FIRST GENERAL MEETING
WHO-NATIONAL CONTROL LABORATORY NETWORK FOR BIOLOGICALS
(WHO-NNB)

31 October – 2 November 2017
held at the National Institute of Biologicals (NIB), Noida, India

MEETING REPORT
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1 Executive Summary

The First General Meeting of the WHO Network for Biologicals (WHO-NNB - “the Network”) was held on 31 October – 2 November 2017 in Noida, India. The meeting was organized by WHO, Department of Essential Medicines and Health Products (EMP), Regulatory Systems Strengthening (RSS) hosted by the National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, Government of India. Participants from 21 national control laboratories (NCLs), comprising 20 out of the 24 NCLs currently responsible for lot release and/or contracted for testing of WHO-prequalified vaccines attended the meeting. Furthermore the meeting was attended by representatives from two industry associations, namely the Developing Countries Vaccine Manufacturers Network (DCVMN) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and a member of the European Directorate for the Quality of Medicines & HealthCare (EDQM) as well as WHO (Annex 1 presents the full list of participants).

The meeting was made possible thanks to funding from the Bill & Melinda Gates Foundation, which is gratefully acknowledged.

The First General Meeting marked the start of the operational phase of the Network. Participants discussed the expected benefits of the Network for stakeholders and agreed approaches to its operationalization. The importance of involving manufacturers and procurement organizations was highlighted, as they provide the links to the destination, synonym for recipient, countries where redundant testing needs to be addressed. Participants provided feedback about the information-sharing platform and made suggestions on the structure and content of future meetings.

One meeting day was devoted to sharing of best practices in designing and using of vaccine quality control charts and in handling out-of-specification results. Topics were suggested for best practice-sharing sessions at future meetings.

The following action points were agreed:

1. Membership agreements by additional members will be pursued.
2. The WHO electronic information-sharing platform (pilot version) should be developed further and made operational by a first validation by certain NCLs (Network members) as the users.
3. WHO will distribute the laboratory inventories among the contributing laboratories.
4. WHO will approach manufacturers to extend existing information-sharing agreements with manufacturers and consequently allow information exchange among granted Network members.
5. The Second General Meeting of the Network will be held in Rome, Italy, in 2018 and be hosted by the Centro Nazionale per il Controllo e la Valutazione dei Farmaci / Istituto Superiore di Sanità (CNCF/ISS).
2 List of Acronyms

CDSCO Central Drugs Standard Control Organization
CGGS Central Government Health Scheme
CNCF/ISS Centro Nazionale per il Controllo e la Valutazione dei farmaci / Istituto Superiore di Sanità
DCVMN Developing Countries Vaccine Manufacturers Network
EDQM European Directorate for the Quality of Medicines & HealthCare
EMP WHO Department of Essential Medicines and Health Products
GEON General European Official Medicines Control Laboratories Network
ICDRA International Conference of Drug Regulatory Authorities
IFPMA International Federation of Pharmaceutical Manufacturers & Associations
MoHFW Ministry of Health and Welfare
NIB National Institute of Biologicals
NLCs National Control Laboratories
NRAs National Regulatory authorities
OCABR Official Control Authority Batch Release
RSS Regulatory Systems Strengthening
TGA Therapeutics Goods Administration
WHO-NNB WHO Network for Biologicals
WHO World Health Organization
3 Background and information about the Network

Immunization is one of the most cost-effective health interventions. Quality assurance of vaccines is paramount to achieve the intended benefits and maintain confidence in immunization programmes. WHO prequalifies vaccines[1], the oldest of the WHO prequalification production streams, for use in UN-funded programmes, and many governments and other entities rely on prequalified vaccines in procurement. However, much has changed in the world of vaccines since 1987 when prequalification started. NCLs of producing countries, responsible for release and monitoring vaccines quality, need to deal with greater numbers and complexity of vaccines which require much more sophisticated test methodologies and skills. This also applies to vaccine prequalification since the number of vaccines and complex vaccines increased at the same time. However, while the production and supply of vaccines have become globalized, this is not the case for the regulation. Quality assurance of vaccines is becoming more demanding and efficient use of existing resources indispensable. Although NCLs of producing countries are responsible for lot release of prequalified vaccines, vaccine batches are often re-tested multiple times under national requirements in destination countries, resulting in significant barriers to the timely supply of vaccines in WHO Member States. There is a need for networking and reliance, with a risk-based approach to lot release testing as recommended in WHO guidelines [2].

