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
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
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

**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 list to use CRP and inform WHO
- Inform WHO of decision by NRA

**Dossiers in CTD format**

**Availability of WHO reports**

**Country acceptance of Procedure and capacity to review**

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

 بهذا resumen, para la facilitación de la registración y alineación.....

- Todos los fabricantes de la DCVMN (en general y en particular el asesoramiento regulatorio) deben estar al tanto y entender totalmente la opción CRP de la OMS para la registración facilitada de vacunas
- Los fabricantes adoptan el CTD de ICH (EU) para la presentación a la OMS y al NRA
- Se podría necesitar más formación sobre cómo preparar el CTD de ICH (EU)
- Para cualquier nueva presentación de un nuevo precalificado de vacunas a un país donante, invitar al NRA (si ya está en la lista de medicamentos) a utilizar el CRP para la registración de la vacuna
- Los fabricantes pueden trabajar con los NRAs del país de origen para la aceptación del CTD de ICH (EU) como alternativa al formato nacional (enfoque flexible)
- Alineación de módulo 1: Solicitar aceptación por el NRA del país donante de la forma de la OMS con información adicional como sea necesario.
- En el contexto de la pandemia COVID, es posible trabajar con ICH para solicitar el desarrollo de un formato estándarizado de módulo 1 que incluya la solicitud (IFPMA?)
THANK YOU