



**Essential medicines and basic health technologies for  
noncommunicable diseases: towards a set of actions to improve  
equitable access in Member States**

**WHO Discussion Paper**

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# 1. Objectives

1. The main objectives of this paper are:
  - To describe some of the key bottlenecks Member States face in relation to access to essential medicines and basic health technologies for noncommunicable diseases (NCDs) in accordance with achievement of voluntary target 9 of the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020, which states as follows: “An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major noncommunicable diseases in both public and private facilities.”
  - To present ideas on how the World Health Organization (WHO) and relevant stakeholders can support Member States to improve access in order to meet the NCD global targets.
  - To stimulate and elicit feedback through questions provided in order to give input to WHO work on how to support Member States to improve access to essential medicines and basic health technologies for NCDs.

## 2. Background

2. In 2012, NCDs were responsible for more than 16 million premature deaths (under the age of 70 years). The majority (82%) of these premature deaths occurred in low- and middle-income countries.

3. Improving accessibility, affordability, availability, safety and accountability in the use of medicines and technology requires not only awareness and response from national governments, but also from industry, academic institutions, health professionals, nongovernmental organizations (NGOs), financing agencies, patients' organizations and the population at large. The role of the government is to bring these stakeholders together to address the problem, and to provide incentives to stakeholders to accelerate implementation of new policies. Providing support and incentives to encourage use of information technology in innovative ways can help create new opportunities to combat NCDs.

4. To strengthen national efforts to address the burden of NCDs, the sixty-sixth World Health Assembly endorsed the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 (resolution WHA66.10).<sup>1</sup> The Global Action Plan on NCDs offers a paradigm shift by providing a roadmap and a menu of policy options for Member States, WHO, other United Nations organizations and intergovernmental organizations, NGOs and the private sector, which, when implemented collectively between 2013 and 2020, will help attain the nine voluntary global targets, including that of a 25% relative reduction in premature mortality from NCDs by 2025. These interventions are laid out in Appendix 3 of the Global Action Plan on NCDs 2013–2020.

5. WHO has recommended a set of low-cost policy interventions to improve access to basic health care interventions, including essential medicines and affordable medical technologies required for early detection and timely treatment of NCDs. Both prevention and health care interventions are excellent economic investments. These interventions were assessed giving consideration to four key criteria: (a) health impact; (b) cost-effectiveness; (c) cost of implementation; and (d) feasibility of scaling up, particularly in resource-constrained settings. The estimated cumulative cost of implementation of the population-based and individual-based best buys for NCDs over the period 2011–2025 is US\$ 170 billion, at an average of US\$ 11.4 billion per year.<sup>2</sup> On the other hand, should business as usual continue, the estimate of the cumulative output lost due to the four major NCDs (cardiovascular diseases, diabetes, chronic respiratory diseases and cancers) in developing countries between 2011 and 2025 is US\$ 7 trillion.

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<sup>1</sup> Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020: <http://www.who.int/nmh/publications/ncd-action-plan/en/>.

<sup>2</sup> Although not costed as part of the population-based interventions in the plan for scaling up, the increased availability and affordability of nicotine replacement therapy could indirectly help to address the risk factor of tobacco use, highlighting the relevance of essential medicines and basic health technologies for NCDs to population-based interventions.

6. The individual-based interventions for the prevention and control of NCDs implicitly require equitable access to essential medicines and basic health technologies in order to be successful. They include the following:

- provision of counselling and multidrug therapy (including glycaemic control for diabetes mellitus) to individuals who have had a heart attack or stroke, and to persons with a high risk (> 30%) of a cardiovascular disease event in the next 10 years;
- aspirin therapy for acute myocardial infarction;
- prevention of liver cancer through hepatitis B immunization;
- prevention of cervical cancer through screening (visual inspection with acetic acid) and treatment of precancerous lesions.

The population-based interventions include interventions to address tobacco use, harmful use of alcohol, unhealthy diets and physical inactivity.

7. Essential medicines and basic health technologies for NCDs are defined by the Global Action Plan on NCDs to include a minimum list of medicines and technologies agreed upon with Member States. The list includes:

- medicines: at least aspirin, a statin, an angiotensin-converting enzyme inhibitor, a thiazide diuretic, a long-acting calcium channel blocker, metformin, insulin, a bronchodilator and a steroid inhalant;
- technologies: at least a blood pressure measurement device, a weighing scale, blood sugar and blood cholesterol measurement devices with strips and urine strips for albumin assay.

8. Note also that this paper considers, and occasionally refers to, medicines and other health technologies that are outside the group of the minimum list as defined by the indicator specifications in the global monitoring framework of the Global Action Plan on NCDs. These include, but are not necessarily limited to, all medicines and other technologies (including those present in the WHO package of essential noncommunicable disease interventions for primary health care in low-resource settings<sup>3</sup> and the most recent WHO Model Lists of Essential Medicines for adults and children) relevant for the prevention, treatment and control of NCDs, including cancers and mental health diseases, and for the alleviation of pain during palliative care.

