DRAFT FINAL DECLARATION

We, Ministers of Health, and Heads of delegation of States and organizations, gathered on 22 May 2018 in Geneva, Switzerland, on the occasion of the International Conference on Access to Quality Medicines and Medical Products in French-speaking Africa;

We, Ministers of Health, signatories to this Declaration, gathered on 22 May 2018 in Geneva, Switzerland, on the occasion of the International Conference on Access to Quality Medicines and Medical Products in French-speaking Africa;

Bearing in mind the 2030 Agenda for Sustainable Development (Agenda 2030), adopted by the United Nations General Assembly on 25 September 2015 (A/RES/70/1), particularly the Sustainable Development Goal on health and well-being (third objective);

Recalling that, within this framework, the Member States of the United Nations have chosen to consider access to "reliable, effective, quality and affordable essential medicines and vaccines" as a vital element of universal health coverage;

Recalling UNAIDS' commitment to universal access to quality medicines and medical products and local production of medicines and medical products;

Recalling the conclusions of the Thirtieth Summit of the African Union on the fight against corruption (Addis-Ababa, January 2018);

Recalling the Cotonou Declaration of Heads of State against fake medicines (12 October 2009);

Recalling the WHO commitment to access to affordable, quality medicines and other medical products as indicated in Resolutions: WHA61.21 of 2008 on Global strategy and plan of action on public health, innovation and intellectual property; WHA67.22 of 2014 on Access to essential medicines; and WHA 69.20 of 2016 for Promoting innovation and access to quality, safe, efficacious and affordable medicines for children; WHA 69.25 of 2016 to combat global shortage of medicines and vaccines, and act for the safety and accessibility of pediatric medicines, as well as the efforts made by the *Member States on inferior-quality and falsified medical products* within the framework of the *Mechanism for monitoring inferior quality and falsified medicines* (SF);

Recalling Resolution AFR/RC66/13 of the WHO regional Committee for Africa, which approved the Regional Strategy for regulation of medical products in the African region, 2016-2025 and the reports from the Regional Director AFR/RC63/7 and AFR/RC56/11 on the capacity of the African region for regulating medicines and other medical products;

Recalling Resolutions A/HRC/RES/32/15 of the UN Human Rights Council on *Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (1 July 2016) and A/HRC/35/L.18/Rev.1 on *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development (21 June 2017);*

Recalling the commitments of the international community against the trafficking or circulation of fake medicines and falsified medical products, especially l the Rabat Resolution on *Fake medicines in Africa* (Rabat, 2018); the Council of Europe Convention on the *counterfeiting of medical products*

and similar crimes involving threats to public health (MEDICRIME Convention, Moscow, 2011); the INTERPOL Resolution on the *Fight against counterfeit medical products and pharmaceutical crime* (Doha, 2010); as well as the Resolution adopted by the ACP Council of Ministers at their 92nd meeting on the *Fight Against the Production and Sale of Fake Drugs and Counterfeit Medicinal Products* (Brussels, 2010); the United Nations Convention against Corruption (New York, October 2003); and the African Union Convention on Preventing and Combating Corruption (Maputo, July 2003);

Recalling the amendment to the TRIPS (Article 31bis) in the spirit of the Doha Declaration on the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health* adopted by the Ministerial Conference of the World Trade Organisation (November 2001), which confirms that *the TRIPS Agreement does not and should not prevent the WTO Member States from taking measures to protect public health* and that, while reaffirming their will to implement the Agreement, they stated that *the said agreement can and should be interpreted and implemented in such a way as to support the right of the organisation's Member States to protect public health and, in particular, to promote access to all medicines* and recognised, in this regard, *the right of the organisation's Member States to have recourse to the provisions of the TRIPS agreement, which are flexible to this end*;

Recalling the long-term commitment of the United Nations Industrial Development Organisation (UNIDO) to the development of the pharmaceutical industry in Africa, including assistance to the African Union Commission (AUC) for the accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA);