3.1 Network creation

The WHO-National Control Laboratory Network for Biologicals (WHO-NNB) was constituted in 2016 [3] in response to increased challenges faced for the independent vaccines’ testing by WHO and by NCLs in vaccine regulation including release processes to the markets through the globalization of the vaccine industry e.g. shortages and supply challenges are posed by redundant lot release testing of imported vaccines in destination countries. Furthermore, to constantly enhance the prequalification processes and efficiency and the utilization of existing resources. WHO owns the sole global mandate to coordinate such a strategic network and its creation responds to World Health Assembly resolution no. 67.20, which calls for regulatory systems strengthening for medical products through strengthening WHO’s prequalification programme, including its integration and coherence and through supporting the building-up of effective national and regional regulatory bodies and networks.

This operational network is a platform for collaboration and technical exchange on quality control and quality assurance of vaccines or other biological medicinal products. Its main objectives are to share quality and technical information related to prequalified products (vaccines or other biological medicinal products), to facilitate recognition of the responsible national regulatory authority/NCL’s lot release by recipient countries, thereby reducing redundant testing, and to promote the development of harmonized common standards and share best practices.

The mission of the Network is to share quality and technical information, to facilitate access to and availability of prequalified vaccines (or other biological medicinal products) through reliance on the batch release of the respective Network Members by recipient countries, thereby reducing redundant testing, and contributing to more cost-effective testing and more effective regulatory oversight and to promote the development of harmonized standards and best practices.

The First General Meeting of the Network marked the start of its operational phase. In the lead-up to the First General Meeting of the Network the terms of reference for the Network and along with them a Participation and Confidentiality agreement were established. National regulatory authorities (NRAs)/NCLs of 15 countries out of five of the six WHO regions confirmed and committed their active participation in the WHO Network and 20 NCLs provided extended information relating to their operations, guidelines, policies and procedures as a basis for sharing vaccine lot release information among Network members. A demonstration version of an information-sharing electronic platform on a secure WHO server was developed and presented at the meeting.
3.2 Terms of reference

Draft terms of reference for the Network were discussed at the 2016 meeting and subsequently finalized by WHO with involvement of the WHO Legal Department. The revised terms of reference were circulated to participants ahead of the meeting and were presented for information.

It was clarified that the name of the Network has been adapted to allow a possible future extension of its scope to other biologicals such as antivenoms or biosimilars. Secondly, the terms of reference no longer provide for a steering committee. This is in line with WHO legal advice against a management body with limited representation, as the Network should be based on a premise of equal representation of all WHO Member States.

3.3 Participation and confidentiality

A participation and confidentiality agreement has been drawn up with the WHO Legal Department and was presented at the meeting. The agreement is signed by the Heads of the relevant authority (NRA/NCL) and countersigned by the appointed focal point for the day-to-day activities of the Network and his/her alternate. It has comprehensive provisions to ensure confidentiality and appropriate use of the shared information.

As at 1st November 2017, signed participation and confidentiality agreements were on record from the following NRAs/NCLs: Full members (NCLs from countries producing WHO-prequalified vaccines, or WHO-contracted NCLs): Australia, Belgium, Cuba, France, Germany, India, Indonesia, Italy, Senegal, South Africa, Switzerland, Thailand, The Netherlands, and the United Kingdom. Associate member (NCL / NRA in a country that is a recipient of UN-procured vaccines): Hungary.

Feedback about the Network terms of reference and the participation and confidentiality agreement was discussed by the audience. There were no questions about the provisions of these documents as such. The discussions revolved around the types of information that might be shared confidentially within the Network to enable it to achieve its objectives. Specific points were raised regarding the participation of certain NCLs in the context of their own organizational set-up. Remaining questions in this regard will be followed up with legal advice as needed.

Representatives of NCLs gathered for discussions in a confidential setting closed session at the end of Day 1.

