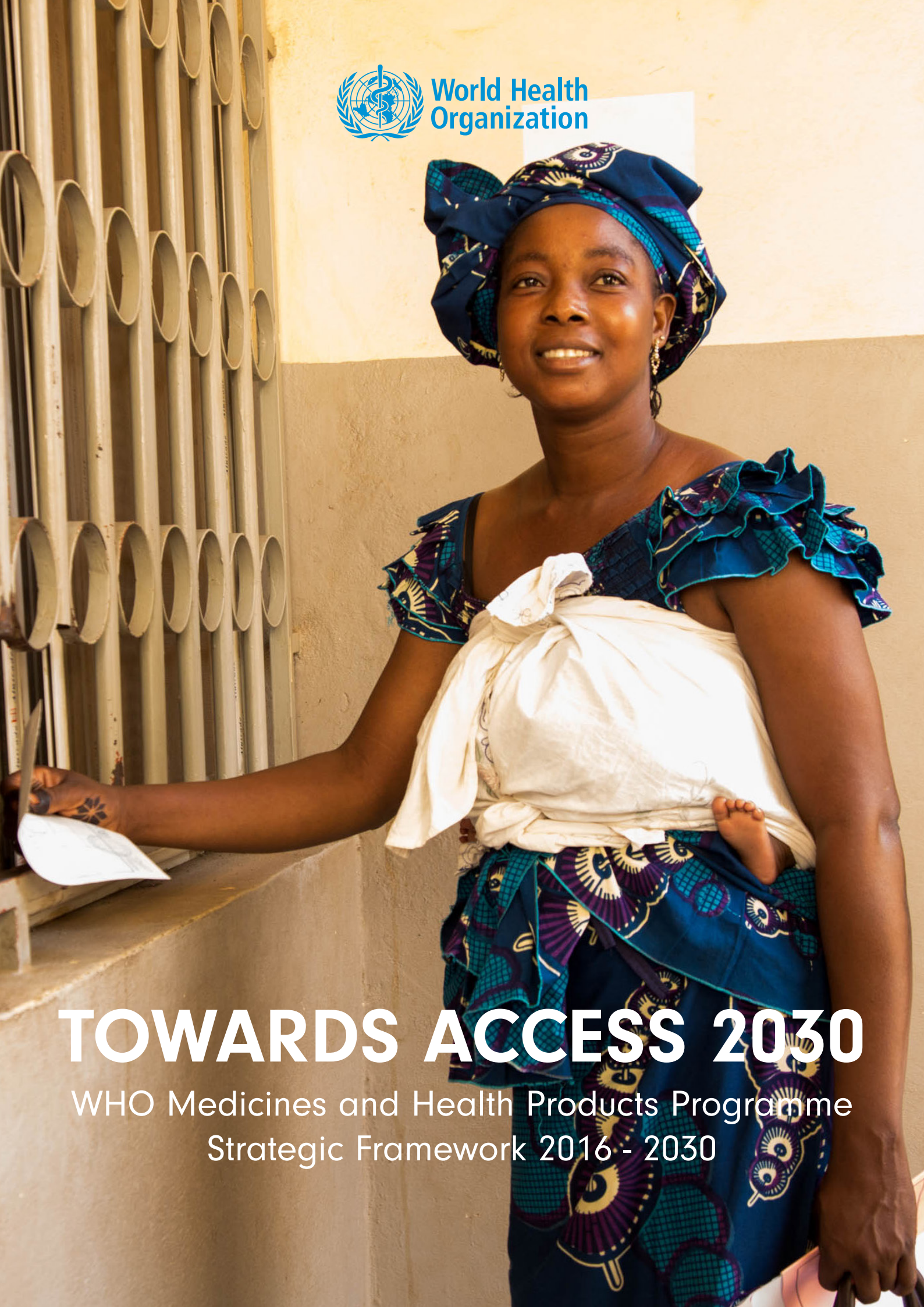

World Health Organization

TOWARDS ACCESS 2030

WHO Medicines and Health Products Programme Strategic Framework 2016 - 2030

WHO/EMP/2017.01

Suggested citation. Towards Access 2030: WHO Essential Medicines and Health Products Strategic Framework 2016-2030. Geneva: World Health Organization; 2017 (WHO/EMP/2017.01). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.
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Printed in Geneva, Switzerland

Cover photography: WHO / 2016 / Fatoumata Diabaté
Printed in Geneva, Switzerland

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INTRODUCTION

The essential medicines and health products programme is a critical WHO area with a number of flagship and successful initiatives. Its core focus - **TO INCREASE ACCESS TO ESSENTIAL, HIGH-QUALITY, SAFE, EFFECTIVE AND AFFORDABLE MEDICAL PRODUCTS** – is highlighted in the Sustainable Development Goals and is represented agency-wide through programmes at regional and country levels.

The new 2030 development agenda and increasing globalization of health products development and supply have generated a need—and an opportunity—for WHO to adjust and strengthen its work in this area at all three levels of the Organization. WHO needs to ensure that headquarters, regional and country offices function more organically to deliver on development targets, and that health systems strengthening activities result in tangible progress for people everywhere. This new long-term framework for 2016–2030 aims to provide a broad vision and strategic direction to focus and reinforce WHO's ability to help Member States achieve universal access to safe and quality-assured health products and universal health coverage.

