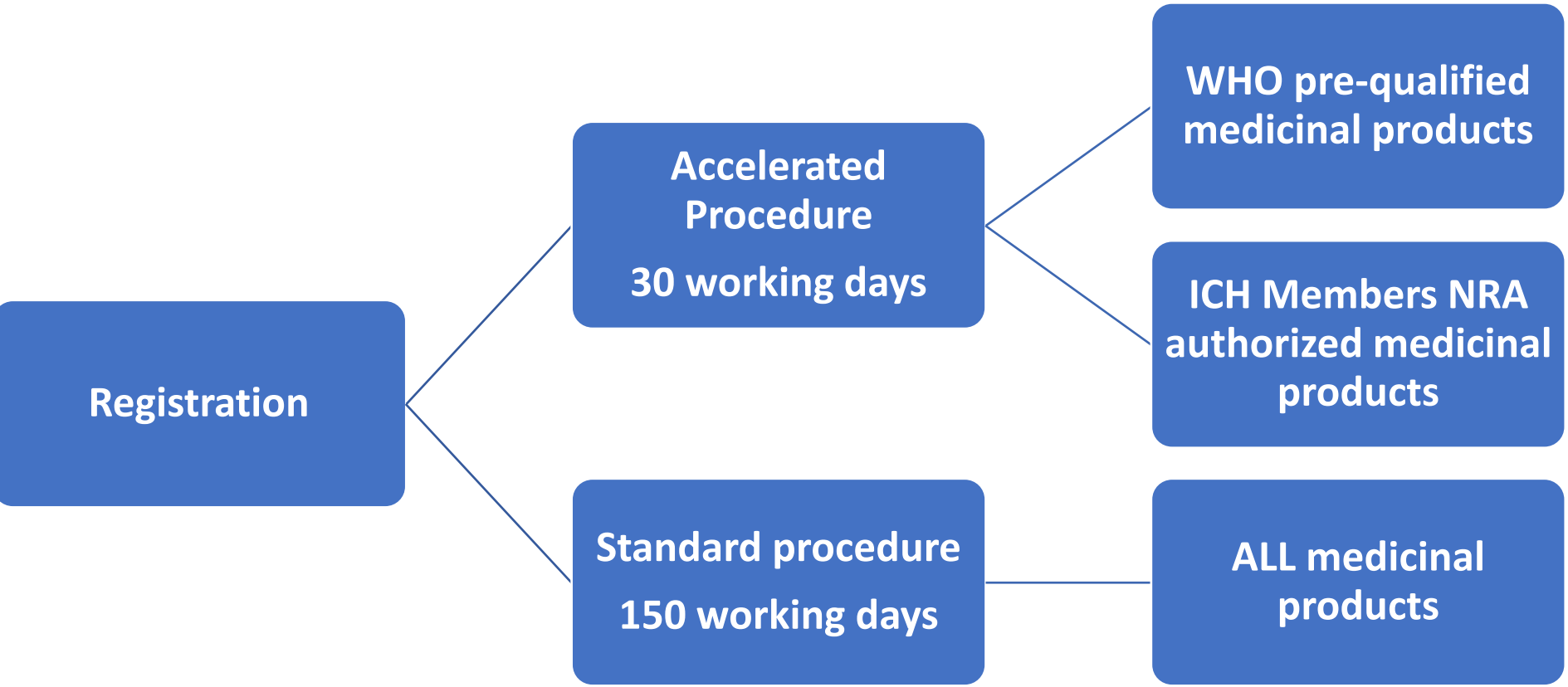


LEGAL AND REGULATORY TOOLS TO SUPPORT AVAILABILITY

- **Labelling and patient leaflet-** use of several languages (Russian, English), translation of PIL and SmPC by NMRA
- **Compassionate *use*-***bedaquiline, delamanid***

- **Fees-**reduction of fees for low-turnover medicinal products assessment
- **Procedure on emergency import of non-registered essential medicines** approved by other regulatory agencies or prequalifid by WHO
- **Abbreviated Evaluation Procedures**, fast –track review based on prior approval by other regulatory agencies or WHO prequalification (participation in WHO collaborative procedures)

NATIONAL REGISTRATION PROCEDURES



INTERNATIONAL COLLABORATION

- **WHO Programme for International Drug Monitoring (Uppsala, Sweden) since 1997**
- **European Pharmacopoeia Commission, observer since 2008**
- **United States Pharmacopoeial (USP) Convention, observer since 2013**
- **WHO collaborative procedure, since 2014**
- **ICH, observer since 2018.**

