SESSION 1

Criteria for election of Chair and Co-Chair

Chair's role

- Calling, scheduling and presiding RWG meetings with support from Co-Chair and facilitator
- Ensuring the group moves forward the workplan towards objectives and meets deadlines
- In collaboration with Co-Chair, fundraising to ensure self-sustainability of the group

Eligibility

- ≥ 2 yrs experience in RA, or IM dealing with regulatory submissions
- Excellent knowledge of English
- Participation in 50% of meetings in the year
- 2 yrs contribution to the RWG is desirable

Co-Chair's role

- Seconding the Chair in driving the working group forward to meet its objectives and planned commitments
- Coordinating meetings in the absence of the Chair or upon his/her request
- Supporting fundraising activities to seek the sustainability of the group

Eligibility

- ≥ 2 yrs experience in RA, or IM dealing with regulatory submissions
- Excellent knowledge of English
- Participation in 50% of meetings in the year
- 2 yrs contribution to the RWG is desirable

CRP priorities (countries and vaccines)

Vacs	Prioritized countries								
	Nigeria	Ethiopia	Pakistan	South[1] Africa	Bangladesh	DRC	Egypt	Philippines	Jordan[1]
Oral cholera		★			★	★			
Rotavirus	★	★ ★		★					★
PCV	★	★ ★							★ ★
JE (live)			★					★	
Penta	★		★	★			★		

[1] likely small supply. All other countries are high supply countries

Next steps

- WHO was satisfied with the results of the survey and committed to work with countries and interested manufacturers to implement CRP in prioritized countries for priority vaccines.

- **VERY IMPORTANT:** Manufacturers are advised to contact Dr Emer Cooke directly (cookee@who.int) to put forward the request to start a CRP process for specific country/ies and vaccine/s

- Although certain vaccines have been prioritized in this exercise, WHO is open to requests for other vaccines as well, as long as they are new and submission is on CTD format with same info as that presented to WHO during PQ process.

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SESSION 2

Training needs identified during regulatory pathways training course

Registration/PQ

Secretariat proposals (endorsed by 50% of participants)

1) Preparation and management of regulatory pre-submission meetings

2) ICHQ10 implementation

Additional proposals (participants)

1) Strategies and planning for testing
2) Training on new vaccines testing methods
3) Training on WHO Global Benchmarking tool for NRAs

Post- approval changes (PACs)

Secretariat proposals (endorsed by 50% of participants)

1) ICH Q12 and Post-Approval Change Management Protocol (PACMP)
2) Quality by Design

Additional proposals (participants)

1) Classification of changes
2) Strategies for PACs submissions
3) Common problems in PACs management and std solutions

Work done so far by the RWG

1) Identification of challenges for registration; Vaccine 36 (2018): 3389-3396

2) Identification of opportunities for improvements; Vaccine 37 (2019): 2982-2989

