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PLAN OF ACTION FOR UNIVERSAL ACCESS TO SAFE BLOOD: FINAL REPORT

Background

1. In 2014, the countries of the Region approved the Plan of Action for Universal Access to Safe Blood for the period 2014-2019 (Document CD53/6) (1) and the associated resolution (Resolution CD53.R6) (2), which urges Member States to implement the Plan and the Director to monitor and evaluate its implementation and to report periodically to the Governing Bodies. The goal of the Plan is to promote universal access to safe (blood through voluntary non-remunerated donation, using quality systems and hemovigilance in blood services organized on the basis of efficient and sustainable models. The Plan established four strategic lines of action that seek to maintain the progress made and tackle new challenges in order to achieve blood self-sufficiency, safety, efficiency, and availability and to ensure universal access to blood and blood products.

2. A midterm review conducted in 2017 (3) found that most Latin American and Caribbean countries had specific national entities to coordinate the response to blood needs and implement quality and safety standards. The review also noted slow progress in the restructuring of blood services networks. Moreover, updated national blood policies and plans with an integrated approach were still needed, as were functioning intersectoral national commissions to facilitate implementation. The purpose of this document is to inform the Governing Bodies of the results obtained as of the end of the period covered by the Plan of Action for Universal Access to Safe Blood.

Analysis of Progress Achieved

3. The Plan of Action for Universal Access to Safe Blood sought to improve access to and availability of safe blood through voluntary non-remunerated donation. By 2017, Latin American and Caribbean countries had increased blood collection to more than 10 million units per year, 46% of which came from unpaid voluntary donors, a slight increase from the 44.2% recorded in 2015 (4). The blood donation rate stood at 17.7 units per 1,000 population in 2017. Significant advances were made in blood quality and safety through the implementation of serological screening for transfusion-transmissible infection markers and external serology quality assessment programs. Progress was also made with

regard to information systems, strategic plans, and legislation. Less progress was noted in surveillance of services, monitoring of donation- and transfusion-related events, and monitoring of the Plan of Action. Further information on progress under each strategic line of action is provided below.

Strategic line of action 1: Effective and sustainable integration of national blood programs and services into the national health system to achieve blood self-sufficiency, safety, efficiency, availability, and universal access to blood and blood products

4. Progress was made under this strategic line in relation to indicator 1.2.1, with the number of countries with a national blood plan climbing from 13 to 22; and indicator 1.3.1, with the number of countries that have improved efficiency and are processing more than 5,000 units of blood per blood bank/year rising from 12 to 19, an increase that is due to higher blood collection rates in some blood services and not to restructuring of the network (5). Indicators 1.1.1 and 1.1.2—relating to the number of countries with a specific functioning entity in the ministry of health that is responsible for the national blood system and an intersectoral national blood commission—showed the least progress. The poor performance with regard to these indicators, together with the modest progress made in monitoring and use of information on blood services, indicates weaknesses in the management and implementation of national policy, both intra- and intersectorally.

| Objective 1.1: Strengthen planning, implementation, monitoring, and evaluation processes in national blood programs | |
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| Indicator, baseline, and target | Status |
| <p>1.1.1 Number of countries that have a specific functioning entity in the ministry of health that is responsible for planning, monitoring, and evaluation of the national blood system</p> <p>Baseline (2014): 27/41 Target (2019): 36</p> | <p>The target for this indicator was not met: 27 countries have a specific entity, 17 in Latin America and 10 in the Caribbean (in comparison with the midterm review, one country in Latin America made progress and another changed its status; in the Caribbean, one country made progress and another did not report).</p> |
| <p>1.1.2 Number of countries that have a functioning intersectoral national blood commission or advisory mechanism</p> <p>Baseline (2014): 14/41 Target (2019): 21</p> | <p>The target for this indicator was not met: 16 countries have an intersectoral national commission, 8 in Latin America and 8 in the Caribbean.</p> |

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| Objective 1.1: Strengthen planning, implementation, monitoring, and evaluation processes in national blood programs | |
| Indicator, baseline, and target | Status |
| 1.1.3 Number of countries whose blood policy includes self-sufficiency, availability, and universal access to safe blood and blood products Baseline (2014): 18/41 Target (2019): 26 | The target for this indicator was not met: 23 countries have a national blood policy, 14 in Latin America and 9 in the Caribbean. |
| Objective 1.2: Include the issue of safe blood in national health plans in order to ensure resources and intersectoral support | |
| Indicator, baseline, and target | Status |
| 1.2.1 Number of countries that have an integrated intersectoral national strategic blood plan that includes human resources training, monitoring and evaluation of the plan, and guaranteed resources for its implementation Baseline (2014): 13/41 Target (2019): 21 | The target for this indicator was exceeded: 22 countries have a national strategic plan, 14 in Latin America and 8 in the Caribbean. |
| Objective 1.3: Organize and consolidate an integrated blood services network within the health services network, tailored to the needs of each country | |
| Indicator, baseline, and target | Status |
| 1.3.1 Number of countries with more than one processing center that have increased the average number of units processed per blood bank/year (including screening) to over 5,000 units as a result of the restructuring of the blood services network Baseline (2014): 12/25 Target (2019): 17 | The target for this indicator was exceeded: 19 countries are processing more than 5,000 units of blood per blood bank per year, 10 in Latin America and 9 in the Caribbean. The progress on this indicator is due more to an increase in collection than to an efficient restructuring of the blood services network. |