M Medicines

About Medicines Prequalification
What We Do
Documents A-Z
Prequalification Pipeline
Prequalified Lists
FPPs and APIs Eligible for Prequalification ("EOIs")
Prequalification Procedures & Fees: FPPs, APIs & QCLs
Post-prequalification Procedures & Fees: APIs, FPPs, QCLs

Accelerated Registration of Prequalified FPPs

Finished pharmaceutical products (FPPs) that are WHO-prequalified have been evaluated and inspected according to international standards. But they must still be approved for use by the national medicines regulatory authorities (NMRAs) of the countries for which market entry is sought. Repeating assessment and inspection of those FPPs not only consumes scarce regulatory resources but also extends the time needed to make them available to patients. WHO has therefore designed a collaborative procedure that both enables NMRAs to make use of work already carried out by WHO and to strengthen their own regulatory oversight processes, in line with international best practices. Of greatest interest to manufacturers is that application of the procedure enables faster registration.

The procedure (*Collaborative Procedure between the World Health Organization Prequalification of Medicines Programme and National Medicines Regulatory Authorities in the Assessment and Accelerated National Registration of WHO-prequalified Pharmaceutical Products*) is open to NMRAs in all WHO Member States and holders of prequalified FPPs, on a voluntary basis, and its principles are a model for other regulatory collaborative initiatives.

Information for

Manufacturers
Regulatory agencies
Quality control laboratories
Procurement agencies

Participating Countries

- Armenia
- Azerbaijan
- Belarus

M Medicines

Prequalification Reports

Transparency is a key principle of WHO prequalification. For each generic finished pharmaceutical product (FPP) that is prequalified WHO therefore posts on this website a WHO Public Assessment Report which can be accessed via this website:

- WHO Public Assessment Reports (WHOPARs)

A WHO Public Inspection Report (WHOPIR) is posted following inspection of the manufacturing site of a finished pharmaceutical product (FPP), of an active pharmaceutical ingredient, of a contract research organization (that is linked to prequalification of an FPP), or of a quality control laboratory. WHOPIRs are posted only for those sites that have passed inspection and can be accessed via this website:

- WHO Public Inspection Reports (WHOPIRs)

Additional important outputs of WHO prequalification, of particular value to regulators and procurers are:

Information for

Manufacturers
Regulatory agencies
Quality control laboratories
Procurement agencies

World Health Organization

WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

M Medicines

Overview of WHO Public Assessment Report (WHOPAR)

Part 1 - Abstract
Part 2 - All accepted presentations (including photo)
Part 3 - WHO-PQ recommended patient information leaflet*
Part 4 - WHO-PQ recommended summary of product characteristics*
Part 5 - Label
Part 6 - Discussion (status at the time of prequalification)
Part 7 - Steps before Prequalification
Part 8 - Steps following Prequalification (from 01 March 2014, only changes to the published information are included)

MedNet

World Health Organization

- **Access WHO non public reports**

MedNet World Health Organization

Communities for Scientific collaboration, Information exchange and sharing

Welcome to the Community for WHO Collaborative Registration

The collaborative registration procedure serves to facilitate and accelerate national registration of pharmaceutical products which the WHO Prequalification of Medicines Team (WHO/PQT) has already assessed and prequalified. WHO/PQT assessment and inspection reports are shared with participating National Medicines Regulatory Authorities (NMRAs) at the manufacturer's request. The decision about national registration of a product is then expected to be issued within 90 days of information-sharing.

This site serves for sharing of prequalification information with designated regulatory focal points. Access to each relevant product subcommunity is by invitation, subject to a signed confidentiality undertaking and with the prequalification holder's written consent.

More information is found on the WHO/PQT website (http://apps.who.int/prequal) under "Collaborative registration".

