Report on the Expert Consultation on Improving Access to and Use of Similar Biotherapeutic Products

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Executive Summary

On 2-3 May 2017 an expert consultation was convened by WHO to canvas the opinion of stakeholders regarding: the policy initiatives needed to encourage uptake of similar biotherapeutic products (SBPs); technical requirements to manufacture SBPs; the existing WHO regulatory support tools that need to be implemented, including potential use of a Biological Qualifier (BQ) in assigning international nonproprietary names (INNs); additional WHO regulatory support activities which might be needed; and how best to build trust in SBPs. WHO presented current biotherapeutic products (BTP)- and SBP-related work on regulatory support, product development support, and access activities, including preliminary information on a pilot project to prequalify two SBP cancer therapeutics (rituximab and trastuzumab).

The notable benefits of SBPs were presented, such as increased product availability and thus increased competition in the market and increased patient access. It was explained that because SBP development programmes are based on assessing similarity to the reference BTP rather than therapeutic impact in clinical trials, costs to develop SBP could also be lower. On the risk side, poor or inconsistent product quality due to divergent regulatory standards applied in some countries, alteration in quality and/or efficacy due to poor storage and handling, insufficient pharmacovigilance surveillance, and insufficient traceability were highlighted. However, it was pointed out that post-marketing studies have confirmed that SBPs developed and manufactured in line with WHO guidance, properly stored and handled, are as safe and efficacious as their reference BTPs. This illustrates the importance of following stringent regulatory standards which would ensure adequate quality, safety and efficacy of SBPs.

BTP/SBP interchangeability, complexities and diversities of nomenclature and the concept of biosimilarity were also discussed. It was pointed out that while the terms ‘reference biotherapeutic’ and ‘similar biotherapeutic’ imply a significant difference, in reality, difference or variation is an inherent part of biological production (variation occurring from batch to batch). Assuming three-dimensional structural similarities to the reference BTP within an accepted margin, the clinical impact (safety and efficacy) of BTPs and SBPs is expected to be highly similar. Quality, safety and efficacy assured BTPs and SBPs are thus comparable and suitable for use. This does not obviate the requirement to closely monitor reactions to SBPs in the population with effective traceability and pharmacovigilance.

A presentation on the lessons learned from the introduction of small molecule generic medicines regarding establishing trust stated that key ingredients include: clear government commitment to stringent regulation and to use; stakeholder involvement from the beginning; a robust regulatory framework, a balanced IP framework, fair pricing and reimbursement policy, and well-informed health professionals and patients. The importance of an effective market uptake policy was also underlined as was the need for clear definitions and clear guidelines (both developed in consultation with stakeholders).

Lessons learned and recent experience on BTPs and SBPs were presented by representatives from Australia, Norway, India and Brazil. Norway and Australia described qualified but definite progress regarding the uptake of both BTPs and SBPs in their health systems. Presentations from non-state actors included those by industry, patient groups and professional societies. A wide range of perspectives were offered and recurrent themes included: the need to ensure SBP quality, safety and efficacy notably through robust regulation and guidance; clarity regarding nomenclature and other terminology; the need for education regarding SBPs, including effective communication around
core messages and simple slogans. There was considerable interest in the prequalification (PQ) pilot and considerable discussion on the pros and cons of the BQ scheme.

Two rounds of breakout sessions, (A) policy initiatives and regulatory tools and (B) product development and building trust, were set up to identify priority areas for WHO to focus on. The main conclusions of these breakout groups were presented to the plenary and fed into the final overall discussion. The needs identified from the discussions include 1) greater clarity and consistency in terminology; 2) emphasis on therapeutic equivalence rather than biosimilarity; 3) early planning of policy measures prior to marketing approval, including communications and messaging around SBP (focused communication to promote increased uptake of SBPs, stressing similarities to reference BTP); 4) robust regulation to ensure the quality, safety and efficacy of BTPs and SBPs; 5) strengthened pharmacovigilance; and 6) clear global guidance on evaluation of SBPs (the point was made that the current guidance dating from 2009 provides excellent advice but requires additional clarifications based on experience gained). The issue of funding was also raised, bearing in mind the work that WHO might be called on to undertake in support of the SBP agenda.

Outcomes arising from the meeting

1. No consensus was reached on whether WHO should continue with the BQ – it should be noted that WHO will not be proceeding with this at present.
2. WHO will review and provide clarification on the SBP 2009 guidelines to reflect technological and analytical advances.
3. WHO will pilot the pre-qualification of two SBPs and will invite manufacturers of rituximab and trastuzumab to send expressions of interest.
Introduction

An expert consultation was convened on 2-3 May 2017 in Geneva, to discuss improving access to and use of similar biotherapeutic products (SBPs)*. The meeting was attended by members of the WHO Secretariat and experts working across a wide range of stakeholders relating to biotherapeutic products (BTPs) and SBPs, including academia, clinicians, regulators, health economists, and experts in health policy, members of WHO Expert Committees or Advisory Panel and WHO Secretariat (Annex A). Updates and lessons learned from selected countries were presented together with the needs for future support from WHO. Representatives from manufacturers’ associations, patients’ organizations and professional societies also had opportunities to present their views as observers.

This document provides the meeting overview and preliminary outcomes.

