Workshop on proposal for alignment of regulatory requirements for vaccine registration at global level
Royal Manotel, Geneva
11-12 January 2018

Objectives

The workshop is a follow up to the previous held on 15 and 16 May 2017 in which the participating group of experts have completed the comparison of CTDs used in different countries, made an analysis of the registration procedures in 134 countries and compared the requirements in application forms of 8 countries. This work permitted a good understanding of the diversity of requirements between countries which leads to unnecessary redundant work by regulatory affairs staff in vaccine manufacturing companies as well as to unpredictable and normally lengthy timelines for evaluation and approval of marketing authorization applications.

This follow up workshop is aimed at drafting a proposal by vaccine manufacturers (DCVMN and IFPMA members) that will provide suggested options to improve the level of alignment.

Such proposal will be presented to WHO, ICH, PAHO, AVAREF and to Regional Economic Blocks such as ASEAN, EAC and others, to promote implementation. These organizations can work with regulatory agencies to promote small changes that would, if implemented, provide significant improvements in alignment worldwide while not impacting on the quality of the evaluation process; and would have a significant impact in reducing registration timelines (both from manufacturers' perspective in the preparation of submissions and from NRAs' perspective in the review timelines and facilitation of information sharing and reliance).

The challenges are not limited to the vaccine registration step but rather start there. Changes in production methods, capacity increase, improvements in testing methods and other changes introduced to the production process need to go through approval by regulatory agencies.

The process of evaluation and approval of variations is another limiting factor to availability of vaccines. Whenever a change is introduced which impacts the information in the registration file, this needs to be amended according to the new process or method and while the change/variation goes through such approval process, the product manufactured with the change cannot be supplied. This complicates the stock and distribution logistics at the manufacturing companies, where either two production lines need to be maintained in parallel, or enough stocks of the old version of the product need to be maintained, while the new production version awaits approval perhaps for months or years. There is usually the need to maintain both versions of the product to satisfy the needs of countries that have already approved the change while approval by other countries is pending. Otherwise, supply may be hampered.

Looking into options to improve the efficiency of the variations evaluation and approval process seems a desirable exercise that could lead to the identification, as in the case of initial registration requirements, to a facilitated approval process based on alignment of requirements and procedures.

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 with at least two successful registries/marketing authorization outside the respective domestic market.

Expected Outcomes
At the end of the workshop participants will have

- Developed a proposal for alignment of module 1
- Developed a proposal for alignment of modules 2-5
- Developed a model, standard application form
- Proposed improvements to the registration procedures
- Considered options that would improve the management of variations
- Informal discussions on issues related to PQ procedure

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

DRAFT AGENDA

Day 1ay 1		
Schedule	**Topic**	**Speaker**
SESSION 1	**CTD ALIGNMENT AND MODEL APPLICATION FORM**	
9h00 - 9h30	Welcome and introduction to DCVMN	Sonia Pagliusi
9h30 - 10h00	Summary of work done on registration procedures. Establishment of working groups and designation of session facilitators	Nora Dellepiane
10h00-10h15	Presentation of ideas for alignment of module 1	Mic Mc. Goldrick
10h15-10h30	Presentation of ideas for alignment of modules 2-5	Nora Dellepiane
10h30 - 10h45	Proposed model application form	Nora Dellepiane
10h45 - 11h00	Coffee break	
11h00- 11h15	Proposed check list to support application form	Mira Uton
11h15 - 13h00	proposal for alignment of module 1	WG 1
	proposal for alignment of modules 2-5	WG 2
	Finalization of Model application form	WG 3
13h00 - 14h00	Lunch	
14h00 – 14h45	Presentation of proposals by working groups	WG 1, WG 2. WG 3

SESSION 2	IMPROVEMENTS TO REGISTRATION PROCEDURES	
14h45- 15h30	Facilitated discussion on improvements to registration procedure • Leveraging use of WHO-PQ collaborative procedure • Provisions for waivers, worksharing, reliance, etc • Suggestions to avoid redundancies (documents, testing, inspections)	All guided by facilitator Rapporteur captures proposals
15h30- 15h45	Coffee break	
15h45 - 16h30	Wrap up of proposals for improvement of registration procedures	All guided by facilitator or Rapporteur
16h30 - 17h30	Wrap up of proposals for alignment and model application form. Conclusions and wrap up of the day	All guided by facilitator Rapporteur

Day 2 ay 1		
Schedule	Topic	Speaker
SESSION 3	**VARIATIONS**	
9h00 - 10h30	Facilitated discussion: Listing problems related to review and approval of variations	All guided by Facilitator
10h30-10h45	Coffee break	
10h45 – 12h00	Variations: proposed options for improvements	All guided by facilitator Rapporteur
12h00 – 13h00	Wrap up on variations	All guided by facilitator Rapporteur
13h00 - 14h00	Lunch	
SESSION 4	**PQ PROCEDURE**	
14h00 - 15h30	Discussion related to new PQ procedure	All guided by facilitator
15h30 - 15h45	Coffee break	
15h45- 16h30	Proposals regarding improvements to PQ procedure	All guided by facilitator Rapporteur
16h30 - 17h00	Conclusions and wrap up of the workshop	Sonia Pagliusi