Sub-communities

HIDE INACTIVE

5th CRP Meeting Ghana Nov 2017

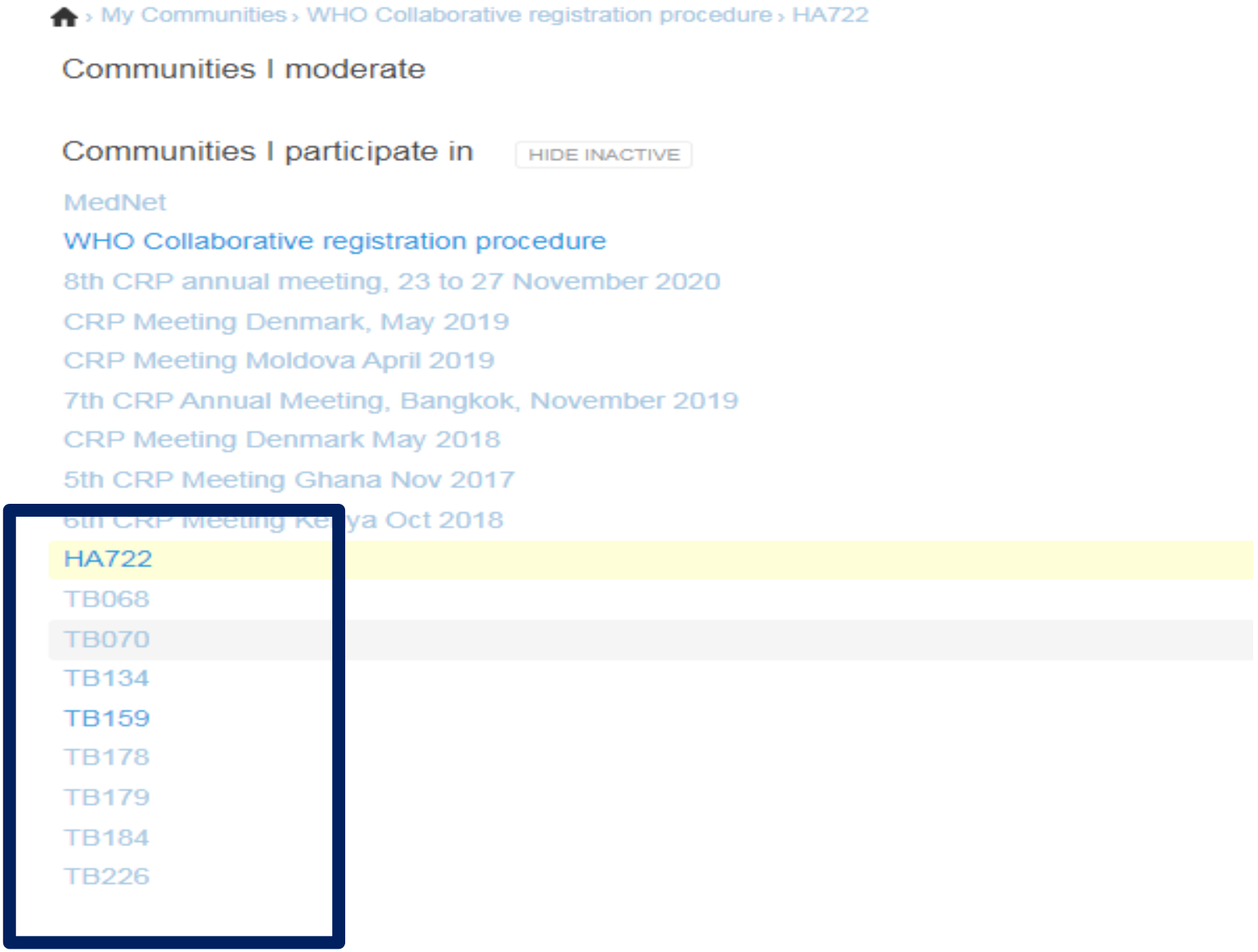
6th CRP Meeting Kenya Oct 2018

7th CRP Annual Meeting, Bangkok, November 2019

8th CRP annual meeting, 23 to 27 November 2020

CRP Meeting Denmark May 2018

CRP Meeting Denmark, May 2019


› My Communities › WHO Collaborative registration procedure › HA722
Communities I moderate
Communities I participate in
HIDE INACTIVE
MedNet
WHO Collaborative registration procedure
8th CRP annual meeting, 23 to 27 November 2020
CRP Meeting Denmark, May 2019
CRP Meeting Moldova April 2019
7th CRP Annual Meeting, Bangkok, November 2019
CRP Meeting Denmark May 2018
5th CRP Meeting Ghana Nov 2017
ya Oct 2018
HA722
TB068
TB070
TB134
TB159
TB178
TB179
TB184
TB226