Background to the consultation

BTPs, such as monoclonal antibodies, growth hormones, cytokines and insulin, refer to therapeutic products that are manufactured using living organisms and recombinant DNA technology. Because manufacturing processes are highly complex and involve the use of living organisms, production of BTPs with high consistency is a challenge.

BTPs have amply demonstrated their value in treating many life-threatening chronic diseases and great research and development efforts are being made for innovative BTPs. In fact, more than 50% of applications to the International Non-proprietary Names (INN) Programme are biological and biotechnological substances that represent key components of BTPs. However, to date, the high cost and restricted market availability of BTPs has limited their use, particularly in developing countries.

SBPs are a part of BTPs that are structurally and functionally similar to an already-authorized reference BTP and manufactured according to a science-based regulatory approach with quality, safety and efficacy specifications determined by US FDA, EMA, WHO or other regulatory authorities. The expiration of the patents on key BTPs presents an opportunity for development of SBPs which will contribute to a substantial increase in their availability at affordable prices.

Although an increasing number of quality, safety and efficacy assured SBPs are available, market penetration of these SBPs in high-income countries is relatively limited, potentially due to lack of trust among physicians and patients, clear information on use, information dissemination channels, and financial incentives.

For the full benefit of SBPs to be realised, it is vital that they be trusted. It is therefore essential that regulatory decisions regarding the approval of such products be made by specialists with adequate knowledge of the products they are assessing. Improving trust in SBPs will also depend on ensuring the highest level of product quality. SBPs (like the BTPs to which they are referenced) are manufactured using living organisms, are structurally complex, micro-heterogeneous and can be difficult to manufacture consistently. It is therefore essential that manufacturing processes be optimally designed, executed, assessed and monitored. Finally, trust in SBPs will be encouraged

* One of the challenges faced in regard to BTPs and SBPs (the accepted WHO terms) is nomenclature. To reflect this reality, the different terms used by participants throughout the consultations have been left unaltered.
where patients and their physicians have a clear understanding that the benefits of the medicines substantially outweigh any risks.

**Purpose of the consultation**

WHO’s support to Member States in regard to SBPs has thus far concentrated on the development and implementation of regulatory guidelines, reference preparations, and nomenclature standards. Going forward, additional types of support will be needed which may include (but not be limited to) the development and dissemination of policy guidance and treatment guidelines. The purpose of the consultation was to canvas the opinion of experts to advise WHO on activities that might be prioritised to facilitate improved access to and use of SBPs.

**Overview of the proceedings/discussions**

**Session 1:** The Assistant Director General (ADG) welcomed the participants and informed that the consultation aimed to discuss with various stakeholders on how best to utilise the assets of WHO to improve access to SBPs.

Mr Nick Henderson and Christian Schneider served as co-chairs for the meeting.

Key challenges were set out, namely encouraging trust in SBPs, and developing and sustaining a fair market in SBPs which balances the interests of pharmaceutical companies and the need for patient access to quality therapeutics. The ADG stated that the meeting was intended to open a dialogue regarding SBPs, and encouraged a free and frank exchange of ideas.

The Model List of Essential Medicines (EML) already includes BTPs, such as rituximab and trastuzumab, where SBP versions are already available in some countries. Considering the needs for treatment of chronic diseases, such as cancer and diabetes, the number of BTPs on the EML will increase in the future and availability of SBP versions is expected to play a critical role in global health. It was also noted that WHO guidelines on evaluation of monoclonal antibodies as SBPs was finalized in 2016 and the WHO Prequalification (PQ) programme is developing PQ procedures for a pilot assessment of SBPs to be launched later in the year 2017, using rituximab and trastuzumab as test products.

It was confirmed that all temporary advisors and participants had completed the Declaration of Interest (DOI) forms which were received and reviewed by the Secretariat in advance. Potential conflicts of interest were declared by three participants, whose participation was allowed through public disclosure.

**Session 2:** The EMP Director affirmed that overarching mission of the Essential Medicines Programme is to support the WHO Member States to improve and sustain access to quality assured essential medicines within the Universal Health Coverage target (3.8) as a step to achieve the Sustainable Development Goals (SDGs) target. Keeping in mind this overarching mission, the Director reiterated the objective of the consultation is to canvas the opinion of experts to advise WHO on activities that might be prioritised to facilitate improved access to and use of SBPs.
Much can be done to improve access to and uptake of SBPs by, for example, elaborating existing initiatives such as the WHO EML, development of treatment guidelines, or prequalification programme. Access can also be improved through market shaping strategies such as those pursued by the Global Fund in relation to medicines and diagnostics for HIV/AIDS, TB, and Malaria.

The broad challenge is how best to align policy to encourage access to and uptake of beneficial products. Specific challenges include optimising the prescribing and use of products. Among the lessons learned over the past decade in regard to SBPs is the importance of managing trust which depends in part on ensuring quality, safety and efficacy of SBPs and making sure that it is understood that the benefits of SBPs outweigh any risk.

It was stated that WHO recognises the complexity of the challenge in regard to SBPs and is seeking advice regarding four key questions:

- What policy initiatives are needed to encourage uptake of SBPs?
- What are the product development needs?
- What existing WHO regulatory support tools, including the Biological Qualifier, need to be implemented and what additional WHO regulatory support activities are needed?
- What is the best way to build trust in SBPs?