9. Following the UN Declaration on the Millennium Development Goals, successful strategies have continued to be implemented to scale up access to medicines for HIV, tuberculosis and malaria. A good example on the demand side is the significant role played by a vibrant civil society in the series of negotiations with the private sector and other key stakeholders that resulted in access to cheaper highly active antiretroviral therapy combinations. The use of innovative financing to pool procurements through global public-private partnerships, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and

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<sup>3</sup> WHO package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings: [http://apps.who.int/iris/bitstream/10665/133525/1/9789241506557\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/133525/1/9789241506557_eng.pdf?ua=1).

the GAVI Alliance,<sup>4</sup> has been an effective tool to increase supply and reach more patients with appropriate treatment (for example, antiretroviral therapy and vaccines in the case of the Global Fund and the GAVI Alliance, respectively). UNITAID has also contributed to shaping market interventions through innovative financing using instruments such as taxation from airline tickets. These practical measures have helped to raise much-needed financing for projects and assistance to countries. Another area to address is the advancement of research and development for newer cost-effective diagnostics and treatment suitable for use in resource-poor settings. Through the work of non-profit organizations such as the Foundation for Innovative New Diagnostics (FIND) and the Medicines for Malaria Venture (MMV), in collaboration with wide-ranging partners and stakeholders, the discovery, dissemination and implementation of new diagnostic and treatment interventions (for example, more effective diagnostics for tuberculosis and newer medicines for the treatment of malaria) have substantially improved. Lessons from innovation also extend to the design of appropriate formulation and packaging to increase patient acceptability and to cater for specific subpopulations. For communicable diseases, for instance, women and children have benefited greatly from more user-friendly health products, ranging from user diagnostic test kits to actual medicines.

10. The full implementation of universal health coverage has been identified as a key step for tackling the burden of NCDs in general. Moving towards universal coverage requires a strong, efficient health system that can deliver quality services for a broad range of country health priorities. This requires health financing systems that raise sufficient funds for health, access to essential medicines, good governance and health information, people-centred services, and a well-trained, motivated health workforce.

### **Question 1**

What lessons can be learned from access programmes for the Millennium Development Goals that are relevant for access to essential medicines and basic health technologies for NCDs, at the global, regional and country levels?

Are there specific examples of best practices and successful case studies on country-led initiatives to improve access to essential medicines and basic health technologies for NCDs?

What were the critical success factors for these initiatives?

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<sup>4</sup> The GAVI Alliance, also Gavi, the Vaccine Alliance; formerly the Global Alliance for Vaccines and Immunization.

### **3. Barriers to accessing essential medicines and basic health technologies for NCDs**

11. Evidence from research indicates that there are substantial barriers to equitable access to essential medicines and basic health technologies for NCDs. It has been found that the rational use of medicines can considerably reduce the burden of NCDs in many countries. Despite this reality, essential medicines have remained unavailable in the public sector and often unaffordable in the private sector of many countries, especially low- and middle-income countries. Poor availability and affordability appear to be outcomes of systemic weaknesses within health systems, including inefficiencies, inequity, lack of coverage and insufficient investments. The necessary level of coordination to realize the much-needed, whole-of-government, multisectoral and intersectoral action is absent in many countries. The WHO framework for access to essential medicines with its four key elements – rational selection and use of essential medicines, affordable prices, sustainable financing, and reliable health and supply systems – provides a structural outline to address adequate access to medicines, and bottlenecks that might restrict such access. The barriers to access to essential medicines and basic health technologies for mental and neurological disorders are similar to those for the four major NCDs, as illustrated in Table 1.

#### **3.1 Bottlenecks relating to rational selection and use**

12. The appropriate selection of medicines and other technologies is a very important step for the effective management of medicine procurement and for defining essential benefit packages in countries. Countries still have varying levels of discrepancy between their essential medicine, procurement and reimbursement lists. In some cases, a significant difference is noted between medicines available on country lists and those recommended by the WHO Model List of Essential Medicines. In addition, inadequate use of evidence-based tools such as health technology assessment to inform selection decisions on the incorporation of medicines and technologies can result in wastage of resources and reduced affordability and availability.

13. Poor implementation and underuse of standard treatment guidelines and policies to treat and prevent NCDs can result in poor clinical management of patients. Poor availability of basic health technologies to diagnose and treat NCDs can also negatively impact the clinical management of NCDs. The chronicity of taking multiple medicines, especially for NCDs with comorbidities, puts an extra burden on the patient to maintain adherence. Formulation and packaging of NCD medicines designed to ease adherence are not yet commonplace, which can result in reduced acceptability of medicines to patients.

**Table 1. Barriers to access to essential medicines and basic health technologies (by element of WHO access framework)**

<b>Rational selection and use of essential medicines</b>
<ul style="list-style-type: none"> <li>• Issues with the poor use of health technology assessment in decision-making for procurement of medicines</li> <li>• Lack of alignment between essential medicines, procurement and reimbursement lists in countries</li> <li>• Poor implementation and use of standard treatment guidelines</li> <li>• Lack of adherence to good prescription practices</li> <li>• Poor acceptability by patients leading to lack of adherence</li> </ul>
<b>Affordable prices</b>
<ul style="list-style-type: none"> <li>• Suboptimal utilization of generic policies</li> <li>• Market information asymmetry</li> <li>• High markups and taxes</li> <li>• Reduced competition in production leading to market monopolies – a challenge for equitable access to insulin</li> <li>• High prices due to existing intellectual property rights for medicines still under patent</li> <li>• Weak civil structures for advocacy and accountability measures for NCD programmes</li> </ul>
<b>Sustainable financing</b>
<ul style="list-style-type: none"> <li>• Issues of priority setting in governance for health</li> <li>• Slow/partial implementation of universal health coverage</li> <li>• Inefficient public spending for NCDs</li> <li>• Insufficient funding for NCD programmes</li> </ul>
<b>Reliable health and supply systems</b>
<ul style="list-style-type: none"> <li>• Poor health systems and supply chain governance</li> <li>• Poor use of risk pooling and sharing mechanisms</li> <li>• Weak surveillance and information management systems</li> <li>• Weak quality assurance structures in countries</li> <li>• Reduced ability to forecast population needs</li> <li>• Shortage of skilled know-how to manage supply chains</li> <li>• Excessively strict regulation, as in the case of access to controlled medicines for palliative care</li> <li>• Hampered capacity for local manufacturing, especially in low- and middle-income countries</li> <li>• Failure to address inequity in access to medicines and other technologies for NCDs</li> </ul>