HA722

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- 0 - WHO PQ documents (click on subfolder names to filter)
  - 1 - Quality assessment-related 7
  - 2 - Bioequivalence assessment-related 3
  - 3 - Assessment of post-prequalification variations 2
  - 4 - Final assessment outcome & latest QIS 7
  - 5 - GMP inspections
  - 6 - Bioequivalence trial inspections
- Armenia 2
- Botswana 1
- Mozambique 2

Appendix2_TRS996_2016_Annex8 consent form.pdf BOTSWANA

HA722-Appendix2_TRS996_2016_Annex8 consent form (1).pdf

HA722-Appendix3_PartA_WHO_TRS_996_2016_Annex8 expres

Appendix3_PartB_HA722.pdf ARMENIA

Appendix 2_Signed.pdf ARMENIA

108HA722Q2.pdf 1 - QUALITY ASSESSMENT-RELATED

105HA722Q2.pdf 1 - QUALITY ASSESSMENT-RELATED

115-114HA722Q2_LP.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QIS

120-119HA722Q2.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QIS

113HA722Q2_LP.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QIS

HA722_QIS_FINAL Feb2021.pdf 4 - FINAL ASSESSMENT OUTCOME & LA

120HA722Q2_LP.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QIS

HA722_QIS_FINAL.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QIS

114HA722_QIS_FINAL.pdf 4 - FINAL ASSESSMENT OUTCOME & LATEST QI

109HA722Q2.pdf 1 - QUALITY ASSESSMENT-RELATED

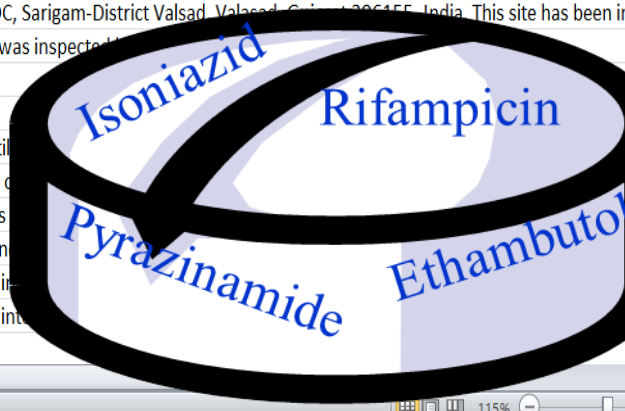
STATUS OF CRP APPLICATIONS

APPROVED	→	9
UNDER REVIEW	→	1
PENDING	→	1

Products registered through the WHO collaborative registration procedure

E5 Country of registration

	A	B	C	D	E	F	G
1	**Products registered through the WHO collaborative registration procedure**				www.who.int/prequal - Collaborative Registration		
2	**List Number 64, updated 12July 2021**				9 marketing authorizations approved		
3	▶ Notes and disclaimer						▶ Update history
4							
5	**WHO PQ number**	**Notes**	**Product**	**Prequalification holder**	**Country of registration**	**Region**	**Registration date**	**Registration numb**
547	TB068		Isoniazid + Rifampicin Tablets 75mg + 150mg	Lupin Ltd	Armenia	EURO	8.Dec.16	16213
552	TB070		Ethambutol + Isoniazid + Pyrazinamide + Rifampicin Tablets 275mg + 7	Lupin Ltd	Armenia	EURO	8.Dec.16	16215
564	TB134		Ethambutol Tablets 400mg	Macleods Pharmaceuticals Ltd	Armenia	EURO	6.Oct.16	16017
576	TB159		Pyrazinamide Tablets 400mg	Macleods Pharmaceuticals Ltd	Armenia	EURO	6.Oct.16	16014
588	TB178		Isoniazid Tablets 100mg	Macleods Pharmaceuticals Ltd	Armenia	EURO	6.Oct.16	16015
592	TB179		Isoniazid Tablets 300mg	Macleods Pharmaceuticals Ltd	Armenia	EURO	6.Oct.16	16016
610	TB184		Isoniazid + Rifampicin Dispersible tablets 30mg + 60mg	Lupin Ltd	Armenia	EURO	5.Oct.17	17059
611	TB185		Isoniazid + Pyrazinamide + Rifampicin Dispersible tablets 30mg + 150m	Lupin Ltd	Armenia	EURO	8.Dec.16	16214
622	TB226		Ethambutol hydrochloride Tablets 100mg	Macleods Pharmaceuticals Ltd	Armenia	EURO	6.Oct.16	16018
701	**Notes:**	1	The product registered in-country is technically the same as RH013, except that it includes 7 inert tablets. Collaborative registration was based on shared prequalification information for RH013.					
702		2	Registration details to be confirmed - the registration number and/or date was not yet available at the time of publishing the updated product list.					
703		3	The product was registered with an additional manufacturing site: Famy Care Ltd, Plot no 1606/1609, Sarigam Industrial Estate GIDC, Sarigam-District Valsad, Valsad, Gujarat 396155, India. This site has been in					
704		4	The product was registered with an additional manufacturing site (PLOT NO. 1606/ 1609 GIDC, Sarigam, Valsad, Gujarat). This site was inspecte					
705		5	[Not used - Note regarding conditional registration in Tanzania, subsequently deleted]					
706		6	[Not used - Note regarding shelf life for a product added 12 Feb 2016, deleted 24 Feb 2016]					
707		7	WHO-PQT found data integrity issues with bioequivalence study. Applicant was informed that importation would be suspended until					
708		8	The product has been registered without considering Anuh Pharma Limited, Boisar, India as a supplier for Pyrazinamide API in view o					
709		9	Of the packaging presentations that have been prequalified by WHO, only the Aluminum foil strip of 5 tablets (1 foil strip in a box) is					
710		10	Of the packaging presentations that have been prequalified by WHO, only the blister pack of 10 tablets (10 blister packs in a box) an					
711		11	Of the packaging presentations that have been prequalified by WHO, only the blister pack of 28 tablets (24 blister packs in a box) is in					
712		12	Of the packaging presentations that have been prequalified by WHO, only the blister pack of 10 tablets (10 blister packs in a box) is int					
713		13	Name change of PQ holder from Jai Pharma to Mylan Laboratories Limited					



