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Addis Ababa, ETHIOPIA P.O. Box 3243 Telephone: 5517 700 Fax: 5517844

[www.africa-union.org](http://www.africa-union.org)

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## **ROADMAP ON SHARED RESPONSIBILITY AND GLOBAL SOLIDARITY FOR**

### **AIDS, TB AND MALARIA RESPONSE IN AFRICA**

## **Executive Summary**

### **Background**

African Union leadership has consistently considered AIDS, tuberculosis (TB) and malaria and other infectious diseases as an emergency on the continent and made several commitments to address the challenge in 2001 (Abuja Declaration), 2006 (Abuja Call) and 2010 (Kampala Declaration).

As a result of strong continental and national leadership, significant progress has been recorded in Africa on AIDS, TB and malaria. Yet progress must be intensified if African targets are to be met by 2015 and sustained beyond. And while these scourges remain of crisis proportions in many Member States, where they exert an unacceptable toll on economic productivity and undermine the social fabric of families and communities as well as the dignity of people, there is an urgent need to set the responses to them on more sustainable footing in the context of national ownership and health security. This urgency is all the more pressing given the dependence of many national responses to AIDS, TB, malaria and other infectious diseases on external financing and foreign produced medicines. In the case of HIV, for example, over 60% of continental investment is mobilized externally and over 80% of treatment is imported. This dependency poses grave risk to the Continent and need not be the case

The opportunity to develop new, more sustainable and more African-inspired models of health development on the continent are given impetus by the conflation of a number of mega-trends. These include on-going economic turmoil in established economies which is putting pressure on development cooperation budgets, strong economic growth in many Member States, the emergence of new trading blocs and partners and the concomitant advancement of development cooperation with emerging countries and non-traditional partners among others. As a result, Africa is developing new industrial platforms and taking greater charge of its development in line with the African Union's vision of "an integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena".

In light of these trends and exigencies, in January 2012, the African Union (AU) Assembly Decision No: Assembly/AU/Dec.413 (XVIII), requested the African Union Commission (AUC) "to work out a roadmap of shared responsibility to draw on African efforts for a viable health funding with support of traditional and emerging partners to address AIDS dependency response".

### **African-sourced solutions for shared responsibility and global solidarity**

This Roadmap presents a set of practical African-sourced solutions for enhancing shared responsibility and global solidarity for AIDS, TB and malaria responses in Africa on a sustainable basis by 2015. The solutions are organized around three strategic pillars: diversified financing; access to medicines; and enhanced health governance.

The Roadmap defines goals, results and roles and responsibilities to hold stakeholders accountable for the realization of these solutions between 2012 and 2015.

Given the extraordinary history of AIDS responses – in terms of galvanizing political support, mobilizing resources, addressing trade related aspects of intellectual property rights and bringing about tiered prices for treatment, among other achievements – the Roadmap treats AIDS as a pathfinder for TB, malaria and other diseases affecting the Continent for which African-sourced solutions are required.

Shared responsibility and global solidarity for the AIDS response rests on three premises: (1) Countries demonstrate political leadership through a willingness and ability to articulate a national AIDS, health and development vision and pull partner efforts in alignment; (2) Development partners and African governments fill the HIV investment gap together, through traditional and innovative means, investing “fair share” based on ability and prior commitments; and (3) Resources are reallocated according to countries’ needs and priorities – among countries, programmes and populations – for greatest results, ensuring rights-based enablers and synergies.

### **Action Pillar One: Diversified financing**

The Roadmap charts a realistic course to ensure country leadership for an orderly and strategic transition to more diversified, balanced and sustainable financing models for AIDS, TB and malaria. Specifically, it elaborates on the following three priority actions:

1. Develop country-specific financial sustainability plans with clear targets through a partnership approach, including with PLHIV and affected populations;
2. Ensure development partners meet existing commitments and with long-term and predictable commitments that are aligned with Africa’s priorities; and
3. Identify and maximise opportunities to diversify funding sources in order to increase domestic resource allocation to AIDS, TB and malaria.

### **Action Pillar Two: Access to affordable and quality-assured medicines**

The Roadmap outlines a suite of high priority actions to ensure accelerated access to affordable and quality-assured medicines and health-related commodities as enshrined in the Pharmaceutical Manufacturing Plan in Africa (PMPA). These four priority actions can be summarized as:

1. Promote and facilitate investing in leading medicines hub manufacturers in Africa – focusing initially on AIDS, TB and malaria medicines;
2. Accelerate and strengthen regional medicines regulatory harmonization initiatives and lay foundations for a single African regulatory agency;
3. Acquire essential skills through technology transfers and south-south cooperation and create incentives to ensure that new capabilities are truly embedded in Africa; and
4. Create a legislative environment that incorporates the full use of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) flexibilities and develops awareness to avoid the incorporation of "TRIPS-plus" measures in trade agreements.

