Principal Focus and Actions of the Research-Based Pharmaceutical Industry in Contributing to Global Health[1]

Overview

In 2005, speaking of the HIV/AIDS crisis in Africa, former Zambian President Kenneth Kaunda said that this challenge "requires the total commitment of all stakeholders, on country, regional and international levels. We need to establish networks and partnerships at various levels."[2] Indeed, a concerted partnership effort by all stakeholders will be necessary to address HIV/AIDS and all of the other serious health challenges facing developing countries. The research-based pharmaceutical industry is a key stakeholder, making a significant and unique contribution to health care on a global scale.

Its primary role is ***innovation - to research and develop new medicines***[3], including vaccines and products of biotechnology. In spite of the progress made over the past decades in developing new medicines for numerous acute and chronic disease conditions, innovation remains critically important because of the remaining unmet medical needs, the emergence of new (and re-emergence of) infectious disease threats, and the development of resistance by diseases to existing treatments. Recent industry innovations - for example, developing more than twenty anti-retroviral medicines for HIV/AIDS and novel vaccines against such conditions as rotavirus, pneumoccocal, and human papilloma virus - indicate that industry is unique in being the predominant developer of innovative medicines. Ongoing efforts in R&D require a global policy environment that supports continuing such innovation, as well as supporting more initiatives in such areas as pediatric medicines and diseases that primarily affect developing countries.

Improving health care in developing countries remains a priority concern of the global health community; thus, ***access to health care, including medicines,*** is on the agenda of not only policymakers, but also of many non-governmental organizations, including

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[1] This is a statement by the member companies and associations of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), representing the world's leading medicines research and development enterprises (see http://www.ifpma.org). These enterprises research and develop pharmaceuticals, vaccines and biotechnology-based medicines. In addition, a number of IFPMA's members also produce and market medical devices, diagnostic tools, self-administered (over-the-counter) medicines as well as off-patent (generic) medicines. This statement reflects their main focus, which is on the research and development of innovative medicines.

[2] See http://www.uneca.org/chga/speech_kaunda22april2005.htm

[3] The term "medicines" here refers to pharmaceuticals, vaccines and products of biotechnology. A concise definition of innovative medicines is given by the EU High Level Committee on Health: "Innovation encompasses many different options going from the development of a completely new medicine for the treatment of a disease otherwise incurable to modifications of known pharmaceutical formulations to improve benefits for the patients, such as a less invasive administration route or a simpler administration schedule." See http://ec.europa.eu/health/ph_overview/Documents/ke02_en.pdf

industry. Industry is committed to support actively efforts to expand access to medicines, in support of the leadership responsibilities of national governments and international agencies. This is shown through a wide range of partnership initiatives such as the Accelerating Access Initiative and sustained donation programs for the fight against river blindness, trachoma, leprosy, lymphatic filariasis, intestinal helminthes and to prevent mother-to-child transmission of HIV/AIDS, as well as partnerships designed to strengthen health care infrastructure, ensure adequate financing for health and build local health care capacity through training and support.[4]

A third area of focus is on ***corporate good governance*** including adherence to high standards of regulatory and legal compliance, high ethical standards in clinical trials and promotion of medicines, working to prevent corrupt activities and addressing other issues that support good health care policies. For example, industry in recent years has organized with public and other private entities joint efforts to fight against the growing threat of counterfeit branded and generic medicines, a problem that significantly affects patients in the poorest countries.

This paper discusses the major actions and commitments of the research-based pharmaceutical industry in these key areas, noting that for most of the actions required, a collaborative or partnership approach is essential if global public health goals are to be attained.

Background

In 2008, the World Health Organization (WHO) will take note of the 30th anniversary of the Alma-Ata Declaration - a declaration arising out of the International Conference on Primary Health Care (PHC) in Alma-Ata, Kazakhstan. This declaration called for "the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life" - i.e., calling for "Health for all" by 2000.

However, eight years beyond this target date, in many parts of the world, people lack adequate food and do not have access to clean water - both critical components of good public health. One billion people live in developing countries on less than US$1 a day, and 2.5 billion are living on less than $2 a day; more than 2.6 billion people lack access to toilets and other sanitation facilities; and 30,000 children under five-years of age die every day, mainly from dehydration, undernourishment, and preventable diseases. Where there are clinics and hospitals, they are too few, and they are inadequately staffed and equipped. Because of this devastating poverty, about a third of the world's population lacks adequate access to quality health care, including medicines - a disturbing constant ratio that leaders of the WHO and other public health experts have cited over several decades.[5]