Product List | Update History

Ready 9 of 695 records found

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ANTITUBERCULOSIS MEDICINES

National List of Essential Medicines 2021	WHO Model List of Essential Medicines 2021	Registration status/ procedure
ethambutol	ethambutol	CRP
ethambutol + isoniazid	-------	Nonregistered
ethambutol + isoniazid + pyrazinamide + rifampicin	ethambutol + isoniazid + pyrazinamide + rifampicin	CRP
ethambutol + isoniazid + rifampicin	ethambutol + isoniazid + rifampicin	Nonregistered
isoniazid	isoniazid	CRP
isoniazid + pyrazinamide + rifampicin	isoniazid + pyrazinamide + rifampicin	CRP
isoniazid + rifampicin	isoniazid + rifampicin	CRP
-------	isoniazid + rifapentine	Nonregistered
pyrazinamide	pyrazinamide	CRP
rifabutin	rifabutin	Nonregistered
rifampicin	rifampicin	National/Standard
rifapentine	rifapentine	Nonregistered

Home | Drugs

Не защищено | pharm.cals.am/pharm/drug_images/index.php

Դեղերի և բժշկական տեխնոլոգիաների փորձագիտական կենտրոն

isoni | Search In Generic name | English | New search | Login

N	Trade name	Generic name	Dosage form	Dosage strength	Country	Manufacturer	Registred till	Dispensing by	Under Controll	Membership country of origin
1	Rifampicin Isoniazid	rifampicin, isoniazid	tablets film-coated	150mg+75mg; (672/24x28) in blister	India	Lupin Limited, A-28/1, M.I.D.C., Chikalthana, Aurangabad 431 210 for Lupin Limited, 159, CST Road, Kalina Santacruz(East), Mumbai 400098, India	08.12.2021	Prescription	-	
2	Rifampicin Isoniazid Pyrazinamide	rifampicin, isoniazid, pyrazinamide	tablets	60mg+30mg+150mg; (84/4x16/ in blister						
3	Rifampicin Isoniazid Pyrazinamide Ethambutol hydrochloride	rifampicin, isoniazid, pyrazinamide, ethambutol (ethambutol hydrochloride)	tablets film-coated	150mg+75mg+400mg+275mg; (672/24x28/) in blister						
4	Rifampicin 60mg-Isoniazid 30mg Tablets	rifampicin, isoniazid	tablets dispersible	60mg+30mg; (84/14x6/) in strip						

Home | Drugs | drug galery

Не защищено | pharm.cals.am/pharm/getinfos.php?p_rand=&p_id_drug=124266&p_id_img=0

Rifampicin Isoniazid_1 | Rifampicin Isoniazid_2 | Rifampicin Isoniazid_leaflet eng-rus | Rifampicin Isoniazid_SmPC