3.4 Benefits of the Network

For producing countries, the Network is a resource for knowledge- and information-sharing. It can enhance NCL’s visibility and support 3R programmes and collaborative studies. For recipient countries the benefits are a better understanding of the lot release performed by producing countries, and of the situations in which additional testing may add value. They will also have access to contact details of other NCLs. For manufacturers, less redundant testing will mean faster market access, while harmonization and standardization e.g. through 3R measures will result in efficiency gains. It was noted that the aims of the network are a good fit with industry’s proposal for risk-based testing and networking as presented at the meeting.
4 Meeting overview

4.1 Meeting objectives
The objectives of the meeting were to:

- Meet in person with representatives of network members and other stakeholders;
- Exchange information on applied control strategies of newly participating NCLs;
- Provide information about progress and activities of the Network;
- Demonstrate a pilot version of the electronic information-sharing platform;
- Discuss content and features of the share point;
- Discuss the path forward to an operational entity;
- Agree on the structure of the general meetings; and
- Share best practices for control charts and handling out-of-specification results.

4.2 Meeting opening
The meeting was opened by Dr Surinder Singh as the host and director of the National Institute of Biologicals (NIB). Dr Singh welcomed the participants on behalf of the Ministry of Health and Welfare (MoHFW) of the Government of India. The Additional Secretary to the Government of India & Director General of the Central Government Health Scheme (CGGS) of MoHFW, Dr R.K. Vats, added his words of welcome.

Mr Mike Ward, the coordinator of WHO’s Regulatory Systems Strengthening welcomed the audience on WHO part and stressed the importance of the Network and overdue for a long time.

The opening of the meeting was attended by various officials and ministry delegates such as Dr G.N. Singh (Drugs Controller General of India, Central Drugs Standard Control Organization, CDSCO), Dr Eswara Reddy (Joint Drugs Controller of India, CDSCO), Ms Shraddha Srivastava and Mr V. Rajappan (Drugs Inspectors, CDSCO), Dr Manisha Shridhar (WHO South East Asia Regional Office), Dr Madhur Gupta (WHO Country Office for India), Dr Reba Chhabra (NIB scientist and focal point for the meeting logistics), and a number of scientists and technical staff from NIB.

The ceremonial lamp was lit to mark the auspicious occasion of this international meeting.

4.3 Progress update
Dr Ute Roskopf presented an update on progress achieved since the establishment of the Network in 2016. The terms of reference and participation agreement have been established together with the WHO Legal Department. NRAs/NCLs from 15 countries confirmed their active participation in the Network so far. A mapping of extended laboratory information as agreed in the 2016 Netherland’s meeting has been conducted. Twenty NCLs returned the provided template with detailed laboratory profiles (see Point 6.2). A demonstration version of an electronic platform has been developed for presentation at the meeting.

Information about the Network has been widely disseminated and fundraising information been compiled and discussed on several occasions. The report of the 2016 Netherland’s meeting as agreed by participants was circulated among stakeholders and published on the WHO website. A presentation about the Network was made by Professor Derek Litthauer at a satellite meeting to the 17th International Conference of Drug Regulatory Authorities (ICDRA), leading to two ICDRA recommendations being adopted in support of the Network and its underlying concept of reliance and networking by regulatory authorities of WHO Member States.[4] An article about the Network was published in a WHO journal.[5] Information papers about the establishment of the Network and
the proposed revised lot release certificate template were presented to the WHO Expert Committee on Biological Standardization (ECBS) at its 68th Meeting, held in Switzerland on 17–20 October 2017.

5 Presentations

5.1 National control laboratories (NCLs)

Brief updates were presented from the 19 NCLs that had participated in the 2016 meeting. No major changes were reported in terms of the number of lots released or the strategies and procedures applied for testing. Some laboratories reported having achieved ISO accreditation for additional vaccines or additional methods. Restructuring was planned, ongoing or completed at several laboratories, but this did not have a major impact on vaccine lot release. On the whole very few lots failed regulatory lot release testing. Noteworthy is the update from Senegal namely to rely on vaccine release of production country’s Network NCL rather than to re-test imported WHO prequalified vaccines as an outcome of last year’s meeting and Network establishment. A second aspect which is worth to be mentioned is that Bulgaria shared its lot release data with WHO based on an already existing collaboration agreement following the Netherland’s meeting.

