

Congress Report

**Implementation of Blood and Blood Product Regulation Training Workshop, South Africa****Atelier de Formation sur la Mise en Oeuvre de la Réglementation du Sang et des Produits Sanguins, Afrique du Sud**

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ABSTRACT

The training workshop on Implementation of Blood and Blood Product Regulation was organised and co-hosted by the Paul-Ehrlich-Institut Global Health Protection Program BloodTrain and the Africa Society for Blood Transfusion (AfSBT) from the 20th to the 22nd of August 2019. This was aimed at strengthening the capacity of African countries in developing and implementing regulatory systems for blood. Over thirty participants from countries across the African continent came together in Johannesburg, South Africa and shared knowledge and experiences among themselves and also with experts from the BloodTrain, Africa Society for Blood Transfusion (AfSBT), World Health Organization (WHO) and the New Partnership for Africa's Development (NEPAD). The workshop addressed a wide range of topics ranging from standards in transfusion, clinical practice, regulatory framework for blood, WHO guidelines related to blood regulation, haemovigilance and regulatory oversight of associated Medical Devices In-vitro Diagnostics. In addition to the context and motivation of the workshop, this report summarises the key content covered throughout the workshop and recommendations for further improvement.

RÉSUMÉ

Un atelier de formation portant sur la mise en œuvre de la réglementation du sang et des produits sanguins a été co-organisé par le programme de protection de la santé mondiale Paul-Ehrlich-Institut BloodTrain et la Société Africaine de Transfusion Sanguine (SATS) du 20 au 22 août 2019. Il visait à renforcer la capacité des pays africains à élaborer et à mettre en œuvre des systèmes de réglementation pour le sang. Plus de trente participants de pays du continent africain se sont réunis à Johannesburg, en Afrique du Sud et ont partagé leurs connaissances et leurs expériences entre eux ainsi qu'avec des experts de BloodTrain, de la SATS, de l'Organisation Mondiale de la Santé (OMS) et du Nouveau partenariat pour le développement de l'Afrique (NEPAD). L'atelier a abordé un large éventail de sujets, allant des normes de transfusion, de la pratique clinique, du cadre réglementaire pour le sang, des directives de l'OMS relatives à la régulation du sang, à l'hémovigilance et à la surveillance réglementaire des diagnostics in vitro des dispositifs médicaux associés. En plus du contexte et de la motivation de l'atelier, ce rapport résume le contenu clé couvert tout au long de l'atelier et des recommandations pour de nouvelles améliorations.

INTRODUCTION

Ensuring the quality, safety and availability of blood and blood products is essential for the establishment and maintenance of effective public health systems. The African region is not yet meeting its requirements for safe blood and other blood products and there is a big gap when compared to developed countries.^{2,3} The World Health Assembly adopted Resolution WHA63.12 in 2010 which among other things recognised that a special effort is needed to strengthen globally the technical capacity of National Regulatory Authorities (NRAs) to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognised standards.¹ The importance of blood in public health was further emphasised by the inclusion of whole blood, red blood cells, platelet concentrates and fresh frozen plasma in the WHO Model List of essential medicines in 2013.⁴

The Africa Society for Blood Transfusion (AfsBT) was formed in 1997 as a Non-Profit Organisation. Its goal is to advocate for the highest ethical and professional standards, practices and skills in blood transfusion across Africa, enabling safe, universally accessible and sustainable national blood programmes. To achieve this they pursue several activities, including research, education and training, organisation of workshops and a biennial congress, and a program for step-wise accreditation of blood establishments. The Step-Wise Accreditation Program (SWAP) was launched in 2014 to endorse, approve or credit officially when a national blood service demonstrates compliance with AfsBT standards.

The Global Health Protection Program (GHPP) of the German Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) assists partner countries and the WHO in epidemic prevention measures. Within the GHPP, the Paul Ehrlich Institut (PEI) supports authorities and organisations in Africa with the expansion and development of regulations to improve the access to safe and effective vaccinations (VaccTrain), as well as blood and blood products (BloodTrain). The goal of the BloodTrain is to improve accessibility, safety and quality of blood and blood products in Africa. To reach this goal, the BloodTrain is supporting the development of blood regulatory structures in Africa and their adaptation to crisis situations.

With this workshop, AfsBT and BloodTrain are responding to some of the needs identified during the benchmarking of regulatory systems in African countries and aiming to build

on the successful previous workshops organised by the WHO. The first regional workshop on blood regulatory systems has been organised by WHO in Johannesburg, South Africa, in September 2013, in order to build national capacity for improving access to blood and blood products. In the same frame, two workshops were organised by WHO AFRO in Cotonou, Benin, in 2015 and 2016 in order: (i) to sensitise National Regulatory Authorities (NRAs) and Directors of National Blood Transfusion Services (NBTS) on blood regulation issue; (ii) to develop guidelines for the establishment of the regulatory system for blood and blood products as well as the related assessment tool specific to the context of the African region.

