IFPMA comments on WHO Discussion Paper: “Essential medicines and basic health technologies for noncommunicable diseases: towards a set of actions to improve equitable access in Member States”

Question 1: Learning from the MDGs, Best Practices and Lessons Learned

The heritage of the MDGs

The heritage of the MDGs is very rich. Firstly, the MDGs have taught governments, businesses and civil society how to work together. Lessons learned and applied since 2000 show the importance of partnerships as a buttress in facilitating the architecture of many interventions on extreme poverty, education, gender equality, and sustainability. Multiple sectors can continue to join forces to strengthen healthcare systems, identify sustainable financing mechanisms, and reduce the add-on costs of health products and services along the supply chain. Secondly, the MDGs have initiated a culture of awareness and change in institutions and the broader public. Actions undertaken in the framework of the new sustainable development goals (SDGs) should continue in this direction, expanding ownership towards communities in an effort to relate to people, who are the final beneficiaries of any commitment as we go forward. Thirdly, the discipline of the world coming together more frequently to identify and commit to the key development goals for the betterment of humanity has helped focus efforts and drive the global community to achieve these goals.

IFPMA and its Members’ engagement in MDGs implementation: best practices

As a key stakeholder in the global health community, the research-based pharmaceutical industry has been engaged since the onset in efforts to address health-related MDGs. One way the research-based pharmaceutical industry works to improve global health is through multi-stakeholder dialogue, establishing and engaging in over 250 currently active partnerships. Experience from these collaborations that involves more than 1000 partners shows that transformative partnerships and accountability frameworks between civil society, the private sector, local authorities and national governments can improve global health and ultimately contribute to more equitable, inclusive and sustainable development. The partnerships bring solutions to address health system infrastructure, increase availability of treatments, prevent the spread of communicable diseases and non-communicable diseases (NCDs), and develop new treatments for diseases of the developing world. In addition to the above, IFPMA also partners directly with international organizations to deliver creative solutions to address issues such as chronic diseases, counterfeit medicines, and medicine donation programs. These partnerships seek to develop innovative approaches to the growing chronic disease burden in developing countries, and include, for example, the use of mobile phones for awareness raising and treatment adherence, or providing door-to-door counselling through volunteers on healthy lifestyles to people in low and middle-income countries.

All the partnerships seek to extend the reach and scale of development programs, involving key stakeholders, and assembling complementary assets. They also allow for knowledge and resource sharing to improve effectiveness and reduce risk. Furthermore, partnerships reduce duplication of investment activities and attract funding by building a common brand.

Lessons learned for the future
To advance sustainable development, some challenges remain. Specifically, IFPMA is working to broaden private sector engagement in emerging economies. There is also work underway to build in “health is wealth” into existing global baselines and reporting on sustainability, and to contribute to make the case for businesses to be included in implementation of the soon-to-be-adopted Sustainable Development Goals (SDGs). To boost implementation of SDGs related to health, there is a need for clear objectives and deliverables. Those goals and deliverables should be agreed by all parties, and should be time-bound, sufficiently resourced and outcome-focused.

Programs need to focus on systemic issues to address patient centric unmet needs. This will in turn help broaden the roster of partners, extending scope and reach. In addition, it is important that programs are designed around the core competences and assets of each partner. Programs designed to leverage existing systems and foster local ownership, involving national and local policy makers, are more likely to be successful. Lastly, impact measurement and continuous improvement should appear in any partnership design. Another perennial challenge is the evaluation of the impact of partnerships.

As recognized in the soon-to-be-adopted SDGs, involving the private sector in the process is crucial to success in achieving the goals. The IFPMA and its members are working on strategies and actions in many areas relevant to the SDGs and are ready to work with the broader community to achieve them.

**Question 2 – Challenges and priority areas to increase access to essential NCDs medicines**

IFPMA believes there are three fundamental areas to focus on: supply chain, primary health care and, regulation of medicines. While government responsibilities are paramount, actions in these areas would benefit from multi-stakeholder collaboration.