3) Opportunities for alignment of PACs guidelines (ready for submission)
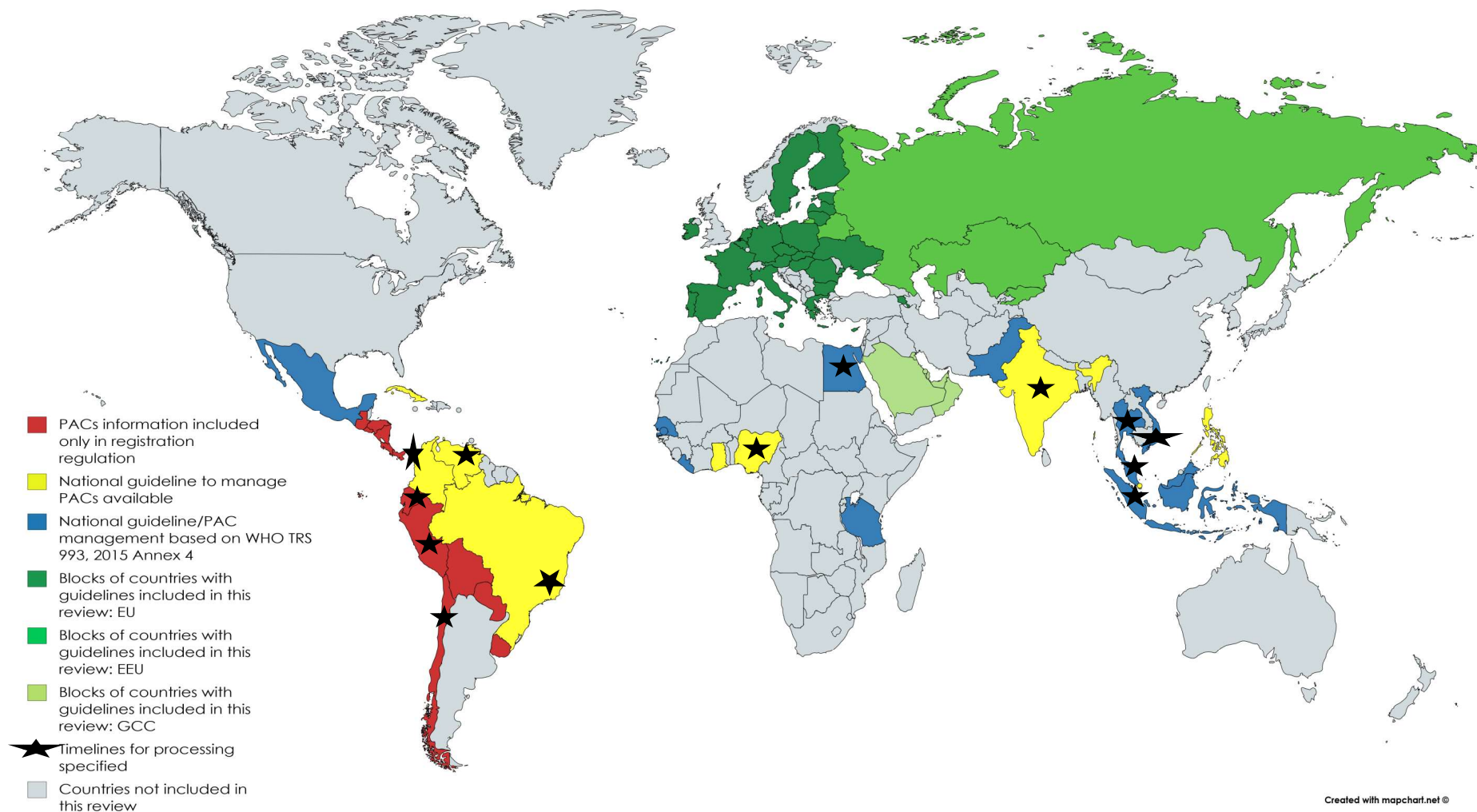
Work done so far by the RWG: registration

From 1) and 2), two major implementation objectives established:

I.   CRP implementation in priority countries for priority vaccines in coming 2 years: agreed by WHO

II. Alignment of dossier format
   a) Standard application form (module 1)
   b) Alignment of numbering system and contents for module 1
   c) Alignment of modules 2-5 to EU CTD

WHAT IS THE LEVEL OF IMPLEMENTATION OF THESE PROPOSALS?

WHAT ELSE IS NEEDED TO ADVANCE THE ACCEPTANCE AND USE OF THE PROPOSALS BY NRAs?

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SESSION 2: WORK DONE BY THE RWG: PACS

Countries with or without PAC GL based or not on WHO GL

Legend:

- **PACs information included only in registration regulation** (red)
- **National guideline to manage PACs available** (yellow)
- **National guideline/PAC management based on WHO TRS 993, 2015 Annex 4** (blue)
- **Blocks of countries with guidelines included in this review: EU** (dark green)
- **Blocks of countries with guidelines included in this review: EEU** (green)
- **Blocks of countries with guidelines included in this review: GCC** (light green)
- **★ Timelines for processing specified**
- **Countries not included in this review** (grey)

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Work done so far by the RWG: PACs

Main proposals from PACs paper to improve alignment,

- Implementation of a tiered, risk-based classification system for changes to MAs based on the principles outlined in the relevant WHO guidance (expand blue color on the map)

- Clear and consistent timelines to be implemented for post approval changes and adherence to them (3-6 months for major changes and 1-3 months for moderate changes), in line with WHO guidelines.

- Revision of WHO guideline in line with ICH Q12. Eliminate req for pre-approval of moderate changes.

- Increased reliance on WHO-PQ or mature NRAs for approval of changes

Work done so far by the RWG: PACs (2)

Additional proposals from PACs paper to improve PACs management,

- Harmonization of administrative documentation *(similarly to appl form and module 1),*
- Cross-referencing mechanism to avoid multiple submissions for same change impacting ≠ licenses,
- Bundling multiple changes under the same dossier, when they are connected,
- Enhance reliance/recognition of site inspections and batch testing,
- Extended use of CRP
- Acceptance of Post Approval Change Management Protocol (PACMP)
- Submit the dossier in parallel to the submission in country of origin (provide approval as granted)

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NEXT STEPS: Workplan priorities