### **3.2 Bottlenecks relating to affordable prices**

14. High taxes and unregulated markups act to increase the costs of essential medicines reaching patients, especially in private health facilities, where prices of medicines are usually higher – even with initial low costs of procurement. Information asymmetry and bias also create problems for pricing structures. Unaffordability due to intellectual property rights is less of an impediment for access to essential medicines for NCDs. With the exception of cancer, the essential medicines to treat the other three major NCDs are available from generic sources, including the NCD medicines present in the WHO Model List of Essential Medicines. In that context, cost savings are more difficult to achieve where higher-priced originator products are procured when quality-assured generic alternatives are available. The problem of single-source medicines and consequently higher prices is also likely to have a larger significance when patented medicines are included in the WHO Model List of Essential Medicines.

### **3.3 Bottlenecks relating to sustainable financing**

15. Mobilization of adequate financing for medicines and other health technologies, especially in resource-poor settings, is a huge challenge. According to data from the IMS Institute for Healthcare Informatics report on the Global Outlook for Medicines through 2018, developing countries (excluding pharmerging countries)<sup>5</sup> accounted for approximately 12% of global spending on all medicines. This has implications for equity, as low- and middle-income countries bear a significantly disproportionate burden of both communicable and noncommunicable diseases. Financing for essential medicines and basic health technologies for NCDs in the public sectors of many countries is currently insufficient. Reasons could be related to the low priority accorded to health care spending and limited availability of funds, especially in low-resource countries. The current efforts of many non-State actors and private sector players with capacity to intervene both financially and through other means are still too fragmented to elicit the robust, multistakeholder response needed to support governments to increase the availability of safe and affordable medicines and technologies for NCDs. The issue of financial protection for patients suffering from chronic diseases, as encapsulated in the principle of universal health coverage, has been under discussion for some time, though progress has been slow and uneven across countries. This is worsened by the fact that medicines often compete with other major household expenditures in many developing countries where access to risk protection mechanisms are often weak or absent, meaning that many individuals must pay unreasonably high out-of-pocket expenditures or significant co-payment fees for medicines.

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<sup>5</sup> Pharmerging countries are defined as those with > US\$ 1 billion absolute spending growth over 2014–2018 and which have GDP per capita of less than US\$ 25,000 at purchasing power parity (PPP). Tier 1: China; tier 2: Brazil, India, Russian Federation; tier 3: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Viet Nam, Pakistan and Nigeria (IMS Institute report: Global Outlook for Medicines through 2018).

### 3.4 Bottlenecks relating to reliable health and supply systems

16. Poor-quality medicines and other technologies are known to cause harm to patients, even leading to serious disability or death. Regulatory authorities for medicines and other health technologies in low- and middle-income countries often have inadequate capacity to properly monitor the quality of medical products along their entire life cycle, including oversight of pharmaceutical company activities to ensure compliance with good manufacturing practices and other standards that ensure that both locally manufactured and imported medicines are of adequate quality and efficacy. Currently, global mechanisms that perform quality assurance for medicines and other health technologies for NCDs are too few and limited in terms of the range of products handled and the level of engagement with procurement agencies in countries.

17. Human rights laws in the context of health system governance and regulations for access to medicines are still too weak to offer effective protection for patients, and prove difficult to implement where they exist. The excessively strict regulation and restriction of opioid use in some clinical settings is an example of a bottleneck to accessing medicines for palliative care, especially in low- and middle-income countries. Patients suffering from chronic diseases (cancers in particular) who require opioids for pain control often lack access to these medicines as a result.

18. At the global level, research and development of newer cost-effective medicines to control diseases such as hypertension is on the decline compared to other disease categories, due mainly to economic disincentives resulting from availability of cheaper generic medicines on the market. Even as access to quality-assured generics can be of immense benefit, especially for resource-poor settings, local capacity to manufacture these medicines and other health technologies for NCDs is severely hindered in low-resource settings, where needs are mostly met by importation.

#### Question 2

Are there other bottlenecks limiting access to essential medicines and basic health technologies for NCDs not mentioned above that need to be addressed?

Which bottlenecks would you consider the three most important to be tackled?

## **4. Discussion: how to improve access to and affordability of medicines and other health technologies for NCDs in Member States**

### **4.1 Promotion of sustainable global efforts to increase coverage, financing and efficient spending for NCDs**

19. Published data tracking exactly how much countries spend on medicines and basic health technologies for NCDs from their health budgets are not yet very common. In July 2014, the United Nations General Assembly noted that despite commitments to increase and prioritize budgetary allocations for addressing NCDs and establish, by 2013, multisectoral national policies and plans for the prevention and control of NCDs, only 50% of countries had such a policy with an associated domestic budget in 2013. Furthermore, funding for national NCD efforts through bilateral and multilateral channels remains very limited, and innovative financing approaches are still only emerging in the field of NCDs.