**Supply Chain**

Delivery and provision of care for NCDs require ongoing access to a broad set of medicines, consistent/ongoing adherence to treatment regimes, and use of diagnostics and medical devices, which vary in complexity, for management of each disease. Insulin, an essential medicine used in the management of diabetes, requires cold chain specifications and utilizes supply chain configurations that are distinct from general NCD medicine supply chains. As a result, NCD supply chains and distribution systems must be equipped to support a diverse set of treatment provisions. While the function and structural organization of supply chains is increasingly understood and is improving, the global medicines market and supply chains for NCDs are still far from optimal.

NCDs require unique considerations, such as a greater number of required treatments and diagnostics/management tools; ongoing treatment and disease management; and an increased level of training and involvement of medical professionals. Improving access to NCD medicines requires a thorough understanding of the structural obstacles in medicine supply chains, along with a holistic examination of access from the top of the supply chain to the end-patient.

Within this context, another challenge faced in improving access to essential NCDs medicines is posed by the various duties, taxes and mark-ups imposed on manufacturers' prices. Lack of appropriate regulation on the retail mark-up in some countries can result in significant build-up in the price of a medicine. In other countries, import duties and medicine sales taxes can also contribute heavily to price build-up and have significant impacts on the end user price and access to medicines. In some countries, four example, medicine prices are two to four times higher than the ex-manufacturer price as a result of the effect of taxes, tariffs, distributor margins and retail margins. Ultimately, policies need to strike a balance between making medicine affordable to
patients and ensuring the viability of the supply chain. Furthermore, there is scope in many countries to capitalize on the value that each stakeholder is already bringing to the healthcare system, and to explore how efficiencies can be gained in the overall system rather than pursuing a narrow focus on the cost of medicine or one particular element of the value chain.

**Primary Health Care**

Much of the opportunity in reducing the health and economic impacts of NCDs lies in prevention, early diagnosis and treatment—the domain of primary care. Primary care—defined here as first-contact care that promotes ease of access, care for a broad range of health needs, continuity, and the involvement of family and community—is perfectly positioned to be the main platform for the health system response to NCDs. However, health systems in low- and middle-income countries are fundamentally unprepared for tackling the NCD challenge because of their historic orientation toward infectious disease and maternal/child conditions, as well as persistently low funding levels. The diagnosis and care of NCDs require a different clinical approach because of the asymptomatic nature of early diseases, their chronicity and frequent co-morbidities. Essential elements in reconfiguring primary health care include integration of care, innovations in service delivery, and inclusion of communities and patients while designing interventions.

**Regulation of Medicines**

While the majority of countries have established national medicines regulatory authorities (NMRAs) responsible for reviewing and approving medicines at the national level, these agencies often have very limited levels of available expertise and capability to fulfill all the essential functions of a regulatory authority. This has led to delayed initiation of clinical trials and approval of medicines, as well as increased circulation of sub-standard products. Furthermore, many national regulatory agencies have limited or no capabilities in the surveillance and control of products’ post-marketing experience. Several initiatives developed to promote regional cooperation between NMRAs have evolved in recent years to increase the sharing of assessment expertise, the adoption of common technical standards, and the conduct of inspection activities to ensure that the quality standards of approved products are maintained. Improving access to medicines aimed at reducing the burden of NCDs will require greater efforts in support of such regional cooperation schemes and in support of capacity building in NMRAs, alongside the appropriate convergence or harmonization of technical standards across regions. Following the path of convergence, some regions may choose to extend collaboration to full harmonization of regulatory systems and procedures, but this will be a decision mostly influenced by their broader economic interests. At a minimum however, convergence is needed, especially in response to the globalization of medicine development and supply. NMRAs from low- and middle-income countries face significant challenges to building capacity and expertise, but they also need to develop science-based regulatory decisions that are aligned with the public health needs of their respective populations. Novel approaches will be required to ensure that the purported benefit-risk profiles of products initially assessed in more developed settings will be extended and examined within the setting of intended uses in less affluent nations to help effectively lower the burden of NCDs. Advancing regulatory science in the more developed countries should come with a renewed policy agenda from all stakeholders to commit human and financial resources to advance the foundations of the regulation of medicines in less developed countries. The objectives of improving access to safe and effective medicines and enabling local manufacturing capabilities to produce quality supplies in these countries can be realized in a timely manner through a more concerted approach.