The NCLs of Australia and Russia were represented in a Network meeting for the first time. They provided brief overviews of their work and their strategies for quality control of vaccines. In Australia, lot release testing is risk-based, with prior to release testing for high risk products and post-release testing for low-risk products. The majority of testing is done for consistency and / or compliance post release. There is reliance on overseas certification. TGA is a WHO Collaborating Centre for vaccines and biological standardization. Furthermore is member of the Regional Alliance for NRAs for Vaccines in the Western Pacific Region and has an observer status to the OMCL network an EDQM expert group 15. The regulatory authority of Russia releases a high number of vaccines annually, of which approximately 90% are produced locally. Russia is a member of the General European Official Medicines Control Laboratories Network (GEON). Three accredited laboratories perform testing of vaccine batches according to quality control parameters laid down in the marketing authorization. Assessment of the production summary protocols is performed in line with Official Control Authority Batch Release (OCABR) guidelines [6], although as a non-EU/EEA country the laboratories are not part of the EU OCABR network and thus not part of the mutual recognition circle mandated by EU law.

5.2 Industry

A position paper from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) was presented, reconfirming the need for harmonization and reliance in lot testing of vaccines. The number of national control laboratories has tripled since 2006, leading to more lot testing. As a result there is more redundant testing of the same batches in multiple countries, often with non-standardized methods. The consequences are delays in vaccine supply, loss of some compliant lots and waste of manufacturers’ and regulators’ resources, unpredictable high consumptions of test reagents of biological origin and hindering the timely supply of needed vaccines to populations in the destination countries.

Industry proposes a risk-based approach to vaccine lot release as recommended in WHO guidelines,[2] complemented by random testing and market surveillance. Criteria for risk-based decisions are shown in WHO guidelines; proposed additional criteria are the types of facility and technologies used, manufacturers’ pharmaceutical quality systems, and statistical approaches. Redundant testing with in vivo assays should be eliminated as a priority. An example of a waiver-based system was described. Industry supports a networking approach with mutual recognition and reliance, based on standardized specifications, tests and criteria.
6 Information-sharing within the Network

6.1 Quality information on prequalified vaccines

Dr Ute Rosskopf outlined the activities of WHO related to quality assurance of prequalified vaccines, the types of information generated, and the use of the information.

WHO tests vaccines during initial evaluation of new products submitted for prequalification, and after prequalification under a targeted testing plan for products supplied to UN-funded programmes. The initial testing results are reported back to applicants. The results of post-prequalification testing (performed on 115 lots in 2016) are reported to donors. Both types of testing are performed by WHO-contracted laboratories, which are listed on the WHO website. WHO audits the contract laboratories every 3-4 years to ensure adequate performance and adherence to WHO written norms.

NCLs of producing countries are responsible for lot release of prequalified vaccines [2] and have in-depth regulatory oversight of the products. WHO has established 19 agreements with manufacturers, allowing a total of 10 NCLs to share their lot release data for prequalified vaccines (whether or not supplied to UN-funded programmes) with WHO. This data-sharing is part of the contract between WHO and the respective NCLs.

The outcomes of the WHO targeted testing and of lot release performed by reporting NCLs are tabulated in an annex to WHO’s annual report to donors. In 2016 the 10 NCLs covered by the above-mentioned agreements with manufacturers reported on lot release of a total of 2543 batches of prequalified vaccines, while 115 lots were tested in the WHO targeted programme. An anonymized extract of the WHO report annex was presented at the meeting as an example of information that could possibly be shared within the Network (Table 1).

Table 1: Format used by WHO in reporting of vaccine quality information to donors

<table>
<thead>
<tr>
<th>No.</th>
<th>Purpose</th>
<th>Manufacturer, Country</th>
<th>Vaccine</th>
<th>Lot number</th>
<th>Parameter 1</th>
<th>Parameter 2</th>
<th>WHO conclusion</th>
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</thead>
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<td>1</td>
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<td>Company 5, Country A</td>
<td>Vaccine</td>
<td>77777</td>
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<td>conform</td>
<td>pass</td>
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<td>WHO-targ.</td>
<td>Company 1, Country A</td>
<td>Vaccine</td>
<td>66666</td>
<td>ongoing</td>
<td>ongoing</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations:
- **WHO-eval.**: WHO initial evaluation (before prequalification);
- **WHO-targ.**: WHO targeted testing (post-prequalification);
- **NCL-rev.**: NCL lot release (based on protocol review);
- **NCL-test.**: NCL lot release (incl. testing);
- **n.a.**: not applicable;
- **n.r.**: not requested;
- **n.p.**: not performed
- **n.d.**: Where five or more lots have been tested, individual lot numbers are not listed. Instead, the total number of lots is given followed by “n. d.”