**Session 3:** The session focused on the benefits and risks of the BTPs and SBPs that are currently on the market. The presentation opened with a discussion of nomenclature by citing the definitions of SBPs used by WHO and by the European Medicines Agency (EMA).

1. WHO: “A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product”
2. EMA: “A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal product) in the EEA (European Economic Area).

The benefits of SBPs were presented as: increased product availability, increased competition in the market, and increased patient access. Because SBP development programmes are based on assessing similarity to the reference BTP rather than therapeutic impact in clinical trials, development costs are also lower. The point was made that quality, efficacy and safety are expected to be highly similar to the reference product.

On the risk side, the main concerns include: BTPs/SBPs of poor or inconsistent quality due to divergent regulatory standards used in some countries; SBPs that have not been developed in line with WHO guidelines; alteration in quality and/or efficacy of BTPs/SBPs that are wrongly stored or handled; insufficient pharmacovigilance surveillance and insufficient traceability.

It was explained that SBP development is based on comparing the physicochemical and functional characteristics of a candidate SBP with respect to its reference product. The similarity profiling of a candidate SBP to its reference product is critically important and technological advances make characterization by assay extremely reliable. If a stringent similarity comparison is made accordingly, clinical studies need only be used to address any remaining uncertainties.

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In the EU, the regulatory assessment work on SBPs started out very cautiously. However, 10 years of experience have demonstrated the safety and effectiveness of the scientific approach taken in their development. As regards to ensuring the quality of the SBPs manufactured, it was presented that SBPs must be manufactured in the same manner as for any new BTP: manufacturing processes must be validated and yield a product of consistent and high quality; stability of the product must be shown for conditions of use; and impurities must be characterised and kept to a minimum.

While concerns have been voiced with regard to safety of SBPs, post-marketing studies have confirmed the efficacy and safety of SBPs in all licensed indications. Immunogenicity, or in this case, the immune response of a patient against a given SBP, is, in most cases, without clinical significance. SBPs are thus as safe and efficacious as their reference BTPs if developed in line with WHO guidance.

Session 4: WHO activities and initiatives related to BTP and SBP were presented. These were broken down into three areas of work:

- regulatory support activities;
- product development support activities; and
- access focused activities.

On the regulatory front, development of global written standards (e.g. guidelines) and physical reference standards, both of which are used to evaluate quality, safety and efficacy of BTPs and SBPs, were highlighted. WHO developed written standards for those applicable to all BTPs and for those specific to SBPs. WHO also runs implementation workshops for guidelines on BTPs/SBPs, bringing stakeholders together to discuss topics ranging from the role of the quality assessment of mAbs in the determination of overall biosimilarity to the immunogenicity assessment of BTPs. A rich pipeline of new candidates will have a significant impact on how risk-based assessment approach will be applied to evaluate SBPs.

Policies to assign International Nonproprietary Names (INN) for BTPs and SBPs were also discussed. It was pointed out that over 50% of applications for INN listing are for BTPs, and that the INN group has done considerable work on the need to include a biological qualifier (BQ) to minimize errors in prescription, dispensing, pharmacovigilance and international transfer of prescriptions.

On the access front, the first WHO model list of essential medicines (EML), published in 1977, has already included insulins as one of the medicines that are considered to be most effective and safe to meet the most important needs in a health system. Three BTPs (filgrastim, trastuzumab, and rituximab) were added to the EML in 2015 and several BTPs are currently being evaluated for the inclusion. As SBPs are a regulatory-defined category of BTPs, specific listings of SBPs will not be mentioned in the EML. The 2017 EML uses a square box symbol to indicate similar clinical performance within a pharmacological class in order to list only one drug for each therapeutic class. The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety and will have implications for procurement and tenders.

The WHO Regulation of Medicines and other Health Technologies unit presented the concept being developed on a pilot project to prequalify SBPs in order to address the lack of a global mechanism for evaluating safety, quality and efficacy of SBPs. Two cancer BTPs, trastuzumab and rituximab,
are proposed for a pilot prequalification. Drawing on international experience with Stringent Regulatory Authorities (SRAs), two pathways, one based on SBPs with SRA approval and the other without, are being considered. The pilot is aimed to investigate how SBPs can go through the PQ process and how PQ listing can contribute in improving access.

Session 5: A presentation on BTP/SBP interchangeability began with a discussion of definitions. Thus:

- **Interchangeability**: “The medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber.”
- **Substitution**: “Practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber.”
- **Switching**: “Decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment.”

It was stated that the concerns around the different definitions tend to focus on adverse immune responses, frequently mentioned when a patient who has been using a BTP starts using a corresponding SBP “at the same dose to treat the same disease”. According to the presenter, there is not much evidence for these concerns. However, a lack of evidence does not mean that these concerns should be taken lightly, but rather SBPs should have the same Risk Management Plan as their reference BTPs with clear traceability.