**Rational selection and use of medicines in UHC**

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As the discussion paper notes, rational selection of medicines and other technologies is an important part of effective management of health services. The ongoing evolution of the Essential Medicines List (EML), the discussion about the appropriate models and scope of health technology assessment and treatment guidelines are all issues that the IFPMA and its members are increasingly engaged in. Ensuring private sector dialogue and contribution to the process of considering the EML will be important to its future success. The evolution of the EML is reaching a point where sound administration and policy making around the EML necessitates a constructive stakeholder input to that discussion, and the IFPMA is developing its thinking on this topic with its members.

Similarly, in the area of health technology assessment (HTA), the IFPMA, together with its member associations and companies, have perspectives and experiences that can contribute to the consideration of HTA as a tool for rational decision making. The experience and expertise of industry in the practicalities of how HTA systems work at both a national and international level should be an important input into the development of best-practice systems. Experience in many countries demonstrates that such constructive consultation on HTA and medicine formularies can lead to better decision making processes that improve the process of decision making in healthcare. IFPMA is keen to engage with WHO and other stakeholders on these issues going forward and would welcome the opportunity for ongoing, constructive dialogue on these issues.

**Question 3(a) – Collaboration with private sector to increase country capacity**

One important way in which governments can better engage the private sector to increase country capacity to improve access to medicines for NCDs is to address the disconnect between achieving health outcomes in the short-term, and the longer-term investment that is required in the management of NCDs. The IFPMA Partnership Directory showcases many best practice examples of collaborations between governments and private sector to increase country capacity.

Transparency is a useful tool for governments to show real progress and impact following engagement with the private sector. Increased transparency leads to increased accountability and interactions. Transparency and accountability are key metrics for governments and International Organizations to assess tangible contributions of non-state actors to achieving its objectives. Political will and commitment to investing in particular health interventions provides reassurance to any potential partner of health being a priority.

International collaborative frameworks such as the WHO Global Coordination Mechanism should foster concrete dialogue and outcomes on shared priorities.

**Question 3(a) – Making the business case for NCDs**

The chronic nature of NCDs and persistent need for medicines to address NCDs has an impoverishing effect in LMICs in particular, where medicines often make up the majority of out of-pocket spending on health. Out-of-pocket spending on medicines increases inequality and results in poorer health outcomes. The economic cost of inaction needs to be more prominently demonstrated, and the evidence base re-emphasized, to help donors and countries better understand the business case for investing in medicines and other health technologies for NCDs. Emerging economies continue to be an engine of global growth, and if people of working age in emerging populations become chronically ill or die from NCDs, the productivity of numerous countries is at risk – providing more quantitative evidence to reflect the potential impact of not
tackling NCDs on wider economies remains a high priority IFPMA would welcome the opportunity to work collaboratively with the WHO and other organizations to further develop its data to demonstrate what is a compelling business case for funding medicines and other health technologies for NCDs.

**Question 5 – What are the outstanding needs to improve patient acceptability of and adherence to medicines and other technologies for NCDs?**

Various studies have demonstrated that one of the biggest single improvements to treating NCDs, and therefore helping achieve relevant SDG targets, is to ensure that patients take the medicines and vaccines they are supposed to take. The billions saved in the health system if patient acceptability and adherence could be improved have already widely discussed, not to mention potential lives saved. IFPMA member companies and associations have experience in working on patient adherence programs around the world and this experience could be drawn upon to inform international efforts in this area.

**Question 6 – Information on procurement prices**

The industry has already demonstrated its capability in contributing to discussion on pricing policy through forums such as GAVI and the Global Fund. Critical to any discussion of such pricing policy is appreciating commercial realities and how such discussions can materially impact on the actual availability and development of medicines. Good procurement practices engage the suppliers as equal partners in that process. Many of these issues are inter-related to other questions. For example, issues around ensuring the quality and safety of medicines and availability of such health technologies is, in part, influenced by the pricing policies adopted by countries and organizations. Having such policies informed by real world realities is important.

