Briefing for the 67th World Health Assembly:
Cancer medicines are essential in reducing the global burden of non-communicable diseases

In 2013, the World Health Assembly endorsed the Global Action Plan for the Prevention and Control of Non-communicable Diseases (NCDs), which set the target of an "**80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs** in both public and private facilities" by 2020.[1] The UN Secretary-General's report on progress made on NCDs since the 2011 UN High-level Meeting, released in early 2014, states that improvements have been made in the availability of essential medicines for diabetes, hypertension and cardiovascular disease since 2010.[2] Yet, in order to reach the 80% availability target, the international community must also ensure that medicines for cancer are more widely accessible across the globe.

The global burden of cancer

Avoidable death and disability from cancer cost the global economy USD 895 billion in 2008 alone, which excludes direct medical costs. These losses represent 1.5% of global GDP.[3] In low-and middle-income countries (LMICs), the cost of inaction against the major four NCDs—cardiovascular disease, cancer, diabetes and lung disease-- is estimated to exceed USD 7 trillion between 2011-2025.[4] The stark disparities in disease outcome between high- and low- to middle- income countries reflect a large gap in access to treatment. Despite LMICs claiming almost 80% of the disability-adjusted life years lost worldwide to cancer these countries only have an estimated 5% of global cancer resources.[5] In 2001, the WHO reported availability of anti-cancer drugs in only 22% of African countries, 43% of South-East Asia and 57% of countries in the Americas, compared to 91% in Europe.[6]

Cancer is a complex set of diseases, which vary in their geographical distribution, etiology, pathology and course of treatment. Effective treatments for cancer, therefore, usually benefit patients whose disease prevalence is often considered low, thus, raising the important ethical question:

Are individual rights at odds with population rights?

Is it ethical for one patient to benefit from a health service and another patient to lack treatment access due to prevalence of their disease? Drugs on the WHO Model List of Essential Medicines (EML) represent priority health care needs and are selected on the basis of disease prevalence, safety, efficacy, and comparative cost-effectiveness.[7] The WHO EML serves as a guide for countries to develop their national formularies, which are the basis for public procurement and reimbursement schemes to ensure affordability of drugs. Listing as an essential medicine increases visibility and is often a requirement for access to a medicine in clinical practice, particularly in the public sector. This also applies for oncology medicines.

Petitions to include exemplary cancer medicines on the WHO EML

In 2012, two civil society groups filed petitions for anti-cancer drugs, imatinib (Gleevec; Glivec) and trastuzumab (Herceptin) to be added to the WHO Model Essential Medicines Lists (EML).[8] The application for imatinib outlined that although CML has a low prevalence of 1 in 100,000, imatinib provides an essential clinical benefit.[9] The Expert Committee noted the low disease prevalence, yet, considered that imatinib meets the criteria for inclusion as an essential medicine. They also considered that cost-effectiveness of the drug depends on the price that countries can negotiate with suppliers and that long-term supply and use is necessary to maintain the therapeutic effect. A generic version of imatinib is available.

In the application for trastuzumab, essential clinical need was also demonstrated for HER2+ breast cancer, as it significantly increases patient survival and reduces the risk of recurrence.[10] However, the cost of trastuzumab, estimated at at over 100,000 USD per year, keeps it out of reach for the majority of patients with breast cancer. In 2013, Herceptin was one of the world's top 10 best selling prescription drugs, generating USD 6,562 million for the pharmaceutical company Roche.[11] Although a generic equivalent of trastuzumab was not available at the time of petition, a potential supplier of the medicine suggested the drug could be manufactured at 242 USD per year. We recommend that WHO include trastuzumab as an essential medicine for countries that can obtain the drug at an affordable price. The WHO commented on the need to

coordinate with the development of WHO treatment guidelines in considering the inclusion of trastuzumab on the EML.

The WHO Essential Medicines Programme is currently reviewing how to best evaluate oncology medicines for inclusion in the EML, which comprises preparation of a framing document for oncology products, estimated for completion by June 2014. Upon completion of the framing document, review of section 8.2 of the WHO EML on cytotoxic and adjuvant medicines will be commissioned for finalization in time for the next Expert Committee meeting in April 2015.

The ability of WHO to create demand for treatment: Evidence from HIV/AIDS and Hepatitis C
Political pressure is extremely valuable in making medicines affordable, as demonstrated through HIV/AIDS and hepatitis C experiences. The price of antiretroviral therapy was lowered from USD 10,000 per patient per year to USD 60 due to political backing of generic competition.[12] Additionally, the recent publication of the WHO treatment guidelines for hepatitis C resulted in the availability of safer, more effective hepatitis medicines.[13] This further demonstrates the importance of WHO treatment guidelines for cancer as a key step in the strategy toward the creation of demand for treatment, including strong generic competition.

Another key step includes prequalification of oncology products, such as imatinib and trastuzumab, by the WHO. The WHO Prequalification Programme (WHO PQP) has helped to save millions of lives, as most international organizations and many governments depend on WHO PQP for the procurement and supply of medicines. PQP played a critical role in expanding anti-retroviral treatment globally by providing a pathway to receive WHO quality approval for generic medicines.[14] Now, PQP is uniquely positioned to give the WHO seal of approval for NCD treatment, and in particular, oncology medicines, in order to expand much-needed affordable alternatives to branded products.