### **Action Pillar Three: Enhanced leadership and governance**

The Roadmap highlights the need to enhance leadership, governance and oversight to implement African solutions for AIDS, TB and malaria in a sustainable manner. In particular, it outlines the following priority actions:

1. Countries use strategic investment approaches, including in social and legal enablers, for effective scale-up of a set of basic programmes;
2. Invest in programmes that support people and communities to prevent HIV, co infection HIV/TB and Malaria, to know and claim their rights and to enable effective participation in planning and evaluating AIDS, TB and malaria programmes;
3. Ensure AIDS, TB and malaria investments are strategically allocated to contribute to health system strengthening; and
4. Ensure that leadership at all levels is mobilised to implement the Roadmap

### **Oversight and implementation of the Roadmap**

In the spirit of partnership and mutual accountability, different bodies and agencies will be held accountable for delivering on their roles and responsibilities for the implementation of this Roadmap. In particular, Member States will have the overall responsibility of implementing priority actions at country level to achieve the results of the Roadmap.

The African Union Commission (AUC) will have the responsibility of coordinating the delivery of the said results of this Roadmap. It would lead the coordination process of monitoring and reporting to the AU organs and systems.

The NEPAD Agency will, in collaboration with the Regional Economic Communities and the AUC, facilitate the implementation of the priority actions contained in this Roadmap.

UNAIDS, WHO and other UN partners as well as other key stakeholders, such the African Development Bank, will provide technical support and undertake strategic advocacy for the implementation of the Roadmap as well as provide targeted investments and assist Member States as they report. Other development partners will be assigned responsibilities based on their areas of comparative advantage.

## Introduction

1. African Union leadership has consistently considered AIDS, tuberculosis (TB) , Malaria and other infectious diseases as an emergency on the continent and made several commitments to address the challenge in 2000 (Abuja Declaration), 2001 (Abuja Declaration), 2006 (Abuja Call) and 2010 (Kampala Declaration).
2. Facilitating progress on these commitments as well as on the drive to zero new HIV infections, zero discrimination and zero AIDS-related deaths in Africa; To dramatically reduce the global burden of TB by 2015 in line with the MDGs and the Stop TB Partnership targets
3. It will require a new partnership paradigm based on shared responsibility and global solidarity, with Africa setting and driving the agenda.
4. The AIDS response can act as a pathfinder to catalyse progress in Africa across health – particularly for TB, malaria, other infectious diseases/health conditions as well as health systems strengthening. The response can be leveraged to support Africa to develop a new health financing partnership, enhance pharmaceutical security for TB, malaria and other health problems confronting Africa as well as promote innovative approaches to health governance.
5. Through shared responsibility and global solidarity, this Roadmap will ultimately contribute to the African Union’s vision of “an integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena”.

## About the Roadmap

6. At the 2000 Abuja African Summit on Rollback malaria, African leaders resolved to initiate appropriate and sustainable action to strengthen health systems. They reflected on real convergence of political momentum, institutional synergy and technical consensus on malaria and other infectious diseases. In April 2001, the AU Assembly of Heads of State in a Special Summit in Abuja committed to take personal responsibility and provide leadership for the activities of the National AIDS Commissions/Councils and lead from in front (**OAU/SPS/ABUJA/3**)
7. This was reaffirmed in July 2006 as Heads of State re-committed to intensify their practical leadership role at national, regional, and continental levels to mobilize society as a whole to fight HIV and AIDS, TB, and malaria more effectively (**Sp/Assembly/ATM/2 (I)**).
8. In January 2012, the African Union (AU) Assembly Decision No: Assembly/AU/Dec.413 (XVIII), requested the African Union Commission (AUC) “to work out a roadmap of shared responsibility to draw on African efforts for a viable health funding with support of traditional and emerging partners to address AIDS dependency response”.
9. This Roadmap thus presents a set of practical African-sourced solutions for enhancing shared responsibility for the AIDS, TB and malaria responses in Africa.

10. The solutions are organized around three strategic pillars: financing; access to medicines; and health governance. The Roadmap defines goals, results and roles and responsibilities to hold stakeholders accountable for the realization of these solutions.

## **A unique moment for shared responsibility**

### **AFRICA IS ON THE MOVE**

11. The Continent is enjoying an economic growth surge that is widespread across countries and sectors. More than half of the countries in Africa have enhanced overall governance quality, with a majority of countries improving in areas of economic and human development.[1] With a growing middle class, Africa is creating new opportunities for African and foreign businesses. Together, these shifts have enabled the beginning of a dynamic cycle of domestic growth.
12. Growth and stability have lifted millions of Africans out of poverty over the past 10 years. The decade also witnessed a decline in child mortality rates, an increase in primary school enrolment and increased access to clean water.
13. Through growing unity, the voice of Africa is being heard. African leaders are advancing a continental vision for integration that includes enhancing trade and transportation, promoting stronger collaboration among Africa's Regional Economic Communities (RECs), and promoting accountability through bodies such as the African Peer Review Mechanism and AIDS Watch Africa (AWA), and AFRO Advisory Committees of Experts on Malaria and TB.

### **PARTNER PARADIGM SHIFT**

14. This changing landscape offers a new paradigm of what collaboration can mean. China became Africa's number-one trading partner in 2009, and other emerging economies, including Brazil and India, now account for 37% of Africa's trade.[2]
15. Aid dependency is decreasing across Africa as growth strengthens domestic revenues. Currently, at least a third of African countries receive aid that is equivalent to less than 10% of their tax revenue. Aid exceeds tax revenue in only 12 countries.[3]
16. Traditional development cooperation, however, has not kept pace with the accelerated changes in Africa. As the international community surveys the implications of a rapidly transforming world, solutions are increasingly being sought to bring about sustainable

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[1] *2011 Ibrahim index of African governance*. London, Mo Ibrahim Foundation, 2011.