**Question 7 – Quantifying resource gaps in addressing NCDs and enhancing capacity on surveillance and data collection.**

There is a significant dearth of locally generated data in LMICs on NCDs in relation to risk factors, incident and prevalent disease, and morbidity and mortality. Methods of data capture where the vast majority of the population engages with lower levels of the healthcare system remain highly primitive and need developing, posing great challenges to effective health sector planning and resource allocation. It is clear that data is fundamental, and that WHO Member States require support in building and sustaining capacity for effective national surveillance and data collection to forecast needs for medicines and other health technologies for NCDs. The private sector has demonstrated a clear statement of interest in helping to improve this capacity over the years, especially in the case of the MDGs.

For example, the PAHO (Pan American Health Organization) Foundation and IFPMA launched in 2014 a collaboration to jointly build regional capacity to fight women’s cancers in Latin America and the Caribbean. The partnership aims to increase awareness of breast and cervical cancer and improve screening and earlier detection services to reduce the numbers of women who prematurely die from these cancers. In addition, the partnership works with healthcare providers to improve their knowledge about innovative screening strategies. The second key component of the collaboration is to improve the quality and completeness of cancer registries in selected Latin American countries. Cancer registries are necessary tools for cancer control, as knowledge of a
country’s particular cancer situation helps make informed decisions on the targeted interventions to reduce incidence and mortality.

As per our response to question 2 (see above), improving supply chain management and regulatory capacity is also crucial.

**Question 8 Ensuring availability of safe, effective and quality-assured medicines and other health technologies for NCDs**

Strong regulatory systems are needed to ensure that people around the world have timely access to quality medicines and vaccines that are both effective and safe. A comprehensive system of regulatory supervision with expertise in inspections, product assessment, and monitoring of quality, including possible side effects, is paramount. Such systems should be in place and operational before medicines or vaccines are introduced and throughout their life cycle.

Today, only 20% of the World Health Organization’s Member States have well developed pharmaceutical regulatory systems. In a globalized world, the regulatory landscape is changing every day to address both old and new challenges. With regulatory systems increasingly under pressure globally, the most promising solution in the journey to make regulatory systems work more efficiently is through regulatory convergence and harmonization. Aligned regulatory systems will not only lead to enhanced safety, in particular helping prevent the introduction of lower quality or falsified (counterfeit) medicines and vaccines, but will also ensure the integrity of the cold chain (needed for example for insulin to treat diabetes), and allow accurate demand forecasting and address shortages in supply, particularly important for treatments targeting chronic diseases where and ongoing adherence to treatment regimens is key (often on a daily basis for the remainder of patients’ lives). Achieving regulatory convergence requires cooperation among governments, international and non-governmental organizations, healthcare professionals, pharmaceutical industry, and patient groups.

IFPMA is committed to regulatory system strengthening and puts particular emphasis on regulatory convergence and harmonization as well as capacity building efforts. Together with partners, IFPMA regularly co-organizes regional regulatory conferences to provide platforms for dialogue and expertise sharing. This, alongside speeding up local review and authorization, are critical measures to make the best use of limited resources while at the same time supporting essential regulatory oversight on quality, safety, and efficacy.

Strong regulatory systems will not only prevent the introduction of low quality medicines, but also of falsified (counterfeit) medicines. Falsified (counterfeit) medicines are found in nearly every country and across all disease treatment areas. Up to 30% of medicines in some areas of Asia, Africa, and Latin America are at high risk of being fake, and worldwide more than 50% of medicines sold via illegal online pharmacies worldwide are falsified (counterfeit). The number of cases of falsified (counterfeit) medicines for chronic diseases is increasing. Falsified (counterfeit) medicines undermine patients’ trust in health systems, their governments, health care providers and manufacturers of genuine medicines, and therefore undermine all efforts made to diagnose and manage life-long conditions, such as diabetes, hypertension, and other chronic diseases.

One of the biggest obstacles to overcoming this public health threat is that many people are simply not aware of what falsified (counterfeit) medicines are and the risks that they pose. While many people think that only life-style medicines are being counterfeited, all therapeutic areas are affected, including hypertensive medicines, medicines for lowering cholesterol, anti-diabetes treatments, asthma inhalers, neurological disorders treatments, etc. Too many people simply do...
not recognize the real danger in purchasing medicines off the street. Nowadays, patients on chronic treatments are also attracted by online pharmacies (most of them being illegal and selling counterfeit products) promising discounted prices.