The presenter explained that the aim of an SBP development programme is not to establish therapeutic benefit (since this has already been established for the reference product) but to establish biosimilarity. While the terms ‘reference BTPs’ and ‘SBPs’ may imply a significant difference between these two categories of products, in reality, individual BTPs, within their own production runs, are inherently non-identical and no batch in a production run can be completely identical to the others. It is therefore important to define specifications which determine what is an acceptable difference between an SBP and its reference BTP and what is not. It was suggested that one way of doing this would be to establish thresholds within which safety and efficacy would not be impacted. However, it was stressed that monitoring reactions to SBPs in the population concerned is crucial, and requires effective traceability and pharmacovigilance. At the same time, the presenter cautioned that regulatory assessors, for example, need to be aware of reporting bias or other elements that may be included in reports related to SBPs.

After the presentation, a participant encouraged WHO to be very clear in its definitions, stating that even the EU definitions remain confusing and are different to those used in the USA.

Other questions addressed the issue of biosimilarity. The presenter stated that, while, scientifically speaking, SBPs are not identical to their reference BTPs, but “‘non-identicality’ is a normal principle in biotechnology”, “no batch of any biological is ‘identical’ to the others” and “the ‘art’ is to demonstrate that the biosimilar is as close as possible to its reference product in all relevant functional and structural aspects, within current technical and scientific limitations”. Within this concept, if there is no difference in clinical impact, they can, from a scientific perspective, be used interchangeably.
Session 6: Four presentations by Member States regarding BTPs and SBPs.

Norway. The presentation of the Norwegian experience reported the successful uptake of both BTPs and SBPs with European approval ensuring efficacy and safety. Policy emphasis is on ensuring quality of products, and quality of distribution. With regard to substitution of SBPs for BTPs, this is not permitted in the pharmacy, but is allowed at the discretion of hospitals/physicians. To date there have been no problems with substitution. SBP use has led to saving of 40-60% on tenders. Use of SBPs in hospitals is encouraged and there are strong financial incentives to switch. SBP market share has also increased as physicians become more familiar with them, but there are regional differences in SBP uptake. There is also a marked difference in uptake between the hospital and retail pharma sectors, the latter being much slower to embrace SBPs (perhaps because of the substitution ban).

Australia. The Australian presentation focused on the regulatory role of the Therapeutic Goods Administration (TGA) and the decision to reimburse two SBPs on the Pharmaceutical Benefits Scheme (PBS). The Australian government sees SBPs as an important way of encouraging competition in the marketplace and thereby enhancing access to medicines. Increased SBP uptake is expected to contribute to the sustainability of the PBS. Methods used to achieve price reductions on SBPs include a statutory 16% price reduction on the first generic/biosimilar listing on the PBS. Prices are reviewed every 6 months. Once a drug has gone through 6 review cycles, the originator BTP is removed from the calculator. This approach was reported to have saved Australia $20 million in one year.

The Australian government launched a Biosimilar Awareness Initiative in May 2015 as part of the PBS Access and Sustainability Package. The aim of the initiative is to support awareness of, and confidence in, the use of SBPs for healthcare professionals and consumers. Education awareness in support of the introduction of SBPs to the PBS includes education of community pharmacists and clinicians since 2015. As a result of these initiatives, attitudes to SBPs are changing. At first there were safety concerns about SBPs, but now these have changed to concerns about BTP/SBP switching. Specialists and general practitioners are concerned about community pharmacists substituting brands. The policy focus now is on disseminating information to prescribers and community pharmacists.

India. The presentation focused on regulatory requirements for approval of SBP in India. The Indian biopharmaceuticals business is growing at a compound annual growth rate of 16% and is estimated to be worth $700 million in 2017 and $2.5 billion in 2025. Indian manufacturers are marketing their biotech products in both the domestic and international markets. There are five regulatory bodies overseeing different stages of product development, two of which focus on genetic materials, one for testing of biologicals and the Drug Controller General of India is the apex regulatory body responsible for the approval of clinical trial approval and permission for manufacturing and marketing.

In India SBPs are called ‘Similar Biologics’ and are defined as products that are similar in terms of quality, safety and efficacy to an approved Reference Biological product, based on comparability analysis. The 2012 guidelines on Similar Biologics was revised to be more aligned with global regulatory systems. The revised 2016 guidelines includes analytical similarity in line with US-FDA and EMA requirements, increased safety data requirements, mandatory PK/PD comparative trails as well as phase III trials, compulsory post-marketing safety evaluation and obligatory immediate reporting of any serious unexpected adverse effects.
Brazil. The Brazil presentation described characteristics of Brazilian Unified Health System (SUS) and its partnerships for productive development (PDP) which aims to increase access to strategic products for SUS, to protect the interests of the public administration, to promote the development and manufacturing in national territory of strategic products for the SUS, to stimulate the development of the network of public production in the country, and more. ‘Biological or biotechnological products of human, animal or recombinant origin’ is one of 10 categories of strategic products that are required by the SUS for health promotion, prevention and treatment with centralized procurement by the ministry of health and whose national production and its active pharmaceutical ingredients or critical technological components are relevant for the Brazilian Industrial Health Complex. Priority products for PDP were launched in 2014 which identified 21 products, 6 being BTPs and 11 equipment.

Session 7: The country presentations were followed by presentations from non-state actors, including industry associations, patient groups and professional societies.