Strategic line of action 2: Self-sufficiency in safe blood and blood products through 100% voluntary non-remunerated donations

5. Under this strategic line of action, a significant number of countries (14) report that they are better able to identify their national blood needs (indicator 2.1.1). This, together with the fact that more than 24 countries reported having a computerized system for the management of blood and blood services, has led to improvements in the recognition of networks and in the distribution of and access to blood and blood products. However, ensuring regular non-remunerated, altruistic, voluntary donation as the first pillar of blood

safety and availability remains a challenge. Countries' progress towards the 100% target for this type of donation was limited (indicator 2.2.1). However, it must be acknowledged that voluntary donation supplied more than 90% of blood units in 11 countries and between 50% and 90% in five countries. Non-remunerated voluntary donors had donated more than 4.8 million units of blood by 2017, which is evidence of the efforts of some countries (5).

| Objective 2.1: Calculate the country's need for blood and blood products to achieve self-sufficiency in safe blood | |
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| Indicator, baseline, and target | Status |
| 2.1.1 Number of countries that have calculated their blood needs at the national and regional level Baseline (2014): 6/41 Target (2019): 12 | The target for this indicator was exceeded: 14 countries have calculated their blood needs, 6 in Latin America and 8 in the Caribbean. |
| Objective 2.2: Reach blood self-sufficiency through non-remunerated voluntary blood donations | |
| Indicator, baseline, and target | Status |
| 2.2.1 Number of countries that reach 100% non-remunerated voluntary blood donations Baseline (2014): 8/41 Target (2019): 16 | The target for this indicator was not met: 10 countries have 100% voluntary blood donation, 2 in Latin America and 8 in the Caribbean. |

Strategic line of action 3: Quality management in the national blood system and screening for transfusion-transmitted infections

6. Progress was made on all indicators related to quality management in the national blood system and screening for transfusion-transmissible infectious agents, and the expected outcome was achieved. By 2017, screening in Latin American and Caribbean countries for markers such as human immunodeficiency virus (HIV), hepatitis B and C, and syphilis had reached 100%, and screening for *Trypanosoma cruzi* (Chagas disease) stood at 95%. Blood services in Latin American and Caribbean countries made significant progress in implementing programs for external serology and immunohematology performance evaluation and the creation of committees and guidelines for the rational use of blood. With regard to discarding of blood products, although the expected regional target was achieved, in several countries this indicator needs to be analyzed in combination with service efficiency, blood needs, and distribution networks with a view to improving their performance and the figures on availability and access to blood and blood products.

| Objective 3.1: Establish, monitor, and evaluate the quality management system in the blood services network, which includes screening for HIV, HBV, HCV, syphilis, and <i>T. cruzi</i> (the latter in endemic areas) | |
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| Indicator, baseline, and target | Status |
| <p>3.1.1 Number of countries that screen 100% of blood units for transfusion for HIV, HBV, HCV, syphilis, and <i>T. cruzi</i></p> <p>Baseline (2014): 39/41 Target (2019): 41</p> | <p>The target for this indicator was not met: 37 countries screen 100% of blood units, 18 in Latin America and 19 in the Caribbean (in comparison with the midterm review, in Latin America one country made progress and another did not report; in the Caribbean, two countries did not report). The midterm review included data from 39 countries.</p> |
| <p>3.1.2 Number of countries that have a national program for external serology performance evaluations</p> <p>Baseline (2014): 22/41 Target (2019): 27</p> | <p>The target for this indicator was met: 27 countries have a national program for external serology performance evaluations, 14 in Latin America and 13 in the Caribbean. In comparison with the midterm review, one additional country in Latin America implemented a program. In the Caribbean, of the 17 countries that had met the indicator, 5 did not report any data and 1 did not implement its program; however, 2 new countries implemented programs.</p> |
| <p>3.1.3 Number of countries that have a national program for external immunohematology performance evaluations</p> <p>Baseline (2014): 12/41 Target (2019): 18</p> | <p>The target for this indicator was exceeded: 24 countries have a national program for external immunohematology performance evaluations, 12 in Latin America and 12 in the Caribbean.</p> |
| Objective 3.2: Adopt the necessary mechanisms to increase the availability and appropriate use of blood and blood products | |
| Indicator, baseline, and target | Status |
| <p>3.2.1 Number of countries that have functioning transfusion committees in at least 75% of hospitals that perform daily transfusions</p> <p>Baseline (2014): 7/41 Target (2019): 12</p> | <p>The target for this indicator was exceeded: 26 countries have transfusion committees, 16 in Latin America and 10 in the Caribbean.</p> |
| <p>3.2.2 Number of countries that have national guidelines in place for the appropriate use of blood and blood products</p> <p>Baseline (2014): 20/41 Target (2019): 30</p> | <p>The target for this indicator was not met: 24 countries have guidelines for the appropriate use of blood and blood products, 15 in Latin America and 9 in the Caribbean.</p> |

| Objective 3.2: Adopt the necessary mechanisms to increase the availability and appropriate use of blood and blood products | |
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| Indicator, baseline, and target | Status |
| 3.2.3 Five percent (5%) reduction, in the Region, in the number of red blood cell units discarded due to expiration Baseline (2014): 10.3% Target (2019): 5.3% | The target for this indicator was met: the percentage of discards due to expiration for Latin America and the Caribbean had been reduced to 3.95% by 2017. |