WHO will explore whether any or all of the existing agreements with manufacturers can be extended to allow exchange of lot release information among Network members.

6.2 Laboratory profiles

As agreed at the 2016 meeting, an Excel template for mapping of laboratory information was developed and circulated among the NCLs. These laboratory profiles (“inventories”) comprise the detailed information that will be shared initially among the Network members.

As at 1 November 2017 completed laboratory profiles had been provided by NCLs of 20 countries. An example was shown at the meeting. The profiles contain the information listed below.

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2. Belgium, Brazil, Bulgaria, Canada, Cuba, Denmark, France, Germany, Hungary, India, Indonesia, Italy, Japan, Republic of Korea, Senegal, South Africa, Switzerland, Thailand, The Netherlands, United Kingdom
• **Laboratory details:** Name; address; website; responsible NRA; mandate and reporting structure of the NCL relative to the NRA; communication processes in place between the NCL and the NRA; NCL contracted by WHO for technical testing (yes/no) / for sharing of lot release data (yes/no); quality system (external audit performed by, latest conformity date, validity period, website where scope is available); description of sampling procedures; sampling procedures published (yes/no); mechanisms to maintain competence for in vivo testing / in vitro testing; approaches for implementation of risk-based decisions on testing; (Testing strategies -yes/no and details): testing for local market; testing of imported vaccines; acceptance of certificate issued by releasing country.

• **Contact details:** Main contact, main QA contact and test-specific contacts.

• **Vaccine types:** Country of production; NRA/NCL having regulatory oversight; details how sampled; batches tested on upstream and/or final product; risk-based approach applied (yes/no); vaccine prequalified (yes/no); number of batches released in the past year.

• **Test methods** (biological, physicochemical): Parameter tested; method; WHO Technical Report Series number, pharmacopoeial monograph, marketing authorization (MA) method (yes/no); modified MA method (yes/no); in-house developed method (yes/no); other methods.

• **3R programme** for reduction, refinement or replacement of animal testing: Vaccine; initial method; replacement method; when implemented; number of tests/runs performed with replacement method in past year.

• **Vaccine-specific information:** Test methods used; accreditation (yes/no, if yes: year of last audit), collaborative studies (yes/no, if yes: year of last participation), proficiency testing (yes/no, if yes: year of last participation); number of tests/runs performed in past year.

The NCLs provided information only if they considered that they have the necessary permissions. The representatives of all 20 NCLs agreed that their inventories can be shared with the other 19 NCLs. The laboratory profiles will be kept updated on a regular basis.

### 6.3 Electronic platform

A prototype of an electronic platform for information-sharing within the Network was developed by a WHO data management team and demonstrated at the meeting. In line with advice from the WHO Legal Department the platform is hosted on a secure WHO server. It uses Microsoft SharePoint, a web-based, collaborative application that integrates with Microsoft Office. SharePoint has functionality for authentication and restriction of access to a particular users or user groups for each uploaded document or webpage. The WHO Regulatory Systems Strengthening team has been using SharePoint successfully for several years to manage extensive content uploaded by NRAs.

The electronic platform has a subsite / country site for each participating NCL. In the prototype version one subsite was populated with information from a laboratory profile and demonstrated at the meeting. In addition to the laboratory profiles, NCLs may share other data on an as-needed basis, subject to appropriate confidentiality agreements. The NCLs will decide on the level of access for each document that they upload. Four types of access are envisaged:

- All registered WHO-NNB SharePoint users (full and associate members and observers)
- WHO-NNB full members only
- WHO only
- One other NCL (bilateral exchange)

WHO will have full control and oversight of the platform and will be notified of uploaded content.

As a next step the WHO data management team will develop the platform further and upload information from the laboratory profiles on record, starting with the confirmed Network members. Information from WHO will be uploaded on the landing page, including which NCLs are responsible
for release and/or contract testing of which vaccines, and which NCLs are reporting lot release data to WHO with permission from manufacturers.

A validation protocol will be provided for evaluation of the site against user requirements in the first half of 2018. NCLs from the following countries volunteered their support for the validation: France, Australia, South Africa, Thailand, Belgium and the United Kingdom.

7 Discussions
The operationalization of the WHO-NNB was discussed in plenary sessions and in smaller groups. The groups discussed the benefits, objectives and next steps towards the operationalization of the network. The groups came up with a similar understanding of the main issues, summarized below.