IGBA. International Generic and Biosimilar Medicines Association is a network of generic and biosimilar medicines associations, promoting access to affordable generic and biosimilar medicines. IGBA has 11 years’ experience with SBPs in the European market, and has accumulated a wealth of data which confirms the efficacy/safety of SBPs. Increased uptake of biosimilars as a result of the regulatory community helping health care professionals to understand biosimilars was noted. However, European governments are realising that they need policies such as non-monetary incentives for prescribers to switch to biosimilars. The presenter suggested WHO to provide technical assistance to support countries with limited experience in regulating biological products for ensuring quality, safety and efficacy of those products. Another area which requires support of WHO is distribution since distribution of BTPs and SBPs is cold chain-dependent.

IFPMA. International Federation of Pharmaceutical Manufacturers & Associations represents research-based pharmaceutical companies and associations across the globe. Presentation focused on the need for patients to have confidence that the regulatory systems will ensure their safety. For discussion, the presenter described that the absence of guidelines and/or constraints on regulatory capability and capacity led to the introduction of noncomparable biotherapeutics (NCBs), with concomitant safety concerns. To overcome concerns on quality, safety and efficacy, IFPMA suggested expanding the scope of the draft WHO pilot prequalification project3 to include BTPs and SBPs. Expansion of the scope would further assist in increasing access to medicinal products. He also suggested that WHO class-specific guidance (similar to the 2016 guidance for monoclonal antibodies) could be developed for insulins to complement current WHO guidelines on BTPs and SBPs. IFPMA strongly supports INN Expert group recommendations on the use of a BQ for naming biological and biotechnological products.

BIO. BIO represents biotechnology companies, academic institutions, state biotechnology centres and related organizations across the United States and in over 30 other countries. The presenter said SBPs can learn from the experience of the generic market, which shows that: patient confidence comes from stringent regulations; innovation, research and development need to be encouraged to allow development of biosimilars; patients and physicians need to be made aware that biosimilars are like their reference products. She underlined the importance of biosimilars in global health and

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stressed the need to demonstrate structural and functional similarities with their originator product. BIO suggested WHO to encourage countries to accept the concept of regulatory reliance; encourage countries to pool resources for supply chain integrity and pharmacovigilance; and commended WHO on its BQ proposal and expressed their support for development and implementation of naming conventions for biologics and biosimilars which allow traceability.

**IAPO.** The International Alliance of Patients Organisations represents 282 member associations in 71 countries covering 51 disease areas. The representative expressed an interest in increasing biosimilar uptake with benefits of greater choices and lower costs but also concerns on lack of clear product identification for SBPs and use of non-medical switching based on cost-saving or other reasons. Distinguishable naming, such as BQ, is key to ensuring confidence and preserving patient-physician control of treatment decisions and especially helpful in countries without a strong pharmacovigilance system. Therefore, IAPO supports the current BQ proposal and suggested that BQ naming should apply to originators and biosimilars, which will allow tracing of each product to its manufacturer. With regard to non-medical switching (for example switching based on cost), the patient and doctor should be involved in the final decision making about treatment choices. He concluded by saying that patients are excited about the benefits of biosimilars and that BQ will help patients worldwide enjoy the benefits of distinguishable naming which will build patient and physician confidence through transparency.

**FIP.** The International Pharmaceutical Federation (FIP) represents 3 million pharmacists and pharmaceutical scientists in 139 national associations and underlined roles of pharmacists with respect to biosimilars as follows:
- Influencing prescription of medicines (hospitals will take up medicines based on pharmacists recommendations)
- Promoting responsible use of SBP
- Ensuring quality (including pharmacovigilance)

The presenter stated that important lessons have been learnt from the experience with generics, namely that communication is crucial particularly to three main groups: patients, prescribers, and pharmacists. He stressed that to support better communication, it is important to have clear technical definitions and nomenclature regarding BTPs and SBPs. Finally, he underlined the importance of policy and regulation being aligned, stating that the regulations need to follow the policy and vice versa in order to optimise the uptake of biosimilars.

**HAI.** Health Action International (HAI) opened with the observation that despite insulin being off patent for many years, there are still access issues. HAI called on WHO to develop and harmonise guidance on manufacturing of SBPs for insulin and to assist in publishing guidelines and information in support of strategic procurement. As regards to the PQ pilot, HAI supports the concept and requested WHO to include insulin in the pilot as the price of analogue insulin is high and continued production of human insulin needs to be encouraged.

**KEI.** The Knowledge Ecology International (KEI) presentation focused on improving access to proprietary genetic information. It was suggested that the production of SBPs could be accelerated if it was possible to access the originators’ production methodology. She also suggested that that pharmaceutical companies can be mandated to share information regarding relevant patents, or be provided incentives such as ‘open source dividends’.
**IABS.** The International Alliance for Biological Standardization (IABS) presentation focused on accessibility to biosimilar products, noting that most current innovative biologics that are copied are licensed in the US and EU with scientific bridging to both the US-FDA and the EMA licensed reference product. An important remaining issue is how to maximise this achievement to shorten delays for global access.

**Session 8:** Two groups (A and B) were formed to discuss a common set of questions relating to potential priority areas for WHO to support/not support in the area of policy initiatives and regulatory support tools.

**Day 2**

**Session 9:** Day 2 opened with a presentation of the discussions of the two breakout groups.

Topics discussed by both groups included WHO’s roles in providing regulatory support, naming of biologicals, pricing of BTPs/SBPs and interchangeability.