Addressing falsified (counterfeit) medicines requires general education and knowledge of the dangers. All stakeholders across the supply chain should receive sufficient education on what they can do if they suspect a medicine to be falsified (counterfeit). Healthcare professionals around the world are placed in the prime position to keep patients safe from these dangerous products. They are the gatekeepers of treatments and medicines, and therefore, should provide to patients on chronic treatments with the information to keep them safe and well-informed. Governments could partner with relevant organizations in setting up awareness and educational campaigns, including promoting basic recommendations such as checking the packaging carefully, taking note of changes in the medicine itself, notifying health professionals should unfamiliar side-effects appear.

Multi-stakeholder campaigns involving every level of the health community – from pharmaceutical manufacturers, pharmaceutical wholesalers, healthcare professionals, diseases specific organizations and civil engagement networks focused on NCDs to patients – have proven effective ways to raise awareness, leverage networks and competencies at local, national, and global levels, and promote responsibility from the beginning to the end of the supply chain. IFPMA is one of the founding partners of *Fight the Fakes*, a multi-stakeholder and multi-disciplinary campaign that has garnered recognition for its effectiveness in highlighting the threat and in demonstrating how collaboration can help deal with the serious threats to patient health.

**Question 9: Awareness raising: focus areas and best practices**

**Awareness raising efforts should start from prevention**

As stated in the paper, good communication and advocacy is vital to raise awareness of the importance of improving access to essential medicines and basic health technologies. Furthermore, in NCDs awareness strategies, high focus should be given to prevention. Literature indicates that half of NCDs are preventable. Prevention can be achieved through increased health literacy, awareness and simple behavioral changes aimed at reducing common risk factors. As the increased prevalence of NCDs poses a mounting challenge to healthcare systems worldwide and to public and private finances, prevention represents a cost-effective solution for alleviating the economic burden of such diseases. Reducing mortality and morbidity through increased investment in prevention programs will contribute to higher economic growth and allow limited resources to be efficiently focused on patients most in need.

**Best Practices: selected IFPMA awareness raising examples**

Partnerships are key frameworks for carrying out awareness raising programs. IFPMA and its members have a long track record of such programs; including the examples outlined below. Comprehensive information is available at [http://ncds.ifpma.org](http://ncds.ifpma.org).

**Four Healthy Habits:** IFRC-IFPMA ‘4 Healthy Habits’ is an innovative partnership which provides information and tools to change behaviors, promote healthy lifestyles in communities around the world and ultimately reduce the rise of noncommunicable diseases (NCDs). Building on the IFRC’s long history of health promotion within communities by using simple tools adapted to local context, also known as the Community-based Health First Aid Manual (CBHFA), the partnership develops and adds to the existing manual a module on healthy lifestyle guidelines and NCDs control and prevention. Tools were deployed for use by the 98 Red Cross Crescent National Societies.
worldwide, reaching more than 2.8 million beneficiaries all over the globe. See the News Release and the Healthy Lifestyle Toolkit

**Be He@lthy, Be Mobile:** The IFPMA is partnering with the International Telecommunication Union (ITU) on Be He@lthy, Be Mobile, an initiative led jointly by the ITU and WHO. The initiative, in its initial 4-year period (2012-2016), will scale up mobile technology in eight priority countries, at least one in each region, for NCDs prevention, treatment and policy enforcement. Activities will be two-fold: mHealth operational projects will be implemented within countries, and standard operating procedures will be developed for running a mHealth NCDs intervention package to support more traditional NCDs prevention and control work. See the IFPMA Publication and Infographic “Health at your fingertips”

**HealthyScoreApp:** The HealthyScore App builds on the Health Improvement Card that was designed by the World Health Professions Alliance (WHPA) with the support of the IFPMA. It uses the same « spotlight-type » rating system than the scorecard. The App allows reaching out to a broader public and provides a tool to both educate and empower users. For example, customizable reminders encourage users to take control of their health and help bridge the gap between awareness and behavioral change. See the HealthyScoreApp