Workshop on proposal for alignment of regulatory requirements for vaccine registration at global level
Royal Manotel, Geneva
15 - 16 May 2017

Objectives
The workshop is aimed at drafting a proposal by vaccine manufacturers (DCVMN and IFPMA members) to be shared with WHO, regulatory networks and other relevant partners that will provide evidence of the diversity of regulatory requirements applicable to vaccine registration across countries and options to improve the level of alignment.

The proposal will focus on the following:

a) Provide background information on the current regulatory situation for vaccine registration,
b) Show similarities and differences between countries/regions in requirements for CTD submissions (modules 1-5),
c) Identify and list additional specific countries' requirements that may negatively impact the duration of the registration process, by looking at the different regulatory pathways used
d) While meeting the requirements, suggest potential options to improve alignment, including (but not limited to) proposing a list of essential documents that could be advocated for by WHO and other partners for common use in all countries.

Participants profile:
Participants will be representatives from companies with prequalified vaccines supplied in the global market or companies very experienced in registration at global level. The selected staff from the companies should be experienced staff in regulatory affairs and exports

Expected Outcomes

1) At the end of the workshop participants will have

- Fully developed a table comparing modules 1 to 5 of the CTDs from selected countries and identified similarities and differences,
- Prepared a comparative table of application forms from selected countries
- Developed a proposed list of documents that are important ("essential documents") and common to the majority of countries,
- Identified steps involved in the registration procedure in different countries and constructed a list of countries

2) At the end of the workshop, DCVMN Secretariat will have gathered the necessary information from regulatory affairs participants to allow for the development of a comprehensive proposal of actions needed in order to improve the alignment of requirements.

The proposal prepared as a result of the meeting will be further discussed with DCVMN and IFPMA members for consensus before being presented to WHO, regulators and other partners.
The working methodology will be working groups

FINAL AGENDA

Day 1ay 1		
Schedule	Topic	Speaker
9h00 - 9h10	Welcome	Sonia Pagliusi
9h10 - 9h30	Introduction	Sonia Pagliusi
9h30 - 10h00	Challenges for registration of vaccines, rationale for comparison of module 1 of CTD	Nora Dellepiane
10h00 - 10h40	Discussion	all
10h40 - 11h00	Coffee break	
11h00 - 11h15	Organising working groups and presenting working doc	Facilitator
11h15 - 13h00	Comparison of module 1 and listing of essential documents	Working Groups 1 and 2
11h15 - 13h00	Registration procedures in different countries	Working group 3
11h15 - 13h00	Comparison of application forms from different countries	Working Group 4
13h00 - 14h00	Lunch	
14h00 - 15h00	Continuation working groups	
15h00- 15h30	Coffee break	
15h30 - 17h00	Presentation by working groups	
17h00 - 17h30	Conclusions and wrap up of the day	all

Day 2ay 1		
Schedule	Topic	Speaker
9h00 - 9h30	Rationale taken for comparison of CTD modules and presenting working doc	Facilitator
9h30 – 10h30	Comparison of module 2	Working Group 1
9h30 – 10h30	Comparison of module 3	Working Group 2
9h30 – 10h30	Comparison of module 4	Working Group 3
9h30 – 10h30	Comparison of module 5	Working group 4
10h30-11h00	Coffee break	
11h00 -13h00	Continuation of working groups	
13h00 - 14h00	Lunch	
14h00 - 15h30	Presentation by working groups	
15h30 - 16h00	Coffee break	
16h00 - 17h00	Ideas for proposal on potential for alignment	Rapporteur
17h00 - 17h30	Conclusions and wrap up of the workshop	Sonia Pagliusi