Recalling the ongoing commitment of the United Nations Conference on Trade and Development (UNCTAD) in favour of the capacity building in Africa, and especially the francophone, for the local production of medicines while ensuring a favourable environment for investments and facilitating the transfer of technologies;

Welcoming the growing number of operations in the field aimed at seizing falsified medicines and medical products and national and international measures taken to fight this scourge, especially thanks to the initiatives and the support of the World Customs Organisation (WCO), the United Nations Office on Drugs and Crime (UNODC) and INTERPOL;

Noting the efforts made by countries and subregional economic and monetary communities to strengthen and harmonise pharmaceutical regulation, strengthen purchasing and supply systems and implement policies and good practices for quality, to reduce the prices of medicines and other medical products and make them more available and affordable;

Noting that, in spite of the measures described above, trafficking and circulation of substandard medicines and falsified medical products is still growing and exacerbating the health and economic challenges that are affecting Africa in particular;

Noting that the trafficking and circulation of substandard and falsified medicines and other medical products results, among other factors, from difficulties in the implementation of, or the absence of,legislation and other means of control of States, particularly African States;

Noting that the weakness of regulatory systems in the country, the lack of implementation of international rules and standards on quality, the high price of medicines and other medical products and the low level of awareness of the population are drivers of the trade in substandard and falsified medicines and other medical products;

Stressing that the low availability and affordability of medicines and other medical products in Africa is a major public health challenge, especially for the most vulnerable who most often bear the financial burden of medicines and other medical products, sometimes leaving them in conditions of extreme hardship;

Convinced of the need for closer international cooperation between States, the United Nations organisations and all the other actors involved in the health, education, legislative, judicial, police, customs, institutional, private and associative fields, in order to contribute to an improvement in access to quality medicines and other medicinal products and fight effectively against the trafficking or circulation of drugs and other substandard and falsified medical products;

Convinced also of the urgent need for effective coordination of national, regional and international actions for the local production of quality medicines and other medical products in Africa, to strengthen the initiatives of the African Union and the regional economic communities and the implementation of the Pharmaceutical Production Plan for Africa (PMPA);

Confident of the importance of strong international mobilisation for the provision of the resources necessary for the local production of quality medicines and medical products in Africa;

We are committed to:

1. Building partnerships, including institutional and public-private partnerships, and take effective action to improve access to quality medicines and other medical products on the African continent;

2. Further raising public awareness of decision makers, health professionals and the public of the health risks of using substandard and falsified medicines and medical products and the importance of building capacities and regulation systems for medicines and other medical products. Information campaigns will use different channels, such as:

   - Réseau Francophone de Diffusion du Droit (RF2D) and its technical tools[1];
   - associations and opinion leaders;
   - the inclusion of this dimension by the initiative *2 million community health agents in Africa* undertaken by the African Union with the support of the WHO and UNAIDS;
   - local media, due to their ability to wage awareness and information campaigns in local languages;

3. Making the security and quality assurance of supply chains effective by taking account of medicines and other medical products prequalified by the WHO by setting up selection of sources of supply and building capacities for implementing good practices in purchasing, storage and distribution:

   - by developing the traceability of medicines and medical products through the use of effective, accessible technologies based on the work and recommendations of the WHO Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

[1] http://legiglobe.rf2d.org/ and RF2D.org

- promoting group purchases and regional distribution channels for medicines and medical products, especially by involving regional economic communities and small island States in Africa;

- by improving detection of fake medicines and falsified medical products and favouring the adoption of procedures that will trigger timely warnings, for example by designating state focal points, as provided for by the WHO Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

- by stepping up the roles of civil society and communities in pharmaceutical governance and monitoring the availability of quality health products;

4. Strengthening and developing national and regional regulatory frameworks to ensure access to quality medicines and other medical products, as well as to combat the trafficking or circulation of substandard and falsified medicines and other medical products, through:

- the strengthening of national and strengthening of national and regional regulatory harmonization processes for pharmaceuticals, capacity, regulatory systems and regulatory harmonisation processes;
- the empowerment of national and regional regulatory authorities for the pharmaceutical sector;
- the development of intersectoral prevention and detection activities;
- the ratification of existing instruments such as the MEDICRIME Convention and the Rabat Resolution;
- the adoption of a regional convention under the auspices of the African Union;
- the undertaking of a joint initiative to adopt a global instrument at United Nations level;