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[4] For a summary list of initiatives see the attached Annex, and for more complete information, see http://www.ifpma.org/healthpartnerships

[5] Poverty is clearly the key element behind the lack of access to health care. However, considering investment in health care also as a contributor to economic growth and social improvement is appropriately highlighted in the Report of the WHO Commission on Macroeconomics and Health. See http://whqlibdoc.who.int/hq/2001/a74868.pdf See also former EU Health Commissioner David Byrne's speech "Health is Wealth" at http://www.europa-eu-un.org/articles/en/article_2856_en.htm

In 2000, the United Nations Millennium Development Goals (MDGs) were created with the target of improving the health and welfare of those living in the poorest countries by 2015.[6] Attaining them will require sustained, concerted global action. While states have the primary role and obligation to improve global health, the research-based pharmaceutical industry plays a unique role: developing innovative, safe and effective medicines.

Moreover, the industry works to reduce mortality and morbidity in the poorest nations through multi-stakeholder dialogue and partnerships. These partnerships enable each stakeholder to use its expertise in a concerted manner. Thus, they can make the joint effort an effective, far-reaching and beneficial undertaking for patients in developing countries, who benefit from the products or services of these partnerships. The factors that create the current, tragic state of health for many people living in the poorest countries are complex, and only in partnership with experts and institutions in other contributing fields can the research-based pharmaceutical industry play its part in creating meaningful access to medicines that will save or improve the quality of lives.

Since the launch of the UN MDGs, the research-based pharmaceutical industry has collectively made available through its own funding over 1.3 billion positive health interventions in developing countries to save and improve the lives of people living in these countries.[7] These interventions are above and beyond the commitment of the R&D-based pharmaceutical companies to perform their main societal task of developing high quality medicines. This assistance includes product donations and sales of medicines at favorably discounted prices, in addition to training, equipment and labor - totaling 4.6 billion Euros (US$ 6.7 billion) over the period 2000-2006. This measure of industry contribution does not include the important emergency relief donations made available by the industry following natural disasters. The training of health care workers amounted to more than 220,000 health workers (a figure that is 1/3 of the total health workforce of Africa). These figures reflect over 150 partnership programs that the industry is engaged with in developing countries.

In spite of the tremendous contributions made by industry and other stakeholders, more needs to be done by all parties. These include, especially, national governments and international agencies, but also NGOs - civil society, the health professions, patient groups and the business community. The focus, actions and commitments of the research-based pharmaceutical industry, represent its vision of essential steps needed, particularly relating to advancing health care in developing countries. The research-based industry's commitments to supporting improved global health for today's and tomorrow's patients are not limited by geography and are grouped around three key areas: a) Innovation; b) Access; and c) Corporate Good Governance.

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[6] Three MDGs relate directly to health, while the others are linked indirectly. See: http://www.un.org/millenniumgoals/index.html

[7] For a summary list of initiatives see the attached Annex, and for more complete information, see http://www.ifpma.org/pdf/2007_11_02_Release_Partnerships_Survey.pdf

A. Innovation

The Research-Based Pharmaceutical Industry is committed to:

1. Researching and Developing Innovative Drugs and Vaccines - its Primary Societal Mission

The research-based pharmaceutical industry's primary role (unique among all stakeholders) is to develop safe, high quality and effective disease treatments that improve patients' health. R&D-based pharmaceutical companies make fundamental and significant contributions through innovative research, development, and manufacture of high-quality drugs and vaccines. These contributions reduce premature mortality as well as prevent or treat diseases, raising the quality of life of patients, avoiding costly hospitalization, and allowing people to go back to more normal working lives instead of being bedridden.

2. Supporting Programs of R&D for Diseases Prevailing in Developing Countries

Industry has developed and is developing a very large number of medicines for diseases that harm patients in both developed and developing countries (e.g., HIV/AIDS, diabetes, respiratory diseases). It also has a commitment to R&D for diseases prevalent primarily in the developing world. Research-based companies are working on over 50 potential medicines and vaccines in the area of "tropical diseases", an increase from around 40 a few years ago. Companies with a level of comparative expertise in this field are increasing their efforts to carry out research on diseases that particularly impact developing countries.[8] These multiple efforts are carried out through: internal research programs; stand-alone research institutes; support given to the WHO / UNICEF / UNDP / World Bank Programme for Research and Training in Tropical Diseases (TDR) and other programs (e.g., Medicines for Malaria Venture, the Global Alliance for TB, and the Drugs for Neglected Diseases Initiative); and collaborating with agencies that operate novel market-based mechanisms, such as the concept of advanced market commitments.[9] The industry continues to