

Statement to be made at the WLA consultation meeting organized by WHO on 2nd July'20

Webex Meeting

Samir Desai- President Zydus Cadila, representing DCVMN, Chair of the RWG of DCVMN

- On behalf of the DCVMN, a large network of Vaccine Manufacturers from Developing Countries, we welcome this endeavor of the WHO & the importance of strengthening regulatory systems in improving access to quality medicines and vaccines; indeed delivery of Universal Health objectives cannot be over emphasized.
- Providing timely and equitable access to all vaccines across countries and populations is a key factor in improving health outcomes; having strong and reliable regulatory systems that recognize reliance as a basic principle is an important enabler for this.
- In general, we welcome the recommendations and would like to offer two comments. Validity of the status (Maturity level achieved) is five years and renewal risk based. Perhaps, risk based assessment for renewal is important at least at the first renewal deadline, with the possibility of extending the period if there are no issues in between.
- Our second comment is that the document does not clarify the level of maturity required for reliance related to the vaccine PQ streamlined procedure. This is very important for vaccines: in the past SRA were eligible and it was expected SRA to be equivalent to ML4. Whatever is the decision, it has to be clearly stated somewhere (policy document or elsewhere?). They refer to a detailed WLA operational guidance under development. This document will be critical for vaccine regulators and manufacturers and should be subject to public consultation as well.
- We reiterate our resolve to work with WHO & support RSS team in further strengthening these processes.