**Breakout group A.** If SBPs are of a high quality and similar to their reference products, many of the currently raised issues would be reduced and products would compete on price. With regard to regulation, there was agreement that WHO should play a role in supporting low- and middle-income countries with limited technical capacity and experience to handle evaluation of SBPs. Capacity building is needed in all countries and WHO should encourage all countries to accept the regulatory reliance concept. It was suggested that mentoring and training are the best way to pass on skills and experience. Caution was raised regarding the regulatory burden of type and number of clinical trials required for approval of SBPs.

It was also noted that policy support needs to be in place at the marketing authorisation assessment stage to prevent delays in getting SBPs into the supply chain. It was stated that WHO has a role to play in collating and sharing country experiences in regard to SBP introduction and uptake.

It was agreed that clear technical definitions regarding BTPs and SBPs are needed in the interest of increased transparency and reduced confusion. There was some discussion about the value of naming conventions, and it was suggested that batch numbers might be a better way of addressing the issue of monitoring which product is used by which patient (since both BTPs and SBPs vary batch to batch). It was felt that earlier introduction of BQ would help establish nomenclature before countries introduce their own naming conventions. It was noted that the justification for BQ is to enhance pharmacovigilance, and suggested that the WHO expert committee on pharmacovigilance get involved to help advise on the best way to monitor SBPs. A participant noted that 3 years ago, the pharmacovigilance committee and Uppsala monitoring centre were consulted on the development and use of BQ and were in favour of the BQ project.

With regard to price, there was consensus around competition (i.e. the introduction of SBPs) being the best way to achieve lower prices. There was also discussion regarding the need for more pricing transparency, and greater support for governments in their procurement processes.

With regard to interchangeability, it was suggested that if high quality, safe and effective SBPs are available, there will be less concern about interchangeability. Although there was a good deal of
discussion around this, it was considered to be a lesser issue from the point of view of WHO involvement. It was suggested that compiling a list of interchangeable medicines might help Member States choose what is best for them. However, it was recognised that opinions on interchangeability are not going to change overnight.

Breakout group B. Terminology such as interchangeability, switching, substitutability was addressed as one of the key issues for facilitating access to BTPs and SBPs. There was a request for WHO help with clarifying definitions and developing good practices as well as prerequisites for interchangeability at the global level.

The importance of regulatory system strengthening in general to build trust in SBPs was discussed. It was suggested that WHO should play a key role in supporting regulatory system strengthening, notably in the area of setting regulatory standards which are critical for global regulatory convergence.

With specific regard to the 2009 WHO guidelines on SBP, it was felt that while they provide relevant and up-to-date principles for evaluation, these could be modernised and more recent examples added. One participant said that she recalled the World Health Assembly calling for a revision of the guidelines, and said that guidelines might need to take into account technological advances since 2009.

There was strong support for INN experts to promote BQ, and the need to reduce regional approaches was underlined. The importance of implementable tools to enable traceability and follow up was also stressed. It was stated that, currently, available tools are not being properly used or implemented, so there is a need to implement BQ.

On pricing, it was felt that a landscape analysis to identify barriers and challenges would be helpful. There was a specific plea for help on improving insulin access, notably through PQ and support on strategic procurement. Many participants agreed and expressed strong support to improve access to insulin as a public health priority.

Session 10: A presentation by the Medicines Patent Pool (MPP) focused on the issue of trust and lessons learned from the introduction of small molecule generic medicines. It was stated that trust is built on: clear government and political commitment and stakeholder involvement from the beginning (to ensure buy-in); a robust regulatory framework, a balanced IP framework, fair pricing and reimbursement policy, and well informed health professionals and patients. The importance of an effective market uptake policy was also underlined as was the need for clear definitions and clear guidelines (both of which discussed with stakeholders). The presenter also stressed the importance of reasonable fees and timely authorisation, good manufacturing, inspections, and a reliable API supply.

Regarding pricing, it was stated that various options are available, but trust is based on price transparency. As concerns stakeholder involvement, it was suggested that the more stakeholders are involved, the more likely it is that trust will be built. Facilitating uptake is key, notably by supporting/incentivising pharmacy substitution.

It was stated that, above all, people need to know that quality assured generics and biosimilars are as safe and effective as the originator. It is also important for people to understand that savings will be made which are of benefit to patients and healthcare professionals (and health systems).
Questions followed. The first focused on the need for champions to encourage uptake. The presenter stated that champions both at the national and international levels have supported the uptake of generics. It was agreed that champions for biosimilars such as health professionals need to be brought together to look at implementation. Hospitals are going to be the key especially in LMIC for introduction of biosimilars. The point was made that clinicians themselves have to be won over. It is very difficult for many clinicians to understand that they can trust similarity data and not just clinical data. They need to understand the evaluation process of biosimilar is thorough.

There was a question regarding the difference between small molecule generics and SBPs in terms of the discounts available. It was stated that in the EU discounts of 15% for SBPs were available as opposed to 80% for generics. The 15% number was challenged, one participant stating that the average reduction for biosimilars in the EU is between 30-40%. The participant said that tendering does work but can have drawbacks (i.e. limiting the number of products in the market). The importance of maintaining a number of suppliers in the market was highlighted, to both create competition and for security of supply.