The goal of the Implementation of Blood and Blood Product Training Workshop was to further strengthen the capacity of participating countries for introduction and implementation of effective regulatory systems for blood and blood products. It also aimed to facilitate and to support the efficient interaction between Blood Regulatory Authorities and Blood Transfusion Services who are the key stakeholders in the blood regulatory systems. AfsBT and BloodTrain were working with partner institutions including the New Partnership for Africa's Development (NEPAD) and the World Health Organisation (WHO) in organising the workshop.

THE WORKSHOP

The AfsBT and the BloodTrain hosted a workshop together from the 20th to 22nd August 2019 Midrand, Johannesburg, South Africa. There were 33 participants from both regulatory authorities and national blood transfusion centres from the following 16 countries (in alphabetical order): Cameroon, Egypt, Ethiopia, Ghana, Kenya, Liberia, Malawi, Morocco, Nigeria, Rwanda, South Africa, Sudan, Tanzania, Uganda, Zambia and Zimbabwe.

Representatives from the WHO HQ, WHO AFRO, and from NEPAD-AMRH were invited in order to facilitate the interaction with these relevant stakeholders of the BloodTrain. WHO-EMRO also participated to present their activities to strengthen blood products regulation in their region. To allow for a better interaction, the EMRO representative was accompanied by participants from Egypt, Morocco and Sudan.

WORKSHOP SCOPE AND PROGRAMME

The scope of the workshop was to provide a training platform for both the SWAP focusing on the blood establishments and BloodTrain's activities to strengthen the regulatory systems in

Sub-Saharan African Countries concerning blood and blood products, focusing on the regulatory authorities. By this approach, both operators and regulators were able to come together to learn and discuss about blood safety. AfSBT gave several presentations to teach the participants about the quality management system in the blood establishments and the standards for blood transfusion. Both are important indicators to be tested during SWAP that AfSBT provides. BloodTrain informed about their activities, and gave lectures and interactive case studies to aspects of the regulation of blood and blood products. This portfolio was complemented by presentations from the other stakeholders that participated in the meeting.

Session 1: Opening Ceremony

The workshop kicked off with opening remarks from AfSBT, BloodTrain NEPAD and WHO. This was followed by the overview of the GHPP Partner Country Program by BloodTrain. There are five partner countries in the program namely Ghana, Nigeria, Tanzania, Zambia and Zimbabwe. These countries are being assisted in developing and implementing regulatory systems for blood by the PEI BloodTrain team. To ensure sustainability, the regulatory authorities will be supported in their efforts to train both internal staff and regulators from their neighboring countries.

Session 2: Overview of the National Blood Supply and Blood Regulatory Systems

Next, François-Xavier Lery from WHO Headquarters presented the “WHO Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020-2023.” The aim of the action framework is to provide strategic direction to efforts to address current challenges hindering accessibility to safe blood products globally. In addition, he gave an overview on the “WHO regulatory systems strengthening activities including the global benchmarking tool” for the assessment of the maturity of National Regulatory Agencies on the other.

André Loua from WHO AFRO presented key elements for successful management of blood supply, as well as regulatory frameworks and system capacities in Africa. Inadequate funding for blood programmes in Africa which results in failure to meet required quality and safety standards has been noted as one of the major challenges. Other challenges include lack of expertise, poor data collection and information, and management systems among others.

Yetmgeta Abdella from WHO EMRO presented a “Review of blood regulatory frameworks in the Eastern Mediterranean

Region”. It was noted in the review that there is a lack of clarity and fundamental principles of blood supply, transfusion, ethics, quality fundamental principles and Good Manufacturing Practice (GMP) are not anchored in the legislations of most countries. Furthermore, plasma derived medicinal products, associated substances and medical devices are not covered in the regulatory frameworks. Review results formed the basis of support strategies to improve blood safety in the region.

Session 3: Standards for Blood Transfusion

AfSBT presented an overview of the organisation, followed by an introduction in the blood safety value chain and the concept of the quality management system in blood establishments. The presentations on the Standards for Blood Transfusion, which are the basis of the SWAP of AfSBT, set the stage for a deeper understanding of the AfSBT accreditation activities. AfSBT SWAP is recognised and supported by the WHO and it recommended African member states to have their blood establishments participate in this programme to improve quality and safety of blood supply in the region. It was clarified that regulation and accreditation are not substitutes for one another but complementary with the former being mandatory and the latter voluntary.

Session 4: Implementation of Blood Regulatory Systems

Paul Tanui (AUDA-NEPAD) explained the “AMA Framework and Blood” to show how the harmonisation activities of the African Medicines Agency integrate different input with the goal to eventually support a harmonised access to blood and blood components of consistently high quality, safety and efficacy in Africa. He also presented the activities that lead to the establishment of the “African Blood Regulators Forum” as a technical working group of the African Medicines Regulatory Harmonization (AMRH) Initiative that will allow an interactive exchange of experiences of blood regulators in Africa.