5. Intensifying the fight against criminal networks and traffickers of substandard and falsified medicines and other medical products by:

- effective enforcement of judicial sanctions;
- ensuring close cooperation between national, regional and international bodies dealing with health, justice, the police and customs with the support of INTERPOL and the WCO;
- providing specialised training to stakeholders, especially thanks to the International Association of Francophone Prosecutors (AIPPF) for training public prosecutors;

6. Encouraging the collection and sharing of data:

- by conducting an effective, reliable record of marketing authorisations, monitoring authorisations and withdrawal of medicines and medical products in the Francophone area;
- by designating and forming networks of focal points for sharing information and experiences among States and providing access to databases provided by the WHO Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;
- by encouraging cooperation between the African Union and regional economic communities in partnership with the WHO and UNAIDS in order to set up a common database that is accessible to health, police, customs and legal authorities;

7. Universalising the introduction and reinforcement of a network of health regulation agencies in francophone countries in charge of marketing, withdrawal and pharmacovigilance in order to foster exchanges between health professionals and the development of a community of practitioners, including engagement of the Africa Centre for Disease Control and Prevention;

8. Reinforcing purchase and distribution systems for medicines and other medical products, improving selection and rational use on the basis of scientific evidence and setting up structures that allow transparency and price control to make them more affordable in order to expedite achievement of universal health coverage, as recommended by the report *Social Protection Floor for a Fair and Inclusive Globalization*, also known as the Bachelet Report (2011);

9. Designing and following specific policies for research, innovation and development of health technologies capable of creating the right conditions for the emergence and propagation of sustainable pharmaceutical sectors;

10. Adapting national legislation to allow full use of the provisions of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), including the flexibilities provided for in the Doha Ministerial Declaration on *the Agreement on TRIPS and public health* and other WHO instruments linked to this Agreement in order to promote access to medicines and other medical products consistent with the Global Strategy and WHO Plan of Action for Public Health, Innovation and Intellectual property;

11. Working towards the creation and/or restructuring of local production chains of quality medicines and medical products on a national and/or regional basis:

- by accelerating the implementation of the recommendations of the Pharmaceutical Production Plan for Africa (PMPA) and pharmaceutical plans of African regional communities;
- by establishing appropriate legislative frameworks and facilitating their use through the training of all the actors involved;
- by supporting efforts to harmonise pharmaceutical regulations such as the Initiative for *Harmonisation of regulations on the regulation of medicines in Africa* and convergence of regulatory practices, including setting up the African Medicine Agency;
- by ensuring a political, legal, economic and commercial environment that complies with international rules and is investment-friendly, in accordance with the recommendations of UNCITRAL[2], UNCTAD, WIPO and other international, regional and subregional institutions, as well as the WTO Agreement on TRIPS and the Agreements on the Promotion and Protection of Private Foreign Investments, with regard to determining the scope and coverage of investments;
- by establishing effective funding mechanisms for the creation of a structure associated with the African Development Bank (ADB) and with recourse to international, regional and subregional investment bodies;
- by encouraging south-south and triangular cooperation in order to generate training, research, innovation and industrial development programmes in the pharmaceutical sector, with particular

[2] Adopted by UNCITRAL on 7 July 2003, the recommendations on legislation and model provisions aim to assist national legislative bodies in establishing a legal framework favourable to privately funded infrastructure projects. They complement the UNCITRAL Legislative Guide on privately funded infrastructure projects adopted by UNCITRAL on 29 June 2000.

focus on the transfer of technologies while respecting intellectual property rights, and setting up mechanisms aimed at cost control with regard to the production and certification of pharmaceutical products;

12. Ensuring effective follow-up of these commitments; Calling on all the Heads of State and Government gathered at the Seventeenth Francophonie summit to subscribe to them and recommending the creation of a network of francophone Ministers of Health.