Session 11: European Medicines Agency (EMA) made a presentation on experience in developing patient and physician trust in products. The presentation focused on the EU, and recapped 11 years in which a solid framework aligned with WHO standards has delivered positive results with no problems with adverse effects. The presenter said that there were a number of biosimilar withdrawals from the market early on, but that it is now very rare. However uptake is slow, and patchy between countries and within countries (better in hospitals, less good in communities). Some countries take up a biosimilar, but others don’t. So the problem appears to be not the biosimilar, but implementation.

A major challenge is educating health care professionals. The presenter said that peer reviewed papers are the best way to get the information across but that they are time consuming to produce. An information guide for health care professionals is being updated. Capacity building is also a key focus. The presenter said that training and education of the existing methods from EU would be something that can be shared.

There were a number of questions about scientific advice for manufacturers provided by EMA online and about EMA training initiatives. It was stated that the information on the EMA website is more for regulators and manufacturers and not necessarily for prescribers or patients, but that there is always a summary in lay language.

Session 12: Two breakout groups (C and D) were formed to discuss potential priority areas for WHO to support, or not support, in the area of product development and building trust.

Session 13:

Breakout Group C. Group C discussed priority areas for WHO and other partners to support. Priorities with regard to product development: investigating which products or diseases would have the biggest impact for health systems in LMIC; encourage NRAs to tailor development of products to local needs; make international standards or other public standards available to support the development of products; WHO providing education on different regulatory approaches, such as standalone versus biosimilar pathways (this may involve advising manufacturers on the challenges of biosimilar development); assuming the PQ pilot is successful, expanding PQ to priority BTPs; and strengthening NRAs in LMICs.
Priorities with regard to messaging and education: WHO developing global uniform messages that can be used by key actors to build trust, working with stakeholders to see if the messages are working; regulatory authorities making available easy-to-find data supporting safety and interchangeability of SBPs. WHO should also assist regulators, pharmacists and physicians to understand what ‘real’ biosimilars are.

Priorities with regard to WHO Standards and Guidelines: selecting a reference product; helping monitor false products (it was noted that it has already been proposed that the BQ database support traceability).

Breakout Group D. Group D reported back that regarding trust, the main challenges identified related to different groups having different perspectives, and some overemphasizing problems with biosimilars. The term biosimilar itself was also discussed, and it was stated that because it implies not equal it may have damaged some trust in these products. On the same theme it was stated that confused messaging has been unhelpful. Other challenges to trust identified were manufacturers having different standards in different countries, and lack of/tardy attention to initiatives to ensure effective uptake.

With regard to needs, Group D identified: reassuring stakeholders about variability issues and the clinical impact of products; making sure regulatory authorities have the competence, experience and tools to assess SBPs; clear (proactive and reactive) messaging that SBPs are as good as the originals; better access to data for BTPs and SBPs; stressing the savings that can be made by using SBPs; stronger pharmacovigilance systems (especially regarding adverse events and holding manufacturers accountable); addressing uptake issues early in the development cycle; and building the capacity of regulatory authorities in LMICs. It was also stated that there is a need to show increased confidence in SBPs, a potential narrative being that early caution/conservative actions are no longer needed. There should be some investment in communication (i.e. bio-equivalents in safety and efficacy).

Proposed WHO interventions: share best practices and information; strengthen collaboration between countries; improve purchasing power, such as through pooled procurement mechanisms; support advocacy efforts; support sending experts or consultants to countries that are in need of capacity, especially regulatory experts; support more effective communication, helping with messaging and explaining context; document lessons learnt and produce necessary guidelines; support discussion of whether a new term should be used.

Session 14: There was an overall discussion of the issues raised during the two days. Key topics were revisited, several relating to messaging/communication, and in particular the need for greater clarity and consistency in terminology. It was stated that communication is key to promoting increased uptake of biosimilars and must involve a wide range of stakeholders, including physicians, and patients. The need for robust regulation to ensure quality of BTPs and SBPs and build trust (biosimilars with authorisation should continue to be monitored and adverse events immediately reported) was also noted. Regarding interchangeability, it was suggested that this is not a major issue as long as there has been a robust regulatory evaluation. Regarding guidance, the point was made that the current guidance (2009) provides excellent advice and should only be revised, if needed, for a very good reason. Work could also be done on education about the guidelines.
Session 15: The co-chairs summarised the meeting. It was stated that WHO needs to review the feedback from the breakout groups and the synthesis from the feedback. The number of issues raised regarding regulatory support was noted and it was stated that WHO will follow up on the issue. WHO could also provide advice on pharmacovigilance system strengthening. As for the 2009 Guidelines, it was stated that while they represent a solid framework, they could be improved to reflect technological and analytical advances.

The importance of early planning of policy measures prior to marketing authorization was reiterated, including communications and messaging around SBP, and the need for WHO support in this area. A key issue in this regard is clarity regarding terms. The importance of building trust through education was also underlined. With regard to improving access, it was suggested that WHO could play a role to support Member States with pooled procurement mechanisms.

There were a number of comments from different stakeholders.

