

Fédération Internationale de l'Industrie du Médicament Federación Internacional de la Industria del Medicamento



News Release

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Global pharmaceutical industry contributes action plan and research to fighting Non-Communicable Diseases (NCDs) in the developing world

19 September 2011, New York - To coincide with the United Nations High-Level Meeting on NCDs, the research-based pharmaceutical industry today outlined the steps it is taking to address the rise of NCDs in the developing world. Building on its Framework for Action released earlier this year, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) revealed the findings of the first report of an independent policy research programme focused on identifying the most significant obstacles to stemming the tide of NCDs in developing countries.

The top line findings of the research show that effective first-line NCD medicines exist and are now available in generic form, but, in many instances, these medicines are still failing to reach many people living in the developing world.

The study identified four priority areas for the research-based pharmaceutical industry to consider:

- innovative ways to improve NCD medicine adherence
- overcoming barriers to availability in poor and remote areas where large mark-ups, tax and duties, along the supply chain, as well as counterfeit products, are an issue
- · improving access to primary care
- removing regulatory restrictions that hamper medicine availability in developing countries.

These priority areas provide the basis for the next four studies in the IFPMA NCD research series. The aim is that the studies will help the research-based pharmaceutical industry and its partners develop and carry out the actions that will most effectively improve access to NCD medicines in developing countries. In parallel, IFPMA and its member companies continue investing in NCD health partnerships and prevention programmes.

Eduardo Pisani, Director General of the IFPMA said, "50 percent of NCDs are avoidable, therefore prevention measures, including lifestyle modifications – doing more physical exercise, stopping smoking and a healthy diet – are some of the most cost-effective and efficient ways to tackle the magnitude of NCDs across the developing world. But we know that while prevention is imperative and cost-effective, its impact can only be felt over the longer term. We also need to know how best to improve access to treatments that patients in developing countries need more urgently. The launch of the first in the series of IFPMA reports illustrates how the research-based pharmaceutical industry is committed to this challenge, and how we want to understand what areas require particular focus."

David Brennan, CEO AstraZeneca and President of the IFPMA said, "The increasing burden of NCDs in low and middle-income countries poses an economic, social and moral stumbling block to global health and prosperity. There is no silver bullet solution because the scale of the problem is so complex. This underscores the importance of partnership to understand what the most significant problems are and to work together to solve them."

Today, the research-based pharmaceutical companies are committed to 213 health partnerships, a quarter of which deal directly with NCDs or help strengthen the primary care to deliver treatments. The IFPMA is also committed to forging new NCD partnerships. On 12 September, the World Health Professions Alliance announced an NCD Health Improvement Card and toolkit, sponsored by the IFPMA. This NCD toolkit will be shared with over 26 million health care professionals in more than 130 countries to help encourage patients to identify and prevent risky behaviours.

David Brennan explains: "The research-based pharmaceutical industry's framework for action clarifies many areas where we are already actively making practical contributions. From training healthcare professionals on diabetes in India, to providing state-of-the-art diagnostic equipment to assist in breast cancer treatment in Ethiopia, we continue to invest in programmes that address the public health needs in developing countries by focusing on strengthening healthcare systems, improving health education and building capacity. We all have an interest in ensuring patients in developing countries have access to the care and treatments they need. Effective first-line NCD medicines that were developed by the industry decades ago are now available in generic form; however, in many instances, these are still out of reach for people who need them. Improving access to these and other effective medicines that we continue to develop remains a priority for us all."

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Notes

Top line results of 1st report in the IFPMA NCD Research Series: <u>IMPROVING ACCESS TO MEDICINES FOR NON-COMMUNICABLE DISEASES IN THE DEVELOPING WORLD</u>¹ – Authors Soeren Mattke, Marla Haims, Nono Ayivi-Guedehoussou, Emily Gillen, Lauren Hunter, Lisa Klautzer, Tewodaj Mengistu – RAND Health

The review shows that NCDs present a growing challenge for developing countries and create the real possibility that gains in health that have been made possible by better control of infectious disease and economic development are being eroded. Since NCD medicines offer substantial public health gains, access to medicines is a critical component of NCD care.

