dcvmn
Developing Countries Vaccine Manufacturers Network

Regulatory forum: implementing regulatory convergence

DCVMN Annual General Meeting

Rio de Janeiro 21-23 October 2019

Dr Nora Dellepiane

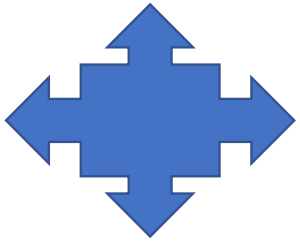
Introduction to Regulatory Convergence Initiative

Developing Countries Vaccine Manufacturers Network

DCVMN promotes access to safe and effective vaccines.

Focus on increased efficiency of regulatory processes

Modalities of work



Regulatory Experts WG DCVMN-IFPMA

Regulatory networks

Dialogue with regulators WHO and other partners

DCVMN Regulatory Convergence initiative: Regulatory working group

Developing Countries Vaccine Manufacturers Network

Informal group of regulatory experts established in collaboration between DCVMN and IFPMA member companies

- Looks at main challenges in regulatory processes and provides data from manufacturers' experience and perspective
- Complements WHO insight and understanding of the current challenges bringing a different perspective into the equation
- Seeks collaboration with WHO to foster improvements in regulatory processes
- Seeks collaboration with Regulatory Networks and other partners as needed

Regulatory challenges over product lifecycle

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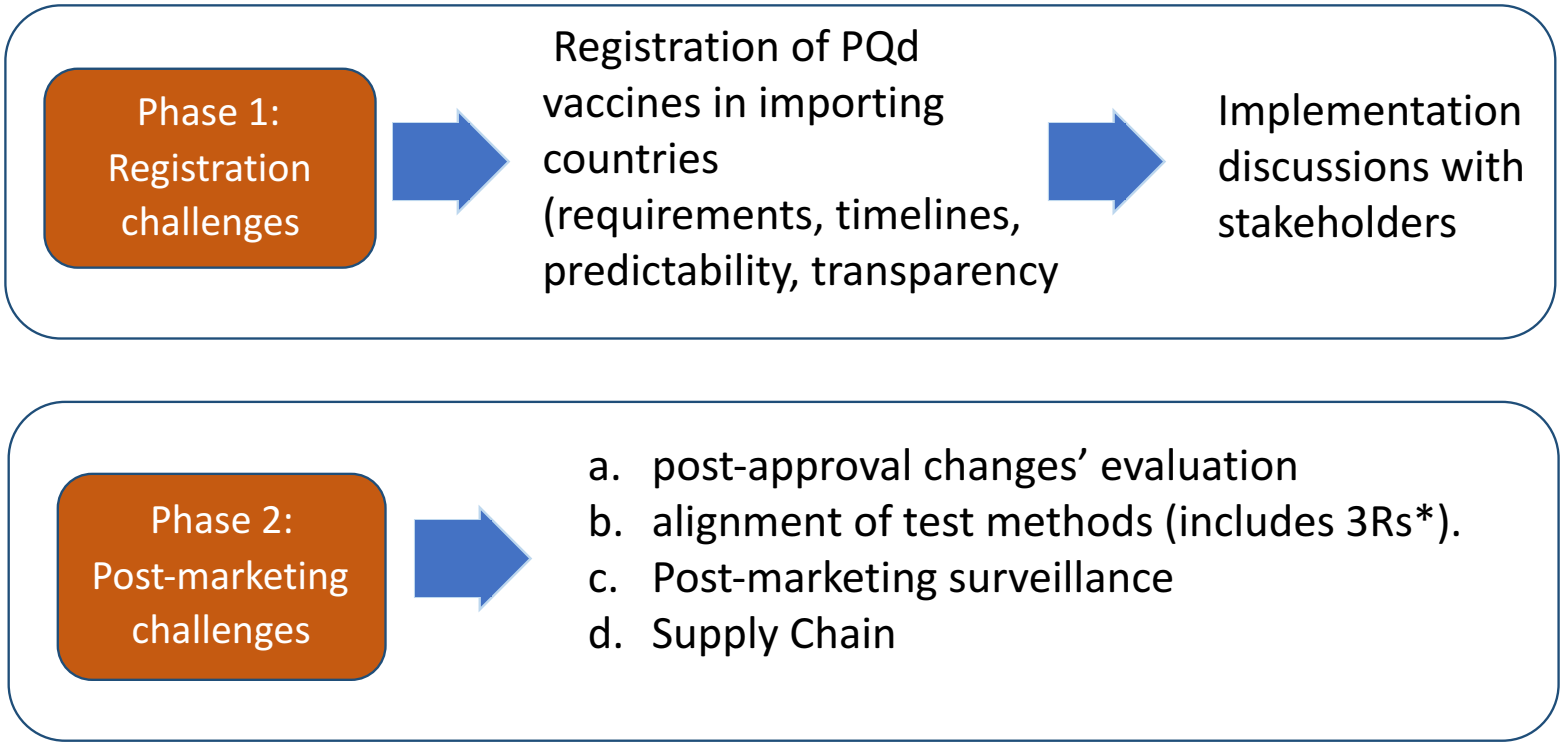

* 3Rs: replacement, reduction or refinement for vaccine potency tests

DCVMN Regulatory Convergence initiative: Objectives

1. Objectives	1. Expected outcomes
1. Increased efficiency of regulatory processes	1. Increased transparency and predictability of regulatory processes both in pre-marketing and post-marketing phases
2. Increased recognition of WHO-PQ	1. Increased reliance on PQ outcomes and ongoing monitoring of vaccine quality, efficacy and safety for registration and post-marketing phases 2. Uninterrupted supply while registration process is ongoing 3. Increased use of CRP to facilitate vaccine registration 4. Waiver of registration in case of emergencies
3. Alignment of requirements and procedures: pre-marketing phase	1. CTD alignment to EU dossier format and requirements 2. Alignment of module 1 format across the board starting with the WHO module 1 as an important incentive 3. Development of aligned format for application form
4. Alignment of requirements and procedures: post-marketing phase	1. Increased reliance on review and approval of PACs by WHO 2. Increased use of WHO variations guidelines as the basis for independent review and approval of variations 3. Increased reliance on review and approval of vaccines and PACs by ML4 NRAs
5. Implementation of 3Rs both during pre-and post-marketing phases	1. Establish a 3Rs working group to assist DCVMN member companies to implement alternative/ aligned testing methods 2. Promote in-house validation of alternative/ aligned tests 3. Promote regulatory acceptance of alternative/ aligned tests

Regulatory Forum

Speaker	Organisation	Focus of talk
B. Moreira	ANVISA- Brazil	Regulatory framework and agency modernisation
C. Rodriguez Hernandez	WHO-HQ	Impact of WHO Prequalification and Systems on access to health
A Guta	PAHO	PAHO updates on regulatory convergence
D. Maiga	WHO-AFRO	AVAREF progress in clinical trial review and reporting standards and status of convergence for vaccine registration
P. Zuber	WHO-HQ	Vaccine Safety Blueprint