20. According to the latest global health expenditure data using the WHO/Organisation for Economic Co-operation and Development (OECD) System of Health Accounts, the Democratic Republic of the Congo spent 41% of its current health expenditure for mental and behavioural disorders and neurological conditions on pharmaceuticals in 2013. In the same year, it spent 44% of its current health expenditure for cardiovascular diseases also on pharmaceuticals. This trend of high cost of pharmaceutical spending relative to current health expenditure is also evident in some other developing countries. In 2012, in the Philippines, NCDs took the largest share of spending, accounting for 39% of current health expenditure by disease type. Close to half of all spending on health care provision was on pharmaceuticals and medical goods (43.6%), while labour accounted for about a third of spending. When comparing the data for these two countries, household expenditure on health care in general accounted for 40% and 62.1% of spending in the Democratic Republic of the Congo and the Philippines respectively. Data from literature show that high out-of-pocket payments can be potentially catastrophic for people with NCDs. A study of 35 developing countries found significantly higher levels of catastrophic expenditure on health services among individuals with diabetes than otherwise similar individuals without diabetes. Where NCD patients are unable to make these out-of-pocket payments, there is evidence that services are not used at all or treatment adherence is compromised. A recent survey of the literature found that patients with cancer and those requiring hospitalization for cardiovascular disease incur the highest levels of catastrophic expenditure from out-of-pocket payments.

21. The WHO Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases (GCM/NCD), in line with its mandate, conducts activities that contribute to improving access to medicines and other health technologies for NCDs in Member States. Through its Working Groups 3.1 and 5.1, it is helping Member States to facilitate a strengthened engagement of the private sector and to seek ways and means of adequately financing NCDs, respectively. Preliminary reports of the meetings of the working

groups, as well as policy briefs and discussion papers, can be found online at the GCM/NCD website.<sup>6</sup>

22. The post-2015 agenda is gathering momentum, with NCDs featuring strongly in the goals and targets of the sustainable development agenda. This will present a unique window of opportunity for governments, development actors and other stakeholders to build on progress gained from existing initiatives to increasingly finance the implementation of universal health coverage in countries. Improving the efficiency of current spending, improving tax compliance and revenue collection, and increasing the application of “sin taxes” are some measures that could help raise extra funds for universal health coverage. This could have a massive impact for increased access to care and medicines for NCDs, especially among the poorest people.

### Question 3

How best can governments utilize multistakeholder collaboration, including the private sector, to increase country capacity to improve access to medicines and other health technologies for NCDs within health systems?

What additional information do donors and countries need in order to understand the business case for funding medicines and other health technologies for NCDs?

## **4.2 Supporting Member States to conduct country-level assessments to map the status of medicines and other health technologies for NCDs**

23. Adequate and equitable access to safe, quality and cost-effective medicines and other health technologies for NCDs is hindered by bottlenecks in many countries. Member States need efficient routine monitoring and data collection systems to identify and solve problems related to demand and supply affecting access to medicines for NCDs. Challenges with particular medicines may exist in health systems and may require the development of specific tools to provide solutions. For instance, the availability of and access to quality-assured steroid-based asthma inhalers is likely to be more of a challenge in low-resource settings because of the cost of procurement and gaps in technical expertise to fully implement quality assurance measures. In general, a systematic approach that strategically assesses all aspects of an extensive medicine and health technology supply system, such as rational selection and use, affordable pricing for patients, sustainable financing and reliable health and supply systems – as outlined in the WHO framework for access to essential medicines – represents a logical approach to undertaking the analysis of bottlenecks.

24. WHO supports Member States by providing technical assistance to strengthen data collection and quantification of medicines and other health technologies. To implement the

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<sup>6</sup> Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases  
<http://www.who.int/global-coordination-mechanism/en/>.

WHO set of recommended best buys, the WHO tool for scaling up action against NCDs<sup>7</sup> can aid countries to understand and estimate the financial requirements needed at national or subnational level and can also help to generate a price tag at global level. It can enhance traditional budgeting mechanisms in countries and provide information to development agencies and international institutions on the resources needed to address the growing burden of NCDs. In addition, the Rapid Assessment Protocol for Insulin Access (RAPIA) tool<sup>8</sup> has been piloted and used in several countries to assess health system bottlenecks that hinder access to diabetes care, including the availability and affordability of insulin, glucose test strips and monitoring devices and other health technologies needed for the management of diabetes. Other tools also exist that could help improve national capacity to generate accurate estimates of medicines for NCDs, although they are not specific to medicines for NCDs. The WHO Service Availability and Readiness Assessment (SARA)<sup>9</sup> provides countries with a tool to survey the availability of medicines in public and private facilities, including those for NCDs. The WHO Regional Office for Europe has also developed a health system assessment tool that includes the availability of essential medicines as one of the building blocks. In the Americas, the Pan American Health Organization has created an online tool – the Regional Platform on Access and Innovation for Health Technologies (PRAIS in Spanish)<sup>10</sup> – that serves as a repository for information on medicine prices in countries of the region. In the South-East Asia Region, country situational analyses on medicines in health care delivery are carried out every four years. This is a new approach, started in 2010, whereby data on drug supply, selection, use, regulation and policy are systematically collected (using a tool developed for the purpose) over a two-week period by a team of government officials, facilitated by WHO. At the end of the two weeks, a one-day national workshop is held to validate the findings and develop a framework for coordinated action for use by ministries of health and partners.<sup>11</sup> This approach identifies bottlenecks, prioritizes problems and enables the development of coordinated action plans. Member States endorsed this approach by adopting resolution SEA/RC66/R7 on effective management of medicines. The WHO toolbox on access to medicines and technologies for NCDs<sup>12</sup> contains a repository of tools that could be implemented at country level to improve access. Going forward, the toolbox

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<sup>7</sup> Scaling up action against NCDs: how much would it cost?

[http://www.who.int/nmh/publications/cost\\_of\\_inaction/en/](http://www.who.int/nmh/publications/cost_of_inaction/en/).

<sup>8</sup> Rapid Assessment Protocol for Insulin Access (RAPIA): multilevel (macro, meso and micro) assessment of the different elements that influence access to diabetes care.