When the WHO considers measures to address the disparate needs of access to new diagnostics and treatments for cancer, it should devote more attention to the promising and logical proposals to delink R&D costs from product prices, and to provide incentives for treatments that are affordable and feasible in low resource settings. Examples of de-linkage include the proposals for cancer prize fund alternatives to patent monopolies, and the proposal for innovation inducement prizes to stimulate innovation in open source low cost cancer diagnostics. De-linkage proposals are designed to introduce new business models that reconcile both innovation and access. The failures of the current business model to address equitable access to treatment in developing countries, as well as current restrictions on access even in high income countries, provide compelling rationales to move the de-linkage debate forward.

Several measures can be employed to lower drug prices. The WHO is well positioned to advise countries on appropriate strategies to expand access to medicines that are currently priced out of reach to most, yet have an essential clinical benefit. Strategies might include overcoming intellectual property-related barriers and application of procurement methods that have effectively lowered the cost of HIV/AIDS medicines in the past.

The global community should not take the cynical approach that was held by wealthy states on the feasibility of HIV/AIDS treatment and care once again in the discussions on long-term care for cancer, and other NCDs. Just over a decade ago, treatment for AIDS was seen as too complex, too expensive, and the delivery of treatment impossible due to inadequate infrastructure. Nevertheless, exceptional public health initiatives involving advocacy, prequalification, simplification of medication regimes, and innovative financing strategies, have contributed to the improvement in access to HIV/AIDS medicines today.

Our call to action
Essentiality for medicines must be redefined to clinical need—as is outlined in the petitions for imatinib and trastuzumab—in order to support the moral, legal and ethical right to health. **We support the WHO in the proposed steps to thoroughly consider the inclusion of oncology products on the WHO EML. Furthermore, we hereby ask that delegates at the 67th World Health Assembly to:**

- **Monitor WHO's process for evaluating oncology medicines for inclusion in the EML, bearing in mind WHO's review of the WHO EML on cytotoxic and adjuvant medicines in relation to the 19th Expert Committee's consideration of the inclusion of imatinib and trastuzumab in 2015**
- **Ensure that WHO guidelines for the treatment of breast, prostate, lung and colon cancers be issued by the 68th World Health Assembly in May 2015**
- **Ensure that WHO's Prequalification Programme (WHO PQP) expand its remit to include the prequalification of oncology biopharmaceuticals, including such products as imatinib and trastuzumab**

References

1. World Health Organization. 2013. Global action plan for the prevention and control of noncommunicable diseases 2013-2020. http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1
2. United Nations. General Assembly: Follow-up to the outcome of the Millennium Summit. 2013. http://ncdalliance.org/sites/default/files/rfiles/SG%20progress%20report_January%202014.pdf
3. John RM, Ross H. 2010. **The global economic cost of cancer**. The American Cancer Society and LIVESTRONG.http://www.cancer.org/acs/groups/content/@internationalaffairs/documents/document/acspc-026203.pdf
4. P. Farmer, J. Frenk, F. M. Knaul, L. N. Shulman, G. Alleyne, L. Armstrong, R. Atun, D. Blayney, L. Chen, R. Feachem, M. Gospodarowicz, J. Gralow, S. Gupta, A. Langer, J. Lob-Levyt, C. Neal, A. Mbewu, D. Mired, P. Piot, K. S. Reddy, J. D. Sachs, M. Sarhan and J. R. Seffrin, Expansion of cancer care and control in countries of low and middle income: a call to action. (2010) 376 Lancet 1186-93.
5. World Economic Forum & Harvard School of Public Health. 2011. The global economic burden of non-communicable diseseases. http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf
6. Alwan AD, Maclean D, Mandil A. 2001. Assessment of national capacity for noncommunicable disease prevention and control: The report of a global survey. World Health Organization.
7. World Health Organization. The WHO model list of essential medicines: 18th List. 2013. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
8. World Health Organization. 2013. The Selection and Use of Essential Medicines. Retrieved from http://www.who.int/medicines/EC19uneditedReport.pdf
9. Kishore SP, Aisola M, Lopert R, Koney N, 2013. Proposal for the inclusion of imatinib mesylate for the treatment of chronic myelogenous leukemia in the WHO model list of essential medicines for adults. http://www.who.int/selection_medicines/committees/expert/19/applications/Imatinib2__8_2_A_Ad.pdf
10. World Health Organization. 2013. Trastuzumab (addition)—Adults. Retrieved from http://www.who.int/selection_medicines/committees/expert/19/applications/trastuzumab/en/
11. Kollewe J. 2014. The world's 10 best-selling prescription drugs. *The Guardian*, March 27, 2014. http://www.theguardian.com/business/table/2014/mar/27/world-best-selling-prescription-drugs-pharmaceuticals-industry
12. Mills EJ and Ford N. 2012. Political lessons from the global HIV/AIDS response to inform a rapid noncommunicable disease response. AIDS **26**(9):1171-3.
13. World Health Organization. 2014. WHO issues its first hepatitis C treatment guidelines. http://www.who.int/mediacentre/news/releases/2014/hepatitis-guidelines/en/
14. 't Hoen EFM, Hogerzeil HV, Quick JD, Sillo HB. 2014. A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme. *Journal of Public Health Policy* **35,** 137–161.