With regard to the WHO guidelines on evaluation of SBPs, it was emphasised that a review should reflect the techniques that have been developed since its publication. It was suggested that an addendum to the guidelines might be sufficient. It was also suggested that the guidelines take into account the different needs for products, such as product-specific guidelines for insulin. It was noted that there is no country consensus on what is needed and what is not needed when assessing biosimilars (e.g. insulin(s) requires phase 3 trials by FDA but not by EU). The Secretariat replied that it would be possible to make a product specific guideline for insulin(s), and start a discussion on what is needed for biosimilar assessment (e.g. phase 3 trials, and animal studies).

On messaging, there was a call for support for policy guidance and clear ‘central’ messages from WHO. As to the objections of people who are against certain biosimilars, it would be useful to get a survey on what the objections are. Some studies have been done but they may have some bias. At the same time efforts need to focus on getting the information out as doctors often do not know where the information is or how to find it. On the positive side, countries are interested in biotherapeutics, and this momentum needs to be seized.

The issue of funding was raised, bearing in mind the work that WHO might be called on to undertake.

**Outcomes arising from the meeting**

1. There was no consensus on whether WHO should continue with the BQ naming convention. WHO will not be proceeding with this at present.
2. WHO will review and provide clarification on the SBP 2009 guidelines to reflect technological and analytical advances.
3. WHO will trial the pre-qualification of biosimilars and will invite manufacturers of biosimilar rituximab and trastuzumab to send expressions of interest.

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Annex A

**Expert consultation on improving access to and use of similar biotherapeutic products**
Salle IV - HQ/ILO, Geneva, Switzerland
2-3 May 2017

**List of Participants 1, Meeting room M 205 at WHO**

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<tr>
<th>Temporary Advisers</th>
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<tr>
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Expert consultation on improving access to and use of similar biotherapeutic products
Salle IV- HQ/ILO, Geneva, Switzerland
2-3 May 2017

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Annex B

Expert consultation on improving access to and use of similar biotherapeutic products
Salle IV, ILO, Geneva, 2-3 May 2017
AGENDA

Co-chairs: C Schneider and N Henderson
Rapporteur: F Suleman

Day 1: Tuesday 2 May 2017

Session 1 Welcome and introduction
09:00 - 09:15 Opening remarks: MP Kieny
09:15 - 09:30 Self-introductions
09:30 - 09:40 Statement on DOI assessment Housekeeping information
WHO

Session 2 Background and objectives
09:40 - 10:00 Rationale for the meeting, objectives, and expected outcomes on improving access to, and use of, similar biotherapeutic products S Hill

Session 3 Regulatory
10:00 - 10:30 Benefits and risks of biotherapeutic and similar biotherapeutic products that have been placed onto the market M Weise

10:30 - 11:00 Coffee break
11:00 - 11:15 WHO initiatives to date D Wood
11:15- 11:30 Options for a pilot prequalification scheme for similar biotherapeutic products E Cooke

Session 4 Policy
11:30- 12:00 Available evidence on benefits and risks of switching similar biotherapeutic products and remaining scientific gaps C Schneider

12:00- 13:00 Lessons learned by countries from recent experience
   - Australia
   - Norway
   - India
   - Brazil
13:00 - 14:00 Lunch break

14:00- 15:30 Perspectives from non-state actors: patient groups; industry; and professional societies
- IAPO
- IGBA
- IFPMA
- BIO
- ALIFAR
- FIP
- HAI
- KEI
- IABS

15:30 - 16:00 Coffee break
Session 5 Breakout groups
16:00 – 17:30 Two groups discuss a common set of questions on potential priority areas for WHO to support, or not support, in the area of (a) policy initiatives and (b) regulatory support tools
Group A: ILO Salle IV Facilitator Sue Hill, Rapporteur Andrew Rintoul
Group B: WHO Room M205 Facilitator Emer Cooke, Rapporteur Ivana Knezevic

18:00 Reception at WHO

Day 2: Wednesday 3 May 2017

Reconvene in plenary session, Salle IV, ILO, Geneva
09:00 - 09:20 Report back from breakout group A Andrew Rintoul
09:20- 09:40 Report back from breakout group B Ivana Knezevic

Session 6 Product development
09:40- 10:10 Current and projected market dynamics for biotherapeutic and similar biotherapeutic products
(to be confirmed)
10:10- 10:30 Discussion

10:30 - 11:00 Coffee break
Session 7 Building trust
11:00 - 11:20 Lessons learned from introduction of small molecule generic medicines Greg Perry, Medicines Patent Pool
11:20 – 11:40 Experience in developing patient and physician trust in products Ana Hidalgo-Simon, EMA
11:40-12:00 Discussions

Session 8 Breakout groups
12:00-13:00 Two groups discuss a common set of questions on potential priority areas for WHO to support, or not support, in the area of (a) product development and (b) building trust

Session C: ILO Salle IV Facilitator Martin Friede, Rapporteur Erin Sparrow
Session D: ILO Salle IV Facilitator Nicola Magrini, Rapporteur Deidre Dimancesco

13:00 - 14:00 Lunch break
Reconvene in plenary session
14:00 - 14:20 Report back from breakout group C
14:20-14:40 Report back from breakout group D

Session 9 Overall discussion of issues raised in the meeting
14:40 – 15:00 Discussions

15:00 - 15:30 Coffee break and end of open part of meeting
Session 10 Closed session – temporary advisors
15:30 - 17:00 Conclusions and Next steps/action-plan
Close of meeting