<sup>9</sup> Service Availability and Readiness Assessment (SARA): an annual monitoring system for service delivery:

[http://www.who.int/healthinfo/systems/sara\\_implementation\\_guide/en/](http://www.who.int/healthinfo/systems/sara_implementation_guide/en/).

<sup>10</sup> Regional Platform on Access and Innovation for Health Technologies: <http://prais.paho.org/rscpaho/>.

<sup>11</sup> The country reports are published on the website of the WHO Regional Office for South-East Asia:

[http://www.searo.who.int/entity/medicines/country\\_situational\\_analysis/en/](http://www.searo.who.int/entity/medicines/country_situational_analysis/en/). The report of a regional consultation in 2013 on this approach can be found at [http://www.searo.who.int/entity/medicines/documents/reort\\_regional\\_consultation\\_effective\\_management\\_of\\_medicines/en/](http://www.searo.who.int/entity/medicines/documents/reort_regional_consultation_effective_management_of_medicines/en/).

<sup>12</sup> WHO toolbox on access to essential medicines and health technologies for NCDs:

<http://www.who.int/nmh/ncd-tools/target-9/en/>.

will be developed to include relevant WHO regional and country-level tools needed to address NCDs.

#### Question 4

Do Member States perceive a need for the development of a bottleneck assessment tool on NCDs?

What assessment tools are countries and partners already using that could be adapted for assessing bottlenecks for NCDs?

### **4.3 Development and implementation of standard guidelines and policies to promote evidence-based management of NCDs in Member States**

25. The development and implementation of standard evidence-based guidelines is key to promoting the evidence-based management of NCDs in Member States. To guide countries in the effective prevention, treatment, palliation and control of the major NCDs, WHO has produced a package of essential noncommunicable disease interventions for primary health care in low-resource settings (PEN).<sup>13</sup> The PEN interventions include treatment guidelines and protocols as well as an essential list of medicines and basic technologies for NCDs. With diligent implementation, the WHO PEN has the potential to improve management standards for the primary care management of the major NCDs at national level, thereby helping to reduce the burden of NCDs. Similarly for mental, neurological and substance use disorders, WHO has produced the mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings, which includes a comprehensive set of evidence-based interventions for these priority disorders.<sup>14</sup> Addressing the first care level in health systems is crucial to reducing the burden of NCDs. These first care level programmes need to be followed up with appropriate secondary and tertiary care guidelines, particularly for cancers. The recently published manual for the early diagnosis and treatment of childhood cancers is an example of a tool that addresses the early detection and referral of suspected cases of childhood cancers at first care level.<sup>15</sup> Initiatives to promote evidence-based management of NCDs should increasingly include interventions that run on mobile technology platforms. Where feasible, this measure can assist health workers and patients with issues pertaining to appointment scheduling, medicines and dosage information, and reminders, which could lead to improved adherence.

26. Member States are encouraged to implement existing WHO standard treatment guidelines and policy documents for the prevention and control of NCDs at all levels of

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<sup>13</sup> WHO Package of Essential Noncommunicable (PEN) disease interventions for primary health care in low-resource settings: [http://apps.who.int/iris/bitstream/10665/133525/1/9789241506557\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/133525/1/9789241506557_eng.pdf?ua=1).

<sup>14</sup> mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: [http://www.who.int/mental\\_health/publications/mhGAP\\_intervention\\_guide/en/](http://www.who.int/mental_health/publications/mhGAP_intervention_guide/en/).

<sup>15</sup> Early Diagnosis of Childhood Cancer: [http://uicc.org/sites/main/files/atoms/files/Manual%20AIEPI\\_ENG\\_DIGITAL.pdf](http://uicc.org/sites/main/files/atoms/files/Manual%20AIEPI_ENG_DIGITAL.pdf).

health care. Country support is vital for the planning and execution of programmes designed to scale up implementation and use of existing guidelines to address good prescription practices and use of opioids for pain relief and palliative care. Widespread education of health workers on the benefits of administering palliative care using established protocols or guidelines could help reduce the fear of opioid prescription by health care workers, leading to safer and more confident use and stimulating increased demand for opioid use in controlled clinical settings. The development of more user-friendly technologies for easy diagnosis by health workers and self-monitoring by patients for diseases such as hypertension and diabetes will help improve overall outcomes.

#### **Question 5**

What are the most pressing needs for Member States as regard the availability of standard guidelines for management of the major NCDs and rational use of medicines for the alleviation of pain during palliative care?

How can Member States strengthen implementation of existing WHO guidelines for management of NCDs at the first level of health care?

What are the outstanding needs to improve patient acceptability of and adherence to medicines and other technologies for NCDs?

#### **4.4 Coordination of WHO platforms to facilitate exchange of information on quality and pricing to support procurement processes for medicines and other technologies for NCDs**

27. Information sharing on prices and quality of medicines and other health technologies can be a useful tool to help governments make informed policy decisions and increase negotiation power for the procurement of medicines for NCDs. The exchange of information and tools, where applicable, to support the selection, procurement, distribution and appropriate use of essential medicines and basic health technologies could contribute to building the trust of the population in their health system and give more credit and visibility to country NCD programmes. Price transparency contributes to increased competition and is critical in efforts to make medicines for the treatment of HIV/AIDS more affordable. This strategy could also be of benefit in the field of NCDs, particularly for cancer medicines, which are currently highly priced.

28. An information and quality exchange platform can also be of value to support Member States that are involved in regional initiatives to pool procurement of medicines, including those for NCDs. Although only a handful of pooled procurement ventures have been successful so far, evidence gathered reveals that pooling procurement for NCD medicines and technologies can indeed be successful if participating procurement authorities align themselves based on shared characteristics, strong political will, prompt sustainable financing and regulatory agreements. The lower prices (due to increased quantities being

purchased) and intrinsic quality assurance mechanisms of pooled procurement initiatives are strong incentives for Member States to explore further opportunities in that area.