[2] *African economic outlook 2011*. Issy les Moulineaux, Development Centre of the Organization for Economic Co-operation and Development, 2011.

[3] *Ibid.*

outcomes within a culture of country ownership and accountability as spelled out in the Busan outcome document Global Partnership for Development Cooperation.

## FINANCIAL AND ECONOMIC CRISIS

17. AIDS programmes around the world have benefitted from unprecedented global solidarity in terms of resource mobilisation and have transformed resources into impressive results. The financing of AIDS programmes is currently characterized by:
- a need for sustained investments well into the future, because the success of AIDS programmes creates lifelong entitlements to HIV treatment, and controlling the epidemic is a long-term endeavour;
  - a high reliance on investments from external sources and a small number of international partners: In 27 African countries, 84% of expenditures for antiretroviral treatment originated from international sources;
  - a significant uncertainty around future partner support caused by a tight fiscal climate globally, which has resulted in no growth in international investments for AIDS over the past 3 years; however, recent years have seen an increase in domestic investment in AIDS in many countries. .
18. In 17 of the 22 high burden countries that account for 80% of the world's TB cases, the 2012 funding gap is estimated at US\$ 0.5 billion. International funding for malaria appears to have peaked at US\$ 2 billion in 2011, well short of the US\$ 5 to 6 billion per year that are required.
19. In this context, in 2011, the Global Fund to Fight AIDS, TB and Malaria (the Global Fund) took the unprecedented step of cancelling a funding round (Round 11) due to financial constraints arising largely from the failure of donors to meet their financial commitments, reduced projected contributions and decreased investment income.
20. This major resource shortfall comes at a time when Member States at the United Nations 2011 General Assembly High-Level Meeting on AIDS committed to ambitious HIV targets, including placing 15 million people on HIV treatment, halving TB deaths among people living with HIV and eliminating new infections in children by 2015.
21. Recent investments are generating significant energy, momentum and unprecedented scaling up of programmes. Now is the time to realize the full return on past investments, to scale up investments on both treatment and prevention – indeed now is the time to front-load investments – paying now so we don't pay forever.

There is need to take into account some unpredictable situation that can hamper progress made by countries such as socio-political conflicts stirring displaced populations, refugees, and destruction of health facilities.

## PROGRESS ON AIDS, TB AND MALARIA SIGNIFICANT, BUT INADEQUATE

22. In 22 African countries the number of annual new HIV infections declined by more than 25% between 2001 and 2009. In 2010, more than 5 million people in Africa were receiving antiretroviral treatment – up from only 50 000 people in 2002.
23. Despite such progress, Africa remains the most heavily affected region in the world. The Continent is home to two out of three people living with HIV but only 10% of the world's population. Today, only half of Africans living with HIV who are eligible for HIV treatment are able to access it.
24. The region also accounts for 26% of all TB cases and 82% of TB cases among people living with HIV. In 2010, 15 countries (33%) in the Region reached the target of 70% case-detection rate and 20 countries (43%) achieved the treatment success rate target of 85%. The proportion of TB patients screened for HIV rose from 56% in 2009 to 59% in 2010. Of those co-infected, 76% were able to access Co-trimoxazole preventive treatment and 42% were on ART.
25. The 2011 WHO World Malaria Report indicates that the African Region accounts for 81% of the malaria cases that occurred worldwide. Over 90% of the deaths due to the disease occur in the Region and 86% of these deaths are among children below five years of age. Pregnant women, people living with HIV and AIDS and victims of disasters are also particularly vulnerable to malaria.
26. By the end of 2010, 12 countries in the region (Algeria, Cape Verde, Botswana, Madagascar, Namibia, So Tome and Principe, South Africa, Swaziland, Eritrea,
27. Rwanda, Zambia and Zanzibar in the United Republic of Tanzania) had recorded over 50% reduction in the malaria burden by the 2010 Abuja Call and MDGs Milestone.
28. A regional SADC malaria initiative which involves four “frontline” countries and four low-transmission countries<sup>20</sup> was established to promote sustained control and capacity strengthening for transition to pre-elimination (Frontline countries are Angola, Mozambique, Zambia and Zimbabwe; low transmission countries are Botswana, Namibia, South Africa and Swaziland).

## STRENGTHENING INDUSTRY TO ADDRESS AIDS, TB and MALARIA

29. The pharmaceutical industry provides critical medicines and vaccine for communities while also contributing to the economy through employment creation, taxes, skills development and saving valuable foreign exchange.
30. Africa's capacity for pharmaceutical R&D and production is, however, among the lowest globally. Although home to 68% of the 34 million people living with HIV globally, Africa imports more than 80% of its antiretroviral drugs. The vast majority of HIV drugs used in Africa come from one country – India. The viability of this arrangement should be of concern to Africa's leaders, given the imminent changes to market incentives and



regulations facing Indian manufacturers, which will likely result in a reduction in reliable, low-cost generic suppliers.

31. As Africa increasingly works to enable and expand local pharmaceutical production and to ensure quality assured medicines and accelerate roll out of locally produced medicines, regulatory harmonisation across the continent will be increasingly critical. Regulatory harmonization provides a platform for strengthening medicines regulatory capacity and systems in Africa. Gains in regulatory harmonisation could be delivered in a phased approach which commences with harmonised registration of generic medicines facilitated through the regulatory approval processes at country levels. In the long run harmonisation will proceed to encompass other regulatory functions and broaden the scope of products including vaccines and new medicines.