EXECUTIVE SUMMARY

By 2030, the international community should have progressed to more sustainable policies and practices to safeguard the environment, end poverty and promote health throughout the life course. The new global agenda, articulated in the Sustainable Development Goals (SDGs), prioritizes equity and human rights-based approaches with an emphasis, in health, on universal coverage. This gives WHO, and the essential medicines and health products programme in particular, an opportunity to build on progress made so far and help to bring about access to quality essential medicines and health products for all.

The path to that goal is not without challenges. Rising prices of new pharmaceuticals, rapidly changing markets for health technologies, and lack of market incentives for older medicines are placing increasing pressure on health systems' capacity to provide full and affordable access to health care. In addition, the growing regulatory burden and lack of regulatory capacity in many Member States, and the rise in substandard and falsified products on all markets, are hampering efforts to ensure health products' quality, efficacy and safety. At the same time, innovation in medical research and development (R&D) has resulted in new products that, with increased access, can bring lasting improvements to public health. It is therefore all the more important now to strengthen health systems and capacities in under-resourced and fragile countries, and to find sustainable solutions through multi-sector partnerships.

WHO will pursue its vision and mission by focusing on two interlinked and mutually reinforcing strategic agendas to better support the development of health systems capable of expanding access to medicines and health products: (i) supporting needs-based innovation and reinforcing health product selection, use, procurement and supply systems to increase access, and (ii) strengthening regulatory capacity and practices to ensure the quality, safety and efficacy of products and improve the efficiency of regulatory systems to secure health gains. To better mobilize resources and to maximize results, the WHO essential medicines and health products programme (referred to below as the Programme) will sharpen its focus on a number of thematic areas that reflect current global challenges to access. These include, among others, antimicrobial resistance, controlled substances, research and development preparedness for epidemics and best regulatory practices, including appropriate regulatory pathways for emerging health products.

Under 'Towards Access 2030', the Programme will strengthen links with other health systems-related initiatives for synergy and policy coherence, leverage the experience and knowledge of WHO Regional and Country Offices to better align policies with implementation, and reinforce partnerships work to improve coordination for better outcomes. The Programme will report on its effectiveness using a results framework based on improved information systems and four broad measures: regional outcomes, by which regions' performance can be assessed through SDGs and other context-specific indicators; contribution to country outcomes; operational effectiveness, which applies indicators used by WHO; and organizational effectiveness, to track performance in key areas.

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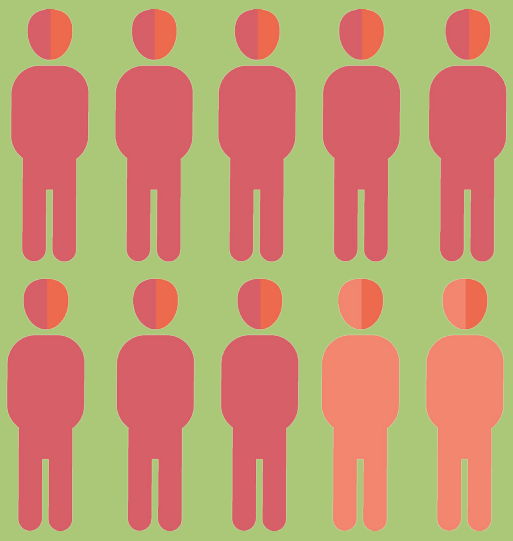
CHANGING LANDSCAPE: FROM THE MDGS TO THE SDGS

The work of WHO on essential medicines and health products has contributed steadily to international development targets for over 35 years and played a significant role in achieving the health related Millennium Development Goals (MDGs).

WHO played a pivotal role in expanding access to medicines and health products under the MDG agenda, including by working directly with countries to develop capacities and by providing a global platform to stimulate a public health driven R&D system. It contributed to the creation of global health financing and procurement programmes (The Global Fund to Fight AIDS, TB and Malaria, the GAVI Alliance, etc.) and facilitated the procurement of priority quality-assured, safe and effective health products.



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PEOPLE ON ANTIRETROVIRAL THERAPY ACROSS THE GLOBE ARE TREATED WITH WHO PREQUALITFIED GENERIC MEDICINES

65%

OF CHILDREN GLOBALLY ARE IMMUNIZED WITH WHO PREQUALIFIED VACCINES THROUGH THE GAVI ALLIANCE

Overall, WHO's work in the last 15 years has:

- Strengthened pharmaceutical systems in low- and middle-income Member States;
- Strengthened the capacities of national regulatory authorities to improve the quality of products;
- Helped to improve the quality of generic medicines production for major infectious diseases and reproductive health, expanding production capacity and spurring competition and reduced prices;
- Ensured availability of quality-assured vaccines and diagnostics;
- Created global platforms for a new health products research agenda that takes into account and addresses market failures;
- Continued to develop norms and standards for new medical products to promote quality, safety and efficacy;
- Convened and hosted an international mechanism to stop the circulation of substandard and falsified medical products.