#### **Question 6**

What constraints do Member States face in accessing accurate and transparent information about procurement prices and quality of essential medicines and other health technologies for NCDs?

How useful do stakeholders consider an initiative on knowledge sharing to be?

### **4.5 Support capacity strengthening in Member States for achieving accurate needs forecasting for medicines and technologies for NCDs**

29. WHO is committed to support health system strengthening in countries by helping to identify challenges and provide solutions through policy initiatives and direct technical support to Member States. The provision of essential medicines and other health technologies for NCDs is hinged on a responsive and efficient health care system. Good needs forecasting is a prerequisite for building an efficient supply system, and more broadly for enabling an effective response to the health needs of the population and optimizing the use of resources. Frequently updated databases on information obtained at the point of care, gathering of epidemiological and research data, and the use of national tools and diagnosis and treatment guidelines are all important resources for estimating needs for NCD medicines. Good linkages between health management information systems and logistics management information systems in countries could facilitate data surveillance and reduce inefficiencies.

#### **Question 7**

Are there any gaps in current tools available to Member States that need to be addressed to adequately capture the quantification of needs for essential medicines and basic health technologies for NCDs?

How best can Member States build and sustain capacity for effective national surveillance and data collection to forecast needs for medicines and other health technologies for NCDs?

### **4.6 Ensuring the availability of quality-assured medicines and technologies for NCDs through the strengthening of regulatory authorities in Member States**

30. National regulatory authorities for medicines and other health technologies in countries have the prime responsibility to ensure that medicines and health technologies in use are safe and of assured quality, preventing the presence in the market of falsified or substandard medicines and other health technologies. WHO supports Member States by providing technical assistance for strengthening the capacity of national regulatory authorities to establish monitoring systems to detect the entry or presence of falsified and substandard products in supply chains. WHO is supporting the harmonization efforts of national regulatory authorities in some regions to improve efficiency of regulatory work in countries

and leverage resources for more stringent quality assurance of medicines and other health technologies.

31. At the global level, the prequalification by WHO of medicines for HIV, tuberculosis and malaria has helped to ensure the widespread availability of quality-assured brand and generic health products for the management of these conditions. There may be a role for prequalification of particular NCD medicines such as insulin, some cancer medicines and asthma inhalers.

#### **Question 8**

How best can Member States ensure the availability of safe, effective and quality-assured medicines and other health technologies for NCDs?

How can Member States strengthen quality assurance capacity for insulin, asthma inhalers and other more complex NCD essential medicines and health technologies?

#### **4.7 Increasing awareness of access to essential medicines and basic health technologies for NCDs at global, regional and national levels**

32. WHO supports Member States in the planning, design and implementation of country programmes and policies to manage NCDs through the development of policy guidance tools, provision of technical assistance, training symposia and conferences. The Global Action Plan on NCDs aims to equip Member States and other stakeholders with policy tools and recommendations to act across a range of different sectors within countries to tackle the scourge of NCDs. Among its nine targets, it requests Member States to set a national target of access to essential medicines and technology guided by the global target of 80% availability of affordable essential medicines and basic health technologies. The United Nations Political Declaration on NCDs in 2011 provided the initial momentum for an increased global response.<sup>16</sup> Major initiatives hosted by WHO, such as the GCM/NCD and United Nations Interagency Task Force on NCDs,<sup>17</sup> provide the necessary platforms to engage major global stakeholders, including civil society, business associations, academia and relevant United Nations agencies. These initiatives will help provide the global leadership and guidance as agreed by Member States in the United Nations Political Declaration on NCDs. Plans are also in place to establish further collaboration and strengthen linkages within WHO programmes that contribute to addressing the gaps between NCD needs and the availability of medicines in countries.

33. Good communication and advocacy is vital to raise awareness of the importance of improving access to essential medicines and basic health technologies for NCDs and for efficient monitoring, evaluation and reporting on the progress made in combating NCDs at

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<sup>16</sup> Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, 2011.

<sup>17</sup> United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases.

national level. WHO, along with its partners, collaborating institutions and civil society, is involved in advocacy activities to increase awareness at both global and country levels on the barriers to access to NCD medicines and the proposed options for improving access. WHO and its partners are taking advantage of the popularity of mobile technology in low- and middle-income countries. To that effect, WHO has launched an mDiabetes programme, the first project established for a French-speaking country under Be He@lthy, Be Mobile, a joint global initiative launched in 2013 by WHO and the International Telecommunication Union. The initiative supports countries to set up large-scale projects that use mobile technology, in particular text messaging and apps, to control, prevent and manage noncommunicable diseases such as diabetes, cancer and heart disease. Other programmes under the initiative include an mCessation tobacco quitting programme in Costa Rica, an mCervical cancer programme in Zambia and proposed mHypertension and mWellness programmes in other countries.

### Question 9

What are the best ways to increase awareness of the importance of essential medicines and basic health technologies to prevent and control NCDs?

What other measures can be taken to enhance advocacy efforts to improve access to essential medicines and basic health technologies for NCDs in countries?