#### INCLUSIVE LEADERSHIP FOR A MORE EFFECTIVE, SUSTAINABLE RESPONSE

32. African health sectors are marked by considerable complexity—not least due to the rapid growth in the volume of external assistance and the concomitant proliferation of agencies delivering health aid. Under these circumstances, ensuring government leadership, country ownership and policy coherence has been a major and persistent challenge. As a result, programmes and people have often suffered.
33. This is clear in the case of HIV where funding grew more than 20% annually for a decade. Such crisis-justified growth invariably generated inefficiencies and perverse outcomes. Partners' priorities often resulted in sub-optimal resource allocation and inefficient programming. With the bulk of external funds provided off-budget, there were few incentives and limited systematic effort to match needs with investments in a focused, context specific manner. Equitable access for key populations also suffered, often as a result of discrimination in the health care system, and inadequate systems to ensure accountability to those most at risk – further driving the epidemic.
34. People living with HIV and those affected by the HIV/TB co infection must own effective HIV and HIV/TB responses to ensure a rights-based, sustainable response and to hold national, regional and global partners accountable. While huge strides have been made in ensuring the participation of affected communities in the design and implementation of AIDS and TB programmes, including through the promotion of the Greater Involvement of People living with HIV (GIPA) principle, and the Promotion of the Patients' Charter for Tuberculosis Care

#### TAKING THE AIDS, TB and Malaria RESPONSE OUT OF ISOLATION

35. Investment in HIV treatment generates economic benefits, including through restored worker productivity, reduced cost of orphan care and savings on healthcare spending. These benefits have been shown to far exceed the initial cost of the treatment. But investments have also delivered broader health benefits including reduced maternal and child mortality as well as TB incidence and mortality.

36. Increasingly we are witnessing signs that we are reaching the end of an emergency approach to HIV – and that achieving sustainable results in AIDS, TB and Malaria will depend on strong health systems as well as resilient community systems that shape people’s lives and complement human resources for health. Countries can capitalize on the significant investments made for AIDS, TB and Malaria for broader health gains.
37. The AIDS response can be a catalyst for broader health and development dialogue and progress in Africa. The need for shared responsibility is also given new impetus as a transition to a post-2015 sustainable development framework is under discussion. In particular, it is imperative that, as priorities shift, health investments move towards a more sustainable approach.
38. Tuberculosis (TB) is contagious and airborne. It is a **disease of poverty** affecting mostly young adults in their most productive years in the African region. In this context, countries, health and development partners should dedicate adequate resources to the fight against TB. This is consistent with the declaration of TB as an emergency by the WHO Regional Committee in Maputo (Mozambique), August 2005. It is also consistent with the call by Heads of State and Government of the African Union for Universal Access to AIDS, TB and Malaria services by 2015.

## **Shared responsibility and global solidarity: Sourcing sustainable solutions**

### OVERVIEW

39. The international community must not falter in meeting the obligations it has made to the AIDS, TB, malaria, and other infectious diseases responses. Protecting development assistance, however, will require more visible southern leadership and commitment to increased domestic and diversified funding and effective and efficient use of resources. Sourcing Africa-led solutions in a context of shared responsibility will not only open more space for African ownership and voices in the broader development discourse but also further the health gains made in the past decade and contribute to sustainable development solutions such as growing new industries and expanding knowledge-based economies.

**Box 1: Shared responsibility and global solidarity for the AIDS response – three premises**

- Countries demonstrate political leadership through a willingness and ability to articulate a national AIDS, health and development vision and pull partner efforts in alignment.
- Development partners and African governments fill the HIV investment gap together, through traditional and innovative means, investing “fair share” based on ability and prior commitments.
- Resources are reallocated according to countries’ needs and priorities – among countries, programmes and populations – for greatest results, ensuring rights-based enablers and synergies.

40. The overarching goal of this Roadmap is to support African countries to exercise leadership to meet AIDS, TB, malaria targets by 2015 and source African solutions to ensure universal access to health-related services for all those in need on a sustainable basis.
41. The Roadmap is structured into three action pillars which present African-sourced solutions to attain this goal, including:
1. Ensure country leadership for an orderly and strategic transition to more diversified, balanced and sustainable financing models for AIDS, TB and malaria and other infectious diseases
  2. Accelerate access to affordable and quality-assured medicines and health-related commodities as enshrined in the Pharmaceutical Manufacturing Plan for Africa (PMPA)
  3. Enhance leadership, governance and oversight to implement African solutions for AIDS, TB ,malaria and other infectious diseases in a sustainable manner
42. Africa’s expanding strength, economically and geopolitically, provides a solid footing to begin to set a more sustainable continental and international agenda for AIDS. Some of these solutions represent long-term undertakings, and Africa must start sowing seeds now for that future.

### THREE ACTION PILLARS

This Roadmap is built upon three action pillars. Each of the pillars will be pursued through coordinated, coherent and purposeful work on three to four high priority actions. The Roadmap charts a course to attain three key results in each pillar area as described below. Collectively the results will reflect a new era of shared responsibility and global solidarity.