BloodTrain presented on “Registration, Approval, Authorisation or Licensing of Blood Establishments”, “Establishing a Haemovigilance System” and “Regulatory Oversight of associated In-vitro Diagnostics (IVDs)”. IVDs for Transfusion Transmissible Infections (TTIs) are an essential part to guarantee the safety of donated blood and ultimately of the transfused blood and blood components, which therefore need to be thoroughly controlled. Furthermore, the BloodTrain also hosted one group work session on licensing/registration of blood establishments, where the participants were confronted with the case study from a hypothetical African state, where the existing blood establishments should start to file for licensing according to the blood legislation of this hypothetical

country. Within this group work, challenges for both the blood establishments and the regulatory authorities were identified. In the following discussion, this situation was compared to the experiences of the participants in their own countries. In a second interactive session, the basic concepts of haemovigilance systems were discussed.

PRESENTATIONS FROM PARTICIPATING COUNTRIES

During day 3 of the workshop, participants from Ghana, South Africa, and Zimbabwe provided an update of the progress as well as future plans on blood regulation in their respective countries. All presented the legislative and regulatory framework in which they operate, as well as the recent advancements in their efforts to strengthen the blood regulation.

Mr Abu Sumaila (Ghana Food and Drug Authority) pointed out that so far Ghana started a voluntary licensing program for blood establishments, even though licensing is mandatory with the new blood regulation that started in 2016. However, this is not yet fully enforced to allow for the blood establishments to adapt to the new regulations. Data from the 66 inspections performed so far were presented and summarised some common findings of the inspections. So far, the inspection reports are used to inform the blood establishments about their shortcomings and they are invited to apply for licensing once the findings are corrected. He further explained the inspection and the licensing process in Ghana and pointed out that until now only five blood establishments were licensed.

Mr Khamusi Mutoti from the South African Health Products Regulatory Authority (SAHPRA) highlighted the step-wise approach that SAHPRA is taking in implementing blood regulation. It was reported that the first step taken is to develop GMP guidelines for blood products which will assist inspectors as well as the blood establishments. These will be developed in consultation with other stakeholders such as the blood establishments and accreditation agencies. The next step will be the mapping of blood establishments in the country and categorizing them according to the activities they perform. The other step would be to develop guidelines for haemovigilance. The human resource requirements are currently being addressed with posts for inspectors and scientists being advertised.

Ms Linda G Mudyiwenyama from the Medicines Control Authority of Zimbabwe (MCAZ) presented the recent advancements for Zimbabwe. Draft MCAZ Blood Regulations

are currently being reviewed with relevant stakeholders and the process is almost complete. Mapping of blood establishments in the country is also ongoing. The framework for step-wise implementation of regulation of associated Medical Devices and IVDs is being worked on and currently at draft stage. She highlighted a few challenges being faced including lack of competence and expertise in regulation of blood which is being addressed by the trainings offered by the GHPP BloodTrain. Regarding the regulation of IVDs, Zimbabwe is gradually starting to implement this and have also drafted an IVD regulation which is still being reviewed by the stakeholders before the final adoption. Furthermore, she pointed out that a lack of skilled staff in this area is a major concern for Zimbabwe.

OUTCOME

The workshop was lively with active participation from all present. By the end of the workshop, participants had gained practical knowledge on how to implement regulatory systems for blood products. Participants from each country could determine their current needs and actions required in setting up blood regulatory systems. Each country developed draft action plan with fundamental steps that should be taken depending on their situation. The baseline situations vary significantly among countries and hence do the action steps in implementing regulation. A step-wise approach was recommended with countries starting to build on what they currently have. Participants were encouraged to take the proposed action plans to their superiors as output from the workshop and for adoption for implementation. Participants from blood establishments, most of whom had no prior knowledge about regulation had good appreciation of the subject by the end of the workshop. Similarly, regulators were aware of the key aspects of blood transfusion.

RECOMMENDATIONS

The following recommendations were made during the workshop:

- WHO should continue encouraging member states to provide resources and support blood systems in their countries and regulation thereof.
- NRAs could make it mandatory for blood establishments in their jurisdictions to be accredited/certified by specific bodies such as AfSBT thus ensuring that they meet internationally recognised quality standards.
- Efforts need to be made in following up on implementation after training workshops. This is against the background that there were some workshops done previously but there was no tangible evidence of

implementation of recommendations thereof.

- BloodTrain and/or other partners were encouraged to support more African countries in setting up regulatory systems for blood as an essential medicine.
- Participants recommended having these kinds of training workshops periodically to build on the momentum created and to ensure the continuity of these programmes.

CONCLUSION

AfSBT has made impact in improving blood safety in the region mainly through implementation of its SWAP for blood establishments. Regulatory systems for blood products have not yet been developed in most African countries. The PEI/GHPP BloodTrain project is making significant progress in assisting countries in setting up blood regulatory systems. Collaboration between BloodTrain and AfSBT is yielding positive results as both operators and regulators could be brought together and share vital information for improvement of blood safety. This is complementing efforts by WHO which has and still is developing and implementing strategies for improving access to safe blood of which strengthening regulatory systems is one of the key strategies. The workshop was successful in achieving the intended objectives.

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