2020 WHO Product Development for Vaccines Advisory Committee (PDVAC)
Virtual Consultation: WHO PPC and TPP Review
22 April 2020
CHAIR: David Kaslow

Concept note

The mission of WHO's department of Immunization, Vaccines and Biologicals (IVB) is to accelerate the development and uptake of safe and effective vaccines and related technologies that could have global public health impact. WHO Preferred Product Characteristics (PPCs) and Target Product Profiles (TPPs), published by the department of Immunization Vaccines & Biologics (IVB), are intended to encourage innovation and promote development of products for use in settings most relevant to the global unmet public health needs. The primary target audience for WHO PPCs is any entity intending to eventually seek WHO policy recommendation and prequalification (PQ) for their products. PPCs are pathogen-specific and do not include minimally acceptable characteristics; they are intended to provide early guidance to inform candidate specific or vaccine-type TPPs. Development of WHO TPPs are typically more appropriate than PPCs for next generation vaccines since the existing product serves as a benchmark to guide definition of minimally acceptable characteristics. TPPs are also developed by WHO's R&D Blueprint for outbreak pathogens to facilitate rapid activation of R&D activities during epidemics (https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts).

Selected disease areas for vaccine PPC or TPP development are identified by WHO's Product Development for Vaccines Advisory Committee (PDVAC), based on the unmet public health need for a vaccine, interest and demand for a vaccine from LMIC stakeholders, and technical feasibility. The first PPC was developed for malaria vaccines, in 2014, before RTS,S received a positive regulatory opinion. IVB has now developed eight PPCs (www.who.int/immunization/research/ppc-tpp/preferred_product_characteristics) and one TPP (www.who.int/immunization/research/ppc-tpp/target_product_profiles) and has led or contributed to the development of several TPPs that are now under the purview of the R&D Blueprint (Ebola, Zika, MERS).

IVB committed to assessing the need to update its PPC and TPP guidance documents every 5 years, or sooner in the event of product or technology innovations or any other change in R&D landscape. This session will be the first PDVAC review of the status of its WHO PPCs and TPPs. It will also be the first time that a PPC for a monoclonal antibody (for RSV) is discussed.

Objectives of the meeting

The objectives for the virtual meeting on 22 April 2020 are to:

1. Review the status of Covid-19 vaccine development, and the role of IVB and PDVAC for providing input into the WHO R&D Blueprint.
2. Provide an overview of existing IVB PPC and TPP documents to identify those for update.
3. To review PPCs/TPPs that are in progress or planned.
4. Update PDVAC on the RSV vaccine and mAb pipeline, including discussion on maternal vaccine and mAb PPCs.
5. Update PDVAC on ongoing activities under the Influenza Vaccine R&D Roadmap aimed at accelerating progress toward universal or broadly protective influenza vaccines.

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Start times:

05:00 Seattle; 7:00 Lima; 8:00 Washington DC; 13:00 London; 14:00 Johannesburg; 14:00 Geneva; 17:30 New Delhi, 20:00 Beijing; 21:00 Seoul

Time (Geneva CEST)	**Topic**	**Duration**	**Detail**	**Moderators, speakers**
14.00 – 14.10	Introduction: session overview & objectives			Martin Friede / David Kaslow / Birgitte Giersing
14.10 – 14.40	COVID-19 vaccine development	15' +15'	**For information:** Overview of ongoing efforts to develop COVID-19 vaccines The role of IVB and PDVAC for providing input into the WHO R&D Blueprint. Discussion	Martin Friede (WHO)
14.40 – 15.20	Overview of vaccine PPCs	20' + 20'	**For decision and discussion:** Re-cap of vaccine PPCs and TPP (existing, in development, planned): Existing: Malaria, TB, GBS, GAS HSV, MR-MAP (TPP) In development: ETEC, Shigella, Gonococcal vaccine, HIV mAbs PPCs PPC for vaccine/mAbs against gram/-/ pathogens, frequently AMR Planned: iNTS PPC, next generation rotavirus TPP o *Which existing PPCs need revision and what is the mechanism to revise them?* o Do WHO PPCs/TPPs influence/shape product development? o Expected timelines for those under development/planned o Need for clarity on PPC vs TPP o Need for an aligned format/template	Johan Vekemans & Birgitte Giersing (WHO)

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15.20 – 16.20	RSV vaccines and mAbs		**For decision and discussion:** ***Please review PPC table in advance of the call***	
		10’	Overview of RSV vaccine pipeline o Recap of Novavax phase 3 results	Daniel Feikin (WHO)
		20’	*For decision: Need for revision of RSV maternal PPC in light of Novavax phase 3 results* o preliminary questions include : 1) Is there a need to revise the efficacy targets; 2) Should a consideration for measuring a reduction in all-cause pneumonia out to 1 year be added; 3) Should pivotal trials include populations relevant for LMICs? 4) If updates are required what is the mechanism forward?	Erin Sparrow / Daniel Feikin (WHO)
		15’	Overview of RSV mAb pipeline o Recap of AstraZeneca’s ph2b results and phase 3 development timelines o Other long acting mAbs in the pipeline (Merck, Gates’ MRI) o WHO activities (Plans for a WHO consultation on RSV mAbs; Plans for an ECBS endorsed guideline, PQ pathway) o PPC for RSV mAbs – introduction and overview of parameters, expected timelines for PDVAC input	
		15’	Preliminary discussion: Comparative full value of vaccine assessment for RSV: Trade-offs between vaccine & mAb o Initial comments/input from PDVAC	

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Time (Geneva CEST)	**Topic**	**Duration**	**Detail**	**Moderators, speakers**
16.20 – 16.45	Influenza Vaccines Roadmap	10’ 15’	**For discussion:** Ongoing activities under the Influenza Vaccine R&D Roadmap aimed at accelerating progress toward universal or broadly protective influenza vaccines. Discussion – what are the data ‘triggers’ that will warrant revision of the existing PPC? • Strategic goals? • Use cases, particularly LMICs? o First infection imprinting? • Benchmark(s) for efficacy/endpoints?	Martin Friede (WHO) -
16.45 – 17.00	Discussion & close		Wrap up Reminder about upcoming virtual sessions	David Kaslow and Birgitte Giersing