**Pillar 1: Ensure country leadership for an orderly and strategic transition to more diversified, balanced and sustainable financing models for AIDS, TB and malaria**

## Results

1. Investment targets for AIDS, TB and malaria met by 2015
2. Financing sources for AIDS, TB and malaria significantly diversified
3. Financial sustainability enhanced through provision of longer-term predictable external resources and greater proportion of domestic investments 'on budget' in the context of compact of shared but differentiated responsibility

## Priority actions

### **1.1 Develop country-specific financial sustainability plans with clear targets through a partnership approach, including with PLHIV and affected populations**

43. As part of a global compact on shared responsibility and global solidarity, countries could agree on target levels for domestic investment in the AIDS, TB and Malaria response that are specifically adapted to the projected level of government revenue, including that from innovative domestic sources, and the size of the disease burden caused by the 3 diseases. In return for verifiable progress towards meeting these financing goals within a medium-term period, a consortium of development partners could provide assurance to fund the remaining financing gap in line with an agreed investment envelope that aims to meet the outcome targets specified in the 2011 Political Declaration on HIV/AIDS and recommendations made during AU and Partners meeting in March 2012 in Addis Ababa.
44. Civil society engagement is critical in the development and monitoring of the implementation of the compacts. People living with and affected by HIV have a legitimate role to play in ensuring that investment frameworks respond to actual needs, in understanding where investment gaps may exist and in holding both partners and countries to account for meeting commitments made in the compacts.

### **1.2 Ensure development partners meet existing commitments and with long-term and predictable commitments that are aligned with Africa's priorities**

45. Given these uncertain times, transparency around financial commitments is more important than ever. African countries can negotiate more multiyear visibility into funding flows from international partners to enable them to plan more effective and sustainable programmes. While the overall quantum of external resources needs to grow, the quality of aid needs to improve as well in line with commitments to the new Global Development Partnership outlined in Busan.
46. High-income countries can invest more in the AIDS response: In 2009, among 14 of the wealthiest nations, there was a 139-fold difference in the share of national resources devoted to international HIV assistance between the most and least generous countries. Several options are available to international partners to generate additional resources to fill the investment gap. For example:

#### **Table 1. Four options to mobilize additional international investments in AIDS, TB and malaria**

US\$ 1.33 billion	if 2010 commitments and pledges for HIV from donor governments were met fully and kept stable by 2015
US\$ 1.26 billion	if the United States Government increased its share of gross national income to official development assistance (ODA) from 0.21% to 0.27% and the proportion of ODA allocated to HIV remained the same
US\$ 0.57 billion	if a 5% increase in health ODA were made, which could pay for the health-related synergies of the AIDS response required in 2015;
US\$ 0.54 billion	if all European governments disbursed at least 0.5% of their gross national income as ODA, and the proportion allocated to HIV remained the same;

47. A tax on financial transactions adopted by the world's largest economies could more than double official ODA globally – and provide a more predictable and long-term stream – if 50% of the new revenue were allocated to development.
48. Emerging development partners are becoming an increasingly important source of funds for health. As countries such as Brazil, China and India have moved comfortably into the middle-income space, they have begun to explore how they can invest in international health cooperation. South Africa is doing the same, and other countries in Africa may follow.
49. In the case of TB, funding gaps in the 17 high burden countries outside BRICS could be halved if international resources for BRICS were redirected to these countries.

### **1.3 Identify and maximise opportunities to diversify funding sources in order to increase domestic resource allocation to AIDS, TB and malaria**

50. While the degree to which individual countries can assume financial responsibility of their AIDS, TB and malaria responses depends on their economic circumstances and the severity of their epidemic, there are several options to strengthen domestic resource mobilisation and tap emerging African wealth. Many are already in practice and showing results –these should be supported, further scaled up and replicated. Options include:
  - Taxes on tobacco and alcohol, levies on existing income or value-added taxes, and taxation reform to minimize tax evasion in favour of the health sector.
  - Making use of the large remittance flows from Africa's diaspora. This could involve a tax on financial and money transfer institutions or issuing bonds to the diaspora. The African Development Bank (AfDB) could join the World Bank as a provider of resources. A united African approach could bring about wider availability of "soft loans" that could begin to reverse the external dependence of the AIDS response as AfDB and World Bank financing is included in government budgets.

- Expanding health insurance provides a mechanism to channel health spending more efficiently and equitably.<sup>1</sup> Issues surrounding social insurance should be addressed especially for vulnerable groups.
- Mobilising resources from the private sector through innovative approaches to philanthropy, corporate social responsibility and the creation of public–private partnerships.

## **Pillar 2: Ensure accelerated access to affordable and quality-assured medicines and health-related commodities as enshrined in the Pharmaceutical Manufacturing Plan in Africa (PMPA)**

### **Results**

1. Medicines security is enhanced by supporting, facilitating and investing in local centres of excellence for innovation, research, development and manufacturing
2. Medicines regulatory harmonization mechanisms are functioning within Regional Economic Communities and lay the foundations of an African Medicines Regulatory Agency
3. Trade in medicines is facilitated through concerted and coherent actions at global, continental, regional and country levels.