A closed session for NCLs was held at the end of Day 2 to discuss remaining questions or concerns in a confidential setting.

7.1 Outreach to recipient countries
Reliance and risk-based systems are already used by NCLs participating in the Network, e.g. in Canada, in Australia, and in Europe where mutual recognition is applied and consequently each vaccine lot is tested only once for release within the EU OCABR Network. The focus of the WHO-NNB network is to promote reliance outside and across these countries and regions. Decisions on a legal basis for this reliance will need to be made in the countries concerned. However, as reported by Senegal, a recognition and reliance in WHO prequalification is worth considering.

It was suggested that all opportunities should be taken to inform countries importing prequalified vaccines about the Network and the possibility to participate as an associate member. Manufacturers have an important role as they provide the links to the countries where they are supplying prequalified vaccines. Network members can encourage NCLs of neighbouring countries and sub-contracted NCLs to participate. Information on the Network and explanations on how to participate should also be posted on the web.

7.2 Operationalization
Meetings
Network meetings of 2 ½ to 3 days should be held annually in the initial phase of the Network operations to keep up the momentum. The agenda should include updates from NCLs, stakeholders and WHO, and discussions on specific topics and harmonization projects and exchange of experiences. Interactive best practice-sharing sessions should be offered at each meeting. Suggested topics for this included 3R programmes, statistical methods, approval and testing of new vaccines, establishment of international standards, qualification and monitoring of reference materials, validation of new methods, and case studies of challenging situations for example in emergencies.

It was emphasized that ongoing communication between meetings is essential to ensure the continuity of Network activities.

In the plenary session, Dr von Hunolstein of the NCL of Italy announced her Institute’s willingness to host the Second General Meeting of the Network.

Information-sharing
The participants discussed the purpose and usefulness of sharing specific types of information among NCLs and stressed the need for mechanisms to ensure timely update of the shared information. Requirements mentioned for the electronic platform were: robustness and ongoing IT support,
traceability of access rights with functionality for appropriate WHO oversight, an audit trail of access by authenticated users, search functionality across NCL subsites, and a user manual.

8 Sharing of best practice
The meeting included sessions for sharing of best practices on control charts and on handling out-of-specification results. Presentations were made by Dr Andrea Gaggioli (invited expert), Dr Christina von Hunolstein (NCL of Italy), Dr Genevieve Waterloos (NCL of Belgium), Dr Martijn Bruysters (NCL of the Netherlands) and Dr Olivier Germay (IFPMA).

The technical discussions were useful for sharing of knowledge and experience. It is envisaged to reserve a full day for best practice-sharing at future Network meetings.

9 Conclusions and way forward
The expected outcomes of the meeting were as follows: Established contacts among meeting participants; overview of vaccine quality control strategies applied by new NCL participants; agreed content and features of the share point; volunteers for the share point (content / validation); agreed position on next steps to an operational entity; volunteers to support Network activities; agreed position on the structure and duration of the general meetings; fixed date of the next general meeting; shared best practices; proposals of themes for best practices at next meeting; and a meeting report (record of discussions and agreed decisions).

The participants considered that the above outcomes were achieved, or will be achieved in the follow-up to the meeting. The following next steps were agreed:

1. WHO will prepare a meeting report of the discussions and agreed decisions and circulate it among meeting participants for comment.
2. WHO will follow up on participation by additional members, seeking advice from the WHO Legal Department on any specific issues as needed.
3. The completed laboratory profiles will be shared among the members that submitted their NCL’s profile, using a secure method.
4. The WHO data management team will further complete the SharePoint in the next few months, and will provide a validation protocol for volunteers from NCLs to validate the platform.
5. WHO will approach manufacturers to extend its existing information-sharing agreements to allow information exchange among Network members.
6. The next face-to-face meeting will be held in Rome, Italy, in 2018 and will be hosted by the Centro Nazionale per il Controllo e la Valutazione dei Farmaci / Istituto Superiore di Sanità (CNCF/ISS).

In closing the meeting Dr Mike Ward pledged WHO’s support to make the Network fully operational.
He thanked the NIB team for hosting the meeting and the participants for their constructive suggestions.

The meeting was followed by a tour of the NIB laboratories. Participants received an USB-card with relevant meeting documents inclusive presentations.
10 References


# Annex 1: List of participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization*</th>
<th>Institution</th>
<th>Country</th>
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