## **4.8 Strengthening the evidence base for cost-effective interventions to improve effectiveness, availability and affordability of medicines and technologies for NCDs in Member States**

34. In 2011, WHO developed a prioritized research agenda for prevention and control of NCDs.<sup>18</sup> In reality, this tool is yet to be widely implemented. It prioritizes research in policy and programme development for thematic areas in key domains, in the context of NCD prevention and control. These thematic areas cover a span of NCD-related topics, including those aimed at improving the availability and affordability of essential medicines and basic health technologies to prevent and control NCDs. An example of a priority research topic included under the thematic area of analysis of problems and development of solutions for prevention and control of diabetes is the development of evidence for the application of cost-effective technologies for glucose monitoring and insulin delivery, including stable insulin preparations. To properly strengthen local capacity for carrying out research in countries, scarce human and financial resources in developing countries must be well utilized to facilitate the conduct and use of research that can produce actionable evidence from these prioritized research areas. Ongoing trainings to boost technical know-how and local retention of a skilled workforce are critical factors for success in this regard. Other components are

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<sup>18</sup> A prioritized research agenda for prevention and control of noncommunicable diseases: [http://whqlibdoc.who.int/publications/2011/9789241564205\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2011/9789241564205_eng.pdf?ua=1).

also involved in a complex web of interactions that includes other equally important non-specific research areas that should be accommodated in the broader research agenda. They include:

- improving the quantity and quality of research data (including through the use of monitoring and evaluation of country NCD programmes) on availability, pricing and affordability of NCD medicines (particularly medicines and technologies for cancers that have been underrepresented in studies done so far) and access to nicotine replacement therapy as part of national strategies to reduce smoking;
- conducting operational research for the implementation of programmes supporting access to essential medicines and basic health technologies for NCDs;
- further investment in research to address adherence to therapy for managing NCDs by building on existing initiatives such as the polypill for the prevention and treatment of cardiovascular diseases or exploring other innovative approaches using mHealth technology to deliver gains for improved access.

35. Regarding research on affordability, the efficient use of innovative financing mechanisms for NCD medicines and technologies within the context of primary health care needs to be explored further. Members of academic communities, health workers involved in research and care of NCD patients and policy-makers in Member States are encouraged to implement existing research tools in order to expand access.

**Question 10**

What key knowledge gaps are present for NCDs and how can these gaps be bridged using research?

## **Annex 1. NCDs and global leadership in the past five years**

Political leadership and commitment to tackling the challenges of NCDs was established in New York in September of 2011, when world leaders adopted a Political Declaration on the prevention and control of NCDs at the United Nations in New York. Commitments were made by governments to develop national plans for the prevention and control of NCDs, set national targets, implement national multisectoral NCD policies and plans, prioritize interventions, and strengthen national surveillance systems for NCDs.

In 2014, the World Health Assembly passed two resolutions<sup>19</sup> (WHA 67.19 and WHA 67.22) underlining the commitment of Member States and WHO to strengthening access to palliative care and essential medicines. These resolutions draw heavily upon previous agreements related to the prevention and control of NCDs, with significant links to the Global Action Plan on NCDs. The Global Action Plan itself is focused on the four major NCDs: cardiovascular diseases, diabetes, chronic respiratory diseases and cancers.<sup>20</sup> It uses a framework of nine voluntary global targets and 25 indicators to illustrate its overarching plan for the global prevention and control of NCDs. The intention is to track the implementation of the Global Action Plan on NCDs through monitoring and reporting on the attainment of the voluntary targets in 2015 and 2020. The focus of this document however is based on actions to achieve target 9 of the Global Action Plan on NCDs (see section 1 of the present document).

Access to affordable essential medicines and basic health technologies for NCDs is anchored under objective 4 of the Global Action Plan on NCDs – aimed at strengthening health systems and ensuring the efficient prevention and control of NCDs through people-centred primary health care and adequate implementation of universal health coverage.

Mental, neurological and substance use disorders accounted for 13% of the total global burden of disease in 2004. Mental disorders often affect, and are affected by, other NCDs, such as cancer and cardiovascular disease, and as such require a common health system response. For example, there is evidence that depression predisposes people to myocardial infarction and diabetes, both of which conversely increase the likelihood of depression. Many risk factors such as low socioeconomic status, alcohol use and stress are common to both mental disorders and other noncommunicable diseases. The economic consequences of losses due to mental disorders are equally large: a recent study estimated that the cumulative global impact of mental disorders in terms of lost economic output could amount to US\$ 6 trillion by 2030.<sup>21</sup>

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<sup>19</sup> World Health Assembly 2014 resolutions on access to essential medicines and palliative care: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA67-REC1/A67\\_2014\\_REC1-en.pdf#page=25](http://apps.who.int/gb/ebwha/pdf_files/WHA67-REC1/A67_2014_REC1-en.pdf#page=25).

<sup>20</sup> It also takes into consideration other NCDs (renal, endocrinal, neurological, haematological, gastroenterological, hepatic, musculoskeletal, skin and oral disease and genetic disorders). Mental disorders, disabilities, blindness and deafness, and violence and injuries are also included.

<sup>21</sup> Mental Health Action Plan 2013–2020: [http://www.who.int/mental\\_health/publications/action\\_plan/en/](http://www.who.int/mental_health/publications/action_plan/en/).

The High-level Meeting of the United Nations General Assembly on the Prevention and Control of Non-communicable Diseases (New York, September 2011) recognized that mental and neurological disorders are an important cause of morbidity and contribute to the global NCD burden, necessitating provision of equitable access to effective programmes and health care interventions. The Global Action Plan on NCDs acknowledges that the comprehensive Mental Health Action Plan 2013–2020 needs to be implemented in close coordination with the Global Action Plan on NCDs, at all levels. The Executive Board resolution on epilepsy recognizes the need to improve access to essential medicines for reducing the epilepsy treatment gap and disease burden.<sup>22</sup> The barriers and challenges discussed for access to NCDs are similar to mental and neurological disorders; therefore the actions discussed in this paper can facilitate the improvement of access to essential medicines and basic health technologies that apply to mental and neurological disorders such as epilepsy.