### **Priority actions**

#### **2.1 Promote and facilitate investing in leading medicines hub manufacturers in Africa – focusing initially on AIDS, TB and malaria medicines**

51. The African Union Commission has developed a business plan for implementation of PMPA. The establishment of production hubs offers a promising opportunity to support the implementation of PMPA. Hubs will allow viable enterprises to emerge faster within any given investment envelope. Clearly defining benefits and roles for all of the countries in the region, including countries that are not hosting the hub manufacturers, will be critical.
52. Governments should use policy levers to create an enabling environment and counter rules that hinder the development of local manufacturing or put local players at a disadvantage relative to their foreign competitors. Examples include eliminating import tariffs for Active Pharmaceutical Ingredients, eliminating export tariffs for finished products to regional countries, and providing targeted tax breaks for the industry.

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<sup>1</sup> Only 3% of Africans currently enjoy health insurance coverage. Expanding access to health insurance in Africa can reduce high, and at times catastrophic, out-of-pocket expenses that especially impact poor and marginalized households. Rwanda introduced national health insurance 11 years ago. Now, more than 90% of Rwandans are covered, paying annual premiums of only US\$ 2.

53. To further bolster a growing pharmaceutical sector, Africa must foster, among other things, dynamic research and innovation programmes in science and technology. Centres of excellence and enhanced ownership of the broader research and development agenda – including advocacy, resources, capacity and community awareness and engagement – will serve to build self-reliance. Centres could also provide African governments with a platform to develop common positions to negotiate as a bloc on pharmaceutical-related matters.

## **2.2 Accelerate and strengthen regional medicines regulatory harmonization initiatives and lay foundations for a single African regulatory agency**

54. RECs can be supported to serve as regional platforms for information sharing, for developing ‘model laws’ and enforcement standards and capacity and promoting greater regional legislative harmonization and implementation of common registration systems. Major economies of scale can be reaped from adopting collaborative approaches to regulatory functions, for example through an African medicines regulatory agency. A regional or full-continental African medicines regulatory agency could more efficiently take on centralized assessment of new medicines and inspection of manufacturing sites using a limited pool of regulatory expertise and a number of other specialized functions to complement and support African countries’ own drug regulatory agencies.
55. Under the aegis of the African Union, an African medicines regulatory agency would bring together regional initiatives and provide a single advocacy, regulatory and coordination platform for availability of quality-assured medicines, including antiretroviral drugs, on the African continent. As the African pharmaceutical manufacturing sector matures, it will become increasingly important meet international quality standards. This is a multi-year process – accelerating regional initiatives such as the African Medicines Registration Harmonisation (AMRH) is critical.

## **2.3 Acquire essential skills through technology transfers and south-south cooperation and create incentives to ensure that new capabilities are truly embedded in Africa**

56. North–south, south–south and triangular technology transfer will play a fundamental role in facilitating centres of excellence for production of antiretroviral drugs and other medical commodities in Africa. Governments can also incentivize the development of local competencies to produce medicines, including through the promotion of greater collaboration among external pharmaceutical companies and local manufacturers. Joint ventures, technology transfers and direct investment, particularly with the BRICS and other emerging development partners, may be pursued for production of both generic and patented medicines.

## **2.4 Create a legislative environment that incorporates the full use of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) flexibilities and develops awareness to avoid the incorporation of "TRIPS-plus" measures in trade agreements**

57. New rules set that seek TRIPS-plus provisions in the area of pharmaceutical patenting raise a number of challenges and should be resisted, while pursuing alternative

mechanisms to foster innovation within the pharmaceutical sector in an affordable and sustainable manner. Extending the waiver to be TRIPS compliant for least developed countries beyond 2016 is currently under negotiation in the World Trade Organization. Countries should adopt a common voice to demand an extension to this transition period to allow for more time to create a sound and viable technological base in the pharmaceutical sector. In concert, legislative language could be amended to better facilitate actions that are needed to import generic drugs from existing suppliers (e.g. from China and India) so that there are no supply disruptions while Africa is building its manufacturing sector.

### **Pillar 3: Enhance leadership, governance and oversight to implement African solutions for AIDS, TB and malaria in a sustainable manner with emphasis on results, transparency and equity**

#### **Results**

1. Investments in AIDS, TB and malaria programmes address most pressing needs and populations, are strategic, evidence- and rights-based, address discrimination and inequality and strengthen health systems
2. AIDS, TB and malaria programmes are designed, implemented and evaluated through fully inclusive processes with the participation of affected communities and Non-Governmental and Civil Society Organizations (NGOs/CSOs)
3. The Continent and its Member States demonstrate strong leadership and ownership for results and have established robust policy, oversight and accountability frameworks for investments in AIDS, TB and malaria

#### **Priority actions**

##### **3.1 Countries use strategic investment approaches, including in social and legal enablers, for effective scale-up of a set of basic programmes**

58. It is estimated that investment needs for the AIDS response will peak in 2015 if, and only if, resources are allocated in a more strategic manner to enhance the effectiveness and efficiency of spending. Strong stewardship is required to ensure that resources are invested in activities that deliver the greatest returns in terms of HIV infections averted and lives saved. This can be done in part through the following:
  - more rigorous prioritization and focus of HIV prevention investments geographically, by population and by intervention.
  - ensure that investments are made in the most efficient way possible, as efficiency savings can be reinvested in the response. The areas for the greatest potential for efficiency savings are related to drug/commodity and personnel costs and service integration and realising economies of scale.



- increase the impact of basic programme investments by overcoming barriers to the adoption of evidence-based HIV policies and addressing the factors that limit uptake (see paragraph 63).