The research identifies the structural obstacles across health care systems and ways to systematically overcome them, but also illustrates that overcoming those obstacles will not be a trivial task. NCDs are the result of multiple causative factors over the course of a life time and require a horizontal, integrated approach to care with the patient, family, and the entire community as active participants (WHO, *Innovative Care for Chronic Conditions*, 2002). Many potent NCD medicines have already been developed and will continue to be developed. This is contrasted by the experience with many communicable diseases that predominately affect developing countries, making it more difficult for individual pharmaceutical companies to rationalize and recoup the necessary investment in innovative medicines.

Similarly, manufacturer prices play a minor role in impeding access to NCD medicines, as we find that generic alternatives are available for most first-line treatment requirements. Schemes to provide medicines at differential prices to developing countries, which are critical to maintain access to anti-retroviral medicines, are less relevant for many first-line NCD medicines and exist for many NCD medicines that are still under patent protection, such as insulin and inhalers for asthma and COPD.

The complexity of the challenge of improving access to NCD medicines means that a multistakeholder effort will be necessary to make a fundamental difference. The research sets the priorities for the policy research agenda of the research-based pharmaceutical industry. It identifies a number of promising ideas that build on the industry's core capabilities and that can realistically be implemented. The analysis points to four areas for further study that emerged from the research that was undertaken²:

- 1. Realizing product improvement beyond the chemical compound. While the analysis reveals that the gains from development of additional compounds will be comparatively small, innovative ways to improve NCD medicine adherence are still dearly needed. The report suggests compiling industry best practices in the areas of packaging, pricing and patient education to achieve better drug treatment adherence. A particular focus should be research into the viability of fixed-dose combination products (polypills) for NCD treatment. While conceptually intuitive, actual development and manufacturing of polypills is less then straightforward, because a limited range of population-adequate formulations has to be defined and produced at consistent quality. Similarly, regulatory approval may be difficult to obtain, as manufacturers would have to prove safety and efficacy of the co-administration of different compounds.
- 2. Enhancing supply chain efficiency and integrity. In contrast to many consumer products, the secure and efficient distribution of NCD medicines is far from guaranteed in developing countries. Availability in poor and remote areas remains limited, hefty mark-ups along the supply chain common, the share of counterfeited product substantial. At the same time, the review points to several creative ideas that should be further studied. A specific area of research could be an assessment of policy options to improve supply chain integrity, for example, comparing the potential impact of a public section solution to prove

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¹ http://www.rand.org/pubs/occasional_papers/OP349.html

² Given that effective medicines for NCD treatments already exist, we are not advocating for additional research into promising ideas for compound development to address NCDs because this is already the main focus of the research-based pharmaceutical industry.

- supply chain integrity for all medical products with a private sector approach to market medicines, whose value proposition is the security of the supply chain and ability to verify product authenticity.
- 3. Achieving gains from regulatory harmonization. While potent NCD medicines exist, their actual availability in developing countries can be hampered by regulatory obstacles. Uncertain timelines and variable requirements for product registration, Good Manufacturing Practice (GMP) inspections, labeling, and product identification codes can increase cost, sometimes to a level that makes product registration prohibitively difficult in a country. Many regional initiatives aim at achieving greater harmonization of regulatory requirements that would allow for increased availability. A logical next step would be to quantify the benefits from regulatory harmonization to promote a data-driven dialog with national authorities, and to promote the optimal use of available schemes such as the WHO Certificate of Pharmaceutical Product (CPP) Scheme, Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International Conference on Harmonisation Global Cooperation Group (ICH GCG).
- 4. Improving access to primary care. The study finds consistent evidence that limited access to quality primary care is the key obstacle to improving NCD drug treatment. In the absence of a robust primary care system, NCDs go unnoticed until complications arise, adequate treatment is not initiated, treatment effect is not consistently monitored and terminally ill patients do not receive palliative care. At the same time, improving access to primary care is a complex challenge that requires addressing fundamental issues like resourcing, governance and capacity building. As an initial step, we propose a survey of innovative approaches to deliver effective and efficient primary care in developing countries and an assessment of which approaches can be scaled up in which contexts. Our initial review points to several promising ideas to which an in-depth review could add.

About the IFPMA:

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

IFPMA manages global initiatives including: IFPMA <u>Developing World Health Partnerships Directory</u> catalogues the research-based pharmaceutical industry's long-term partnership programs to improve health in developing countries, IFPMA <u>Code of Pharmaceutical Marketing Practices</u> sets standards for ethical promotion of medicines, IFPMA <u>Clinical Trials Portal</u> helps patients and health professionals find out about on-going clinical trials and trial results.

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