Regulatory Pathways part II

E training

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Strategies to improve CRP implementation and alignment

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What is the CRP?

The CRP or Collaborative Registration Procedure, is a WHO procedure aimed at facilitating registration of medicines and vaccines in developing countries procuring vaccines internationally.

Based on the establishment of an agreement between WHO, the relevant NRA in the procuring country and the manufacturer of the vaccine

WHO shares with the NRA their reports produced for the evaluation of the product for prequalification and continuing compliance thereafter

The country NRA bases its decision on such reports but can require additional information as per country specific requirements and/or make queries to the manufacturer or contact WHO for clarifications

The country NRA commits to

- keep the information received confidential
- Issue its decision within 90 calendar days of regulatory time
- Able to terminate the procedure and switch to regular procedure
- The decision to register or not remains the prerogative of the NRA

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What is the CRP? (2)

Details of the procedure can be found in

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 996, Annex 8 at

https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex08.pdf?ua=1

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Role of manufacturers in CRP implementation

CRP implementation
Pre-conditions

- Medicines list of countries potentially interested in using the CRP for vaccines registration
- Agreement between NRA, WHO and manufacturer in place
- Vaccine newly prequalified by WHO

Conditions

- Same product information, manufacturing chain, processes controls and batch release scheme
- Same API and finished product specifications
- Submission of Dossier in CTD format
- Module 1 in WHO format for WHO but may be different for the NRA

Dossiers in CTD format

Availability of WHO reports

Country acceptance of Procedure and capacity to review

Manufacturers' actions
Understanding the procedure
Ability to prepare CTD dossiers
Actual submissions to WHO in ICH (EU) CTD
Full alignment between manufacturers for submissions
Invite NRAs on medicines s list to use CRP and inform WHO
Inform WHO of decision by NRA

ICH (EU) CTD can become the std except for Module 1?

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Current opportunities

Priorities

1. Seek alignment of dossier format among NRAs worldwide including module 1 if feasible
2. Enforce reliance on work done by other NRAs or agencies (e.g. WHO)
3. Shorten review processes
4. Avoid redundant testing of vaccine samples
5. Avoid redundant inspections to manufacturing sites

Current status

More countries willing to apply CRP for registration of vaccine

CRP satisfies the majority of points 1 to 5 (possibly not module 1)

What needs to be done

Manufacturers can push for dossier alignment by adopting ICH (EU) CTD for submission to WHO and to NRA

Manufacturers can work with Country of Origin NRAs to accept ICH (EU) CTD as alternative to national format (flexible approach)

Alignment of module 1: Seek acceptance by NRA of WHO format with additional info as needed.

In the context of COVID pandemic, possible to work with ICH to seek development of a standardised module 1 format including application form (IFPMA?)

In summary, for facilitated registration and alignment…..

- ✓ All DCVMN manufacturers (management in general and regulatory affairs in particular) become aware and fully understand the WHO CRP option for facilitated registration of vaccines
- ✓ Manufacturers adopt ICH (EU) CTD for submission to WHO and to NRA
- ✓ Possibly, more training on how to prepare the ICH (EU) CTD is required
- ✓ For any new submission of a **newly** prequalified vaccine to a procuring country, invite the NRA (if already on the medicines list) to use the CRP for registration of the vaccine
- ✓ Manufacturers can work with Country of Origin NRAs towards acceptance of the ICH (EU) CTD as an alternative to national format (flexible approach)
- ✓ Alignment of module 1: Seek acceptance by procuring country NRA of WHO format with additional info as needed.
- ✓ In the context of COVID pandemic, possible to work with ICH to seek development of a standardised module 1 format including application form (IFPMA?)

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THANK YOU

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Developing Countries Vaccine Manufacturers Network