

October 8th, 2020

Attendees:

Rajanathan Chozhavel (Zydus Cadila),
Pradip Kumar Das (Biological E),
Sunil Gairola (Serum Institute of India),
Sunil Kumar Goel (Serum Institute of India),
Taehyun Kim (LG Chem),
Deepak Mahajan (Panacea Biotec),
Zebun Nahar (Incepta Vaccine),
Irma Riyanti Hidayat (BioFarma),
Indrajeet Kumar (Bio-Net Asia),
Tien Dung Vu (Vabiotech),
Shri T. Sekar (Pasteur Institute of India),
Gopal Singh (Bharat),
Sonia Pagliusi (DCVMN),

Laura Viviani (DCVMN),
Sivashen Cunden (DCVMN),
Tana McCauley (DCVMN-minutes).

Excused:

Adhir Chaubal (Indian Immunologicals),
Lavit Jambu (Panacea Biotec),
D. Mahesh (Indian Immunologicals),
Anand Kumar Manesh (Indian Immunologicals),
Dr. Maya Ramdas (Panacea Biotec)

L. Viviani thanked the working group members for their commitment to the 3Rs WG this year.

1. NC3Rs/WHO project: Decision on DCVMN nomination

L. Viviani briefly presented the NC3Rs/WHO project. The project is to review WHO requirements for vaccines, with an aim to explore 3Rs opportunities. NC3Rs has already started a WG to decide on priorities for the project. DCVMN received an invitation to join the NC3Rs/WHO project in May 2020. DCVMN received 6 candidacies.

DCVMN's expectations for the representative were:

- a person with experience in QC/batch release testing and 3Rs
- a company with a broad portfolio of vaccines
- a company that is not overrepresented in DCVMN
- geographical representation

DCVMN appreciated all the candidacies received. The candidate from Incepta matched the selection criteria and was presented for nomination.

L. Viviani noted that NC3Rs will create other WGs for specific vaccines. Therefore, other experts from DCVMN may be asked to participate in the NC3Rs/WHO project in the future.

S. Gairola asked about Incepta's portfolio of vaccines for lot release. Z. Nahar presented Incepta's vaccine portfolio for lot release: Hepatitis A, B & E, Tetanus, Rabies and Meningococcal vaccine.

The 3Rs WG endorsed Z. Nahar from Incepta as the NC3Rs/WHO representative.

2. Presentation of ad hoc 3Rs China WG and decision on DCVMN nomination

L. Viviani presented the ad hoc Humane Society International 3Rs China working group. With the new 2020 Chinese pharmacopeia, there have been some 3Rs-related changes. In July 2020, HSI invited DCVMN to nominate a Chinese member for this ad hoc WG. DCVMN presented the candidate from IMCAMBS for nomination.

S. Pagliusi explained that DCVMN circulated an email to all Chinese manufacturers and received an expression of interest from 2 manufacturers, but one withdrew their candidacy.

L. Viviani pointed out that going forward, it would be ideal if the 3Rs WG became more geographically diverse and would be able to engage more members.

The 3Rs WG endorsed the candidate from IMCAMBS as the representative for the HSI China 3Rs WG.

3. MoU with ISS: signature and activities

L. Viviani explained that the MoU with ISS, Italy was signed last Spring and that the collaborative activities with ISS have already begun. DCVMN has received strong support from ISS on the PSPT Project. A webinar and Moodle on Tetanus-Pertussis will also be organized with ISS. Regarding MAT, a webinar will take place either in December 2020 or January 2021. Also, there will be a Moodle covering the MAT and the MAT will also be filmed using virtual reality.

4. Brief update on the PSPT project

L. Viviani updated the WG on the PSPT project. The project has started and activities are going at a good pace. In the consortium agreement, there are 11 labs and 1 pending. On the 2nd of September, the steering group had their first call. The SG has been helping with technical aspects of the project. BioLyo, signed the contract with DCVMN on the 11th of September for the coating antigen. The B. Pertussis strain arrived in BioLyo on the 7th of October. They will

start the research batch this week. On the 29th of September, the first PSPT meeting took place. DCVMN signed the contract with IntraVacc on the 5th of October for the coating antigen characterization. The project is now in a very important phase of preparing the coating antigen and coordinating with laboratories. On the 22nd of October, the technical PSPT workshop will take place, where the antigen and the types of vaccines for PSPT testing will be discussed.

5. wP-aP training available on DCVMN Moodle

A training in two parts, on wP and aP and their 3Rs opportunities, will soon be available as a DCVMN Moodle. This Moodle will focus on the safety and potency tests of these two vaccines. L. Viviani recommended that the WG members complete the Moodle on Pertussis and give their feedback. The WG members are also encouraged to complete the 3Rs Moodle.

S. Pagliusi suggested the WG members could disseminate the Moodle to their colleagues who would be interested in the subject.

6. 3Rs paper and survey on animal use

L. Viviani presented updates on the 3Rs paper and the survey on animal use. DCVMN would like to collaborate with the 3Rs group for paper. DCVMN would like to build a survey shared with the network, to ask concrete questions about animal use for specific tests and on current or planned 3Rs opportunities. This survey and subsequent paper would open opportunities to make improvements in production and quality and to reduce vaccine costs.

L. Viviani shared the draft survey and asked the WG for their feedback.

S. Gairola believes the questions are simple and people can answer them. He suggested animal use in production could be deleted. L. Viviani answered that there are still some animals used in production, but for most manufacturers there is no animal use. She suggested splitting the question in 2, one about production and one about release. S. Pagliusi stated that for Polio, monkey kidneys are used and for Rubella, monkey kidney cells are used in Vietnam. She explained that some animals are still used in production. The data gathered on animal use in production would help members move forward and adopt new technologies.

S. Pagliusi suggested designing the survey in a way that there are sub-questions. S. Gairola agreed.

P. Kumar Das explained that the answers to the questions would not be confidential information, as manufacturers are following their respective pharmacopeias.

L. Viviani added that DCVMN would like to collect data on ongoing or planned 3Rs projects. This would be presented as a list of successes that would be shared in the 3Rs paper.

7. AoB/ Key updates and events about 3Rs

L. Viviani updated the WG on the elimination of the specific toxicity test for Tetanus-Diphtheria in the European pharmacopeia, if the company can demonstrate consistency in the production.

P. Kumar Das and S. Gairola explained that India has removed the abnormal toxicity test. Some countries like Brazil, have removed the abnormal toxicity test in all their vaccines, including imported vaccines.

The meeting was adjourned.

DCVMN will communicate the date of the next 3Rs WG meeting, taking place in 2021.

Next PSPT technical workshop will take place on the 22nd of October 2020.


Dr. Sunil Gairola
Serum Institute of India
Chair of the 3Rs WG