29°F Clear

CHALLENGES

- the company has not applied for a MA or Variation or Renewal
- there are discrepancies between the information submitted by the applicant and the one assessed by reference authority
- a product with a valid MA is not placed on the market

New Regional network: Eurasian Economic Union

- **Format of dossier**
- **Product information: structure and content**
- **Joint assessments**
- **Preaproval inspections**

PRODUCT REGULATION REQUIRES A BALANCE

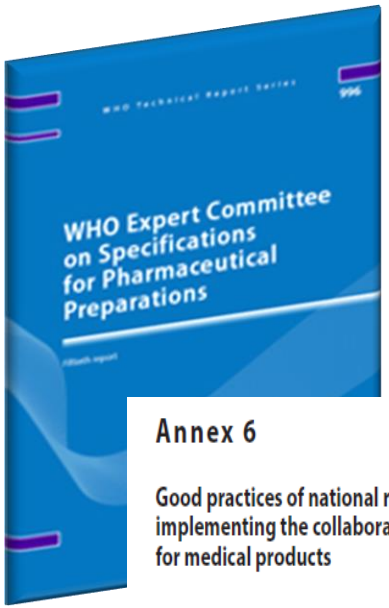
Establishing Strong and Smart Pharmacovigilance System to identify any risk at the earliest possible opportunity

Making earlier access to the medicinal products

KEY ACTION POINTS FOR CRP IMPLEMENTATION

- Establish legal provisions that allow fast track regulatory pathway
- Development of guidelines, including on management of post approval changes
- Development of Internal SOPs
- Development of verification templates
- Training of assessors
- Appointment of Focal Points for communication with WHO
- Update of regulation





Documents approved by WHO Expert Committee on Specifications for Pharmaceutical preparations (ECSPP) https://extranet.who.int/prequal/content/who-technical-report-series

Annex 6

Good practices of national regulatory authorities implementing the collaborative registration proc for medical products

1. Background
2. Aims and objectives
3. Scope
4. Glossary
5. Key principles
6. Essential elements of a registration system (in the context of collaborative registration procedures)

References

Appendix 1 An example of information to applicants for registration via the WHO collaborative registration procedure

Appendix 2 Verification for product submitted under the WHO collaborative proc

Appendix 3 Abridged/abbreviated review for product submitted under the WHO collaborative procedure

Appendix 4 Additional information to be included in the screening checklist

Appendix 5 Example of a national regulatory authority reliance model approach information, documentary evidence and assessment activity

Appendix 6 Model acknowledgement or approval letter for variations of product registered through the WHO collaborative procedure

Annex 9

Guidance on good practices for desk asses compliance with good manufacturing prac laboratory practices and good clinical pract products regulatory decisions

Background

1. Introduction
2. Aim and objectives of the guidance
3. Scope of the guidance
4. Glossary
5. Essential elements of desk assessment
   - 5.1 High-level support and cooperation
   - 5.2 Commonality of quality management systems in inspectorates
   - 5.3 Convergent standards of good practices
   - 5.4 Reliability and accuracy of information
   - 5.5 Management tools to support consistent and objective assessm
   - 5.6 Risk-based assessment of available information
   - 5.7 Mutual trust and confidence among inspectorates
   - 5.8 Quality assurance of the desk assessment process
   - 5.9 Communication of assessment outcomes

Annex 11

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



Looking to the future

- Gradually expand scope of CRP to cover more products including MD and Vaccines

- Encouraged more use of reliance by NRAs at the regional level aimed at reducing duplication building capacity, promoting regulatory convergence and establishing trust.

BENEFITS OF THE COLLABORATIVE REGISTRATION PROCEDURE

Opportunity for work sharing (NRA-WHO) during assessment (assessment REPORT, Variation REPORTS, QIS)

Resource saving abridged review (comparative assessment, no inspection program, no laboratory testing)

Reduced registration timelines and Improved access to quality medicines

Increased regulatory capacity & harmonization of regulatory practices : Detailed reports, Participation in trainings

9th Annual Meeting on Collaborative Procedure Virtual Meeting (Zoom)

13 – 17 December 2021

World Health Organization

Contact:
prequalreg@who.int

THANK YOU FOR YOUR ATTENTION

AND COLLABORATION!!!

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Scientific Centre of Drug and Medical Technology Expertise of MoH of RA

Questions