Strategic line of action 4: Health surveillance, hemovigilance, risk management, monitoring, and evaluation

7. The area of health surveillance (inspection), hemovigilance, and risk management remains a major challenge. There are few countries where the regulatory authority is involved in monitoring activities and where surveillance systems capture adverse events in blood donors and recipients. Weaknesses were found in the organization of blood systems for the identification and assignment of these tasks at the national level and their subsequent implementation in the services network. Ensuring the availability of information on these indicators and analyzing the information in a way that allows for monitoring of blood systems and decision-making for the improvement of management in each country are tasks that remain to be addressed in most countries.

| Objective 4.1: Strengthen the national blood system so that health surveillance is included in blood services | |
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| Indicator, baseline, and target | Status |
| 4.1.1 Number of countries that have a national model for inspection, surveillance, and oversight in blood services Baseline (2014): 20/41 Target (2019): 30 | The target for this indicator was not met: 26 countries conduct inspections of blood services, 16 in Latin America and 10 in the Caribbean. |
| Objective 4.2: Strengthen the national blood system to integrate hemovigilance in blood services | |
| Indicator, baseline, and target | Status |
| 4.2.1 Number of countries that have a national hemovigilance system Baseline (2014): 2/41 Target (2019): 7 | The target for this indicator was exceeded: 13 countries have a national hemovigilance system, 9 in Latin America and 4 in the Caribbean. |

| Objective 4.3: Establish a mechanism to enable countries to monitor the implementation of their national plan | |
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| Indicator, baseline, and target | Status |
| <p>4.3.1 Number of countries that annually report the indicators of their national plan in response to the implementation of the regional Plan 2014-2019</p> <p>Baseline (2014): 0/41 Target (2019): 41</p> | <p>The target for this indicator was not met: 37 countries have reported data for monitoring the indicators of the Plan, 18 in Latin America and 19 in the Caribbean.</p> |
| Objective 4.4: Draft risk management plans based on the information generated by the hemovigilance system | |
| Indicator, baseline, and target | Status |
| <p>4.4.1 Number of countries that have drafted risk management plans based on hemovigilance information</p> <p>Baseline (2014): 0/41 Target (2019): 7</p> | <p>The target for this indicator was not met: 5 countries reported having risk management plans based on hemovigilance information, 1 in Latin America and 4 in the Caribbean.</p> |

8. Finally, the modest progress made in implementing the Plan of Action for Universal Access to Safe Blood suggests some further reflections. The achievement of 100% coverage in testing of blood to be transfused—which led to a very significant reduction in the possibility of transfusion-transmitted HIV and other infections—may have lowered the priority given to the issue of blood on the public health agenda. As a result, other measures proposed in the Plan to increase transfusion safety may have been neglected. There is a need to step up efforts to incorporate the issue of blood into priority public health programs in order to highlight its importance in areas such as maternal mortality, transplants, and control of infectious events related, for example to hepatitis B or C. Weak governance with regard to surveillance and efficient organization of blood services means that fragmented, inefficient, and high-cost service models continue to exist, limiting access to and availability of blood and hindering progress on voluntary non-remunerated donation, among other actions needed to ensure blood safety.

Action Necessary to Improve the Situation

9. In light of the results and challenges described in this report, the following actions are proposed for consideration by Member States:

- (a) Strengthen governance of blood services, with emphasis on health surveillance, hemovigilance, risk management, and organization of blood services.
- (b) Promote activities and the provision of resources, including human resources, to increase voluntary non-remunerated donation, in keeping with the organization of blood services (6).

- (c) Intensify strategies for blood collection and for the implementation of quality standards, optimization of rational use, strengthening of human resources, and adoption of new scientific and technological advances to enhance the accessibility, availability, and safety of blood for transfusion.
- (d) Strengthen the management of information from national blood programs so that it is possible to identify, evaluate, and monitor blood needs, collection, distribution, and use in order to organize integrated blood services networks within the national health system and determine the safety, sufficiency, timeliness, and accessibility of blood for the entire population that requires it.
- (e) Develop a national plan to ensure the supply of blood and blood products in emergency situations, coordinated with the national emergency response plan.
- (f) Propose a new plan of action, incorporating these efforts and renewing the commitment to universal access to safe blood (7).

Action by the Directing Council

10. Considering the extraordinary and unprecedented circumstances presented by the COVID-19 pandemic, and in accordance with Resolution CE166.R7, this report will be published for information purposes only, and will not be discussed by the Directing Council.

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