Ministers of Health and Finance, international partners and others can foster a debate on efficiency, effectiveness and sustainability in order to reap these efficiencies as well as to strengthen ownership of the response to ensure its sustainability.

### **3.2 Invest in programmes that support people and communities to prevent HIV, to know and claim their rights and to enable effective participation in planning and evaluating AIDS, TB and malaria programmes**

59. Effective HIV responses rest on the ability of individuals and communities and their systems, particularly those most vulnerable and affected by HIV to demand and access effective preventive and health services. Programmes that empower affected communities to know and demand their rights are critical to the HIV response and need to be expanded significantly. Hence investments must be made in programmes to reduce HIV-related stigma and discrimination including roll-out of the People Living with HIV Stigma Index, provide legal aid and legal literacy, reform laws, train police on non-discrimination, engage parliamentarians and the judiciary on protective legal responses to HIV, reach out to vulnerable populations, address violence against women and train health care workers on non-discrimination, informed consent and confidentiality. Stronger and positive partnerships should be built with communities and civil society organisations, including people living with HIV, for a more transparent, accountable, rights-based and result-oriented response to HIV that addresses the protection and health needs of all those in need of services.

With regard to Tuberculosis control, empower people with TB, and communities through partnership should be strengthened through pursue advocacy, communication and social mobilization. In order to reduce stigma the efforts should be made to foster community participation in TB care, prevention and health promotion

### **3.3 Ensure AIDS, TB and malaria investments are strategically allocated to contribute to health system strengthening**

60. Countries can deliver quick wins by integrating HIV, TB and malaria services within a primary health care approach. For example, the elimination of vertical transmission of HIV provides a platform to deliver a continuum of care and a package of antenatal, maternal, child health and reproductive health services. This would ensure that pregnant women are not only offered HIV screening but that they and their partners are also offered services to prevent HIV and other sexually transmitted infections, unwanted pregnancies and sexual violence. Investing more strategically to capture synergies and achieve multiplier effects across the Millennium Development Goals is one of the most promising approaches to making resources go further, strengthening health systems, and securing better results in human development.

Investment in TB control should contribute to reinforce **health system based on primary health care particularly in the areas of** human resources development, laboratory networks, financing, supplies, service delivery and information.

### **3.4 Ensure that leadership at all levels is mobilised to implementation of the Roadmap**

61. Champions will play a key role in raising awareness, generating support and building coalitions to take forward the actions identified in this Roadmap. They will need to persuasively engage decision-makers, across a range of sectors, on the benefits of investing in enhancing the sustainability of health programmes in Africa and of promoting critical shifts in practices, partnerships and programmes to achieve stronger results for health and HIV, TB and Malaria. Champions are needed from the local to the international levels, and need to be identified from government, inter-governmental, non-governmental, private sectors as well as from academic, research institutions and celebrities from the world of sports and arts. Insight will be sought from the champions to inform the framing and roll out of the Roadmap.

## **Oversight and implementation of the Roadmap**

In the spirit of partnership and mutual accountability, different bodies and agencies will be held accountable for discharging their roles and responsibilities (see Table X).

62. Member States will have the overall responsibility of implementing priority actions at country level to achieve the results of the Roadmap.
63. The African Union Commission (AUC) will have the responsibility of coordinating the delivery of the said results of this Roadmap. It would lead the coordination process of monitoring and reporting to the AU organs and systems.
64. The NEPAD Agency will, in collaboration with the Regional Economic Communities and the AUC, facilitate the implementation of the priority actions contained in this Roadmap.
65. UNAIDS, WHO and other UN partners and other key stakeholders, such the African Development Bank, will provide technical support and undertake strategic advocacy for the implementation of the Roadmap as well as targeted investments.
66. Other development partners will be assigned responsibilities based on their areas of comparative advantage.

**Table X. Roles and responsibilities**

Priority Actions	Member States	AUC	NEPAD Agency	Regional Economic Communities <sup>2</sup>	UNAIDS, WHO and other UN bodies	Civil society and communities and private sector	Traditional & emerging development partners	Other – including academia <sup>3</sup>
1.1 Develop country-specific financial sustainability plans.	Lead the development and implementation of plans.	Coordinate the development of the plans to ensure they align with regional and continental priorities		Advocate and provide regional coordination for analytical work and development of plans.	Broker agreements.  <b>Technical support for development and implementation of sustainability plans</b>	Undertake advocacy and engage in development and monitoring of plans.	Engage in development of plans.	
1.2 Ensure development partners meet existing commitments.	Develop common position that development partners meet AIDS, TB and malaria resource obligations.	Institutionalize continental accountability mechanisms while advocating to Member States.		Advocate both with Member States and development partners	Advocate and support analytical work on new sources.	Civil society to advocate.	Meet commitments and identify new sources of support.	
1.3 Identify opportunities to increase domestic resource allocation to AIDS, TB and malaria.	Mobilize new resources to fill investment gap	Advocate to continental (ministerial structures) to coordinate the mobilization of domestic resources.		Advocate to regional (ministerial structures) to coordinate the mobilization of domestic resources	Advocate and provide technical support to identify innovative sources.  Support public private partnerships	Civil society to advocate.  Private firms mobilize funds.	Support countries through transition period.  Provide technical support to implement innovative financing mechanisms.	African high-net worth individuals and diaspora provide financial support.  Academia analytic work on financing options
2.1 Promote and	Develop and	Coordinate the		Undertake	Advocate and	Civil society to	Provide	Academia