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<sup>22</sup> Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications: [http://apps.who.int/gb/ebwha/pdf\\_files/EB136/B136\\_R8-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_R8-en.pdf).

## **Annex 2. Situational briefs for essential medicines and other technologies for NCDs**

Generic medicines to treat NCDs were less available than generic medicines for communicable conditions in both the public sector (36.0% vs 53.5%) and private sector (54.7% vs 66.2%) of developing countries in 2011.

Cardiovascular diseases:

- Recent studies show that the use of cardiovascular medicines among patients in high-income countries is higher than use in low-income countries.
- For the majority of countries, the availability of medicines was generally higher in the private sector but they were less affordable than in the public sector (an example from Jordan shows that captopril had an adjusted median price ratio (MPR) of 0.67 in the public sector, but only 61% availability. In contrast, in the private sector it had 90% availability, but individuals would need to pay 19.02 times the international reference prices.
- Aspirin and atenolol significantly reduce the relative risk of dying from acute myocardial infarction at an incremental cost of less than US\$ 25 per disability-adjusted life-year (DALY).
- Equitable access to quality-assured benzathine penicillin injections (BPG) for the prophylaxis of rheumatic fever helps prevent recurrences and rheumatic valve disease. This intervention can be delivered in primary health care settings and is cost saving.

Chronic respiratory diseases:

- Patients in developing countries have limited access to care for asthma, including essential medicines.
- Data collected across countries in six WHO regions in 2009 revealed that the availability of salbutamol inhalers was generally higher in the private sector than in the public sector (60.8% compared to 29.1% in the public sector).
- According to the 2014 Global Asthma Report, there are an estimated 334 million sufferers of asthma worldwide. The use of inhaled corticosteroids is necessary for long-term control of asthma. However, they are less likely to be available and affordable and are subsequently underused compared to bronchodilators in low-income settings.
- A 2013 survey from the Global Asthma Report shows that the number of countries using a guideline for the management of asthma is on the rise, although the use of national guidelines is on a slight decline (76% of reporting countries used national guidelines in 2011 as against 72% in 2013).
- The report also revealed that asthma medicines are not being systematically included in the national essential medicines lists of countries. A range of doses of inhaled corticosteroids is needed for effective prescription of doses against varying disease

severity. However, only 40% of high-income countries and 56% of low- and middle-income countries reported having beclometasone 50 µg on their national essential medicines lists. For beclometasone 100 µg, only 40% of high-income countries and 44% of low- and middle-income countries reported having the dosage form on their lists. The inclusion of budesonide 100 µg and 200 µg was also lower in both categories of countries.

#### Diabetes:

- Insulin is still unaffordable in many low-income settings. Its use is also complicated by the cost of syringes and diagnostics for initial diagnosis and follow-up, which are essential for monitoring and adjusting treatment. In 2007, looking at the availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries, Mendis et al. found that the affordability of insulin treatment in terms of the lowest-paid government worker was 2.8 days in Brazil, 19.6 days in Malawi, 7.3 days in Nepal, 4.7 days in Pakistan and 6.1 days in Sri Lanka.
- In 2011, the WHO Expert Committee on Selection and Use of Essential Medicines reviewed the case for the addition of analogue insulin to the WHO Essential Medicines List. It failed to justify additional value when compared to the use of traditional and cheaper human insulin in the management of diabetes.
- The market for insulin is largely dominated by a few players, allowing little room for generic competition to drop prices at manufacturing level.

#### Cancers:

- More than 60% of the world's total cases of cancers occur in Africa, Asia, and Central and South America, and these regions account for about 70% of the world's cancer deaths.<sup>23</sup> The majority of cancers still have no cure although implementing preventive measures can reduce the disease burden through reduced exposure to known risk factors.
- Access to care for cancers is poor in low- and middle-income countries and data on the availability and affordability of cost-effective and quality-assured cancer medicines in these countries are still limited.
- According to an abstract from preliminary data obtained from the European Society for Medical Oncology study on the availability and accessibility of antineoplastic medicine in Europe, results show that the availability of supplementary insurance in Western Europe was instrumental to securing wider access to antineoplastic medicines than in Eastern Europe, where supplementary health insurance was less available.<sup>24</sup>

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<sup>23</sup> International Agency for Research on Cancer: [http://www.iarc.fr/en/media-centre/pr/2014/pdfs/pr224\\_E.pdf](http://www.iarc.fr/en/media-centre/pr/2014/pdfs/pr224_E.pdf).

<sup>24</sup> ESMO European Consortium study on the availability of antineoplastic medicines across Europe: [http://annonc.oxfordjournals.org/content/25/suppl\\_4/iv39.full.pdf](http://annonc.oxfordjournals.org/content/25/suppl_4/iv39.full.pdf).

- The global portfolio of access programmes for cancer medicines and health technologies is very narrow. The GAVI Alliance provides one of the few examples with its support for cervical cancer prevention in selected low- and middle-income countries by financing vaccines against human papillomavirus (HPV) types 16 and 18 for pre-sexually active girls.<sup>25</sup>
- According to International Atomic Energy Agency (IAEA) estimates, there is currently a deficiency of at least 5000 radiotherapy machines in developing countries. In 2009, under the division of its Programme of Action for Cancer Therapy, the IAEA established an advisory group on increasing access to radiotherapy technology in low- and middle-income countries.<sup>26</sup>

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<sup>25</sup> Human papillomavirus vaccine support: <http://www.gavi.org/support/nvs/human-papillomavirus-vaccine-support/#>.

<sup>26</sup> Advisory group on increasing access to radiotherapy technology in low- and middle-income countries: <http://cancer.iaea.org/documents/AGaRTBrochure.pdf>.

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