<sup>2</sup> RECs understood to include regional health organizations

<sup>3</sup> Academic understood to include think tanks, research centers, etc

Priority Actions	Member States	AUC	NEPAD Agency	Regional Economic Communities <sup>2</sup>	UNAIDS, WHO and other UN bodies	Civil society and communities and private sector	Traditional & emerging development partners	Other – including academia <sup>3</sup>
facilitate investing in leading medicines hub manufacturers.	implement country implementation plans within the overall framework of the PMPA	support of technical assistance to Member States to develop and implementation plans.		political advocacy and participate to coordinate technical assistance to Member States.	facilitate south-south cooperation and provide technical support.	undertake advocacy. Pharma firms strive to meet int'l standards	financing and technology transfer.	provides demand forecasting.
2.2 Lay foundations for a single African regulatory agency.	Undertake activities/interventions including legislation to strengthen national regulatory and enforcement capacity and facilitate regional cooperation.	Coordinate the processes and activities that will lead to the adoption of appropriate decisions to promote regional cooperation on regulation		Facilitate the implementation of regional harmonization initiatives including information sharing, developing laws and enforcement standards and capacity.	Undertake advocacy and provide technical support.	Civil society role in quality assurance.	Provide technical and financial support.	
2.3 Acquire essential skills through technology transfers and south-south cooperation.	Develop and implement national guidelines and strategies to promote technology transfer and technical cooperation	Facilitate south-south; north-south and triangular cooperation as well as technology transfer to Member States.		Coordinate south-south; north-south and triangular cooperation as well as technology transfer to member states	UN broker and facilitate cooperation and technology transfer.	Private sector engages in joint ventures.	Undertake joint ventures, technology transfers and direct investment	Academia role in training
2.4 Create a legislative environment that incorporates the full use of TRIPS flexibilities	Ministries of trade, foreign affairs, health and finance develop coherent positions to strengthen national capacity to exploit TRIPS flexibilities	Facilitate the identification and exploration of opportunities to exploit TRIPS flexibilities.		Promote the development and adoption of a common position.	Strengthen national capacity to utilize TRIPS flexibilities;	Generate political will.	Avoid integrating TRIPS plus measures into trade agreements	
3.1 Countries use strategic	Ministries of health, with support of	Coordinate the provision of		Undertake advocacy and	Provide advocacy, technical support.		Traditional and emerging	

Priority Actions	Member States	AUC	NEPAD Agency	Regional Economic Communities <sup>2</sup>	UNAIDS, WHO and other UN bodies	Civil society and communities and private sector	Traditional & emerging development partners	Other – including academia <sup>3</sup>
investment approaches for effective scale-up of a set of basic programmes.	ministry of finance, lead strategic investment approach through the development of a coherent national investment case for HIV.	technical assistance to Member States for the development of national investment cases for HIV.		participate in the coordination of the provision of technical assistance to Member states for the development of national investment cases for more strategic investment for HIV.			partners reprogramme investments more strategically.	
3.2 Invest in programmes that support people and communities.	Develop national systems and processes that create opportunities for civil society and community to input into national planning processes (e.g. budgets, national development plans etc)  Invest in community systems that support and scale up community led interventions.	Coordinate the engagement of civil society at the regional and continental levels to facilitate community input.		Coordinate the engagement of civil society at the regional and regional levels to facilitate community input	Create space and advocate for civil society engagement in policy making.  Advocate for national accountability on rights and gender commitments.  Document best practices and linkages between gender, rights and HIV.	Undertake stigma reduction among health workers and 'know your rights' community campaigns.  Generate demand for equitable, relevant, holistic services.	Invest in community systems that support and scale up community led interventions.	Analytic work on models and cost effectiveness on community engagement.  Religious and cultural leaders to address stigma and discrimination.
3.3 Ensure AIDS, TB and malaria investments are allocated to strengthen health systems.	MoH identify and facilitate opportunities to integrate AIDS, TB and malaria effectively into national strategies and strengthen national health system.	Track and report on level of national integration of AIDS, TB and malaria programmes within health system strengthening		Undertake strategic advocacy.  Utilize regional platforms to build political will and identify solutions.	Document best practices and advocate for their application.  Provide technical advice to funding agencies.  Provide technical support to Member	Advocate for holistic and integrated 'client friendly' services.  Deliver integrated services.	Ensure investments are synergistic to extent possible.  Deliver technical support for integrated programmes.	Generate evidence and best practices.

Priority Actions	Member States	AUC	NEPAD Agency	Regional Economic Communities <sup>2</sup>	UNAIDS, WHO and other UN bodies	Civil society and communities and private sector	Traditional & emerging development partners	Other – including academia <sup>3</sup>
		initiatives			States.			
3.4 Ensure that leadership at all levels is mobilised to implement the Roadmap	Identify and optimize strategic opportunities to mobilise attention and action across sectors and integrate the implementation of the Roadmap within existing multi-sectoral national development initiatives with clear responsibilities for each actor and sector.	Operationalize multi-sectoral continental structures.		Operationalize multi-sectoral regional structures.	Support champions with evidence and provide platforms for coalition building, policy dialogue and advocacy.	Mobilise champions from civil society and the private sector and support coalition building.	Provide support to enable engagement in global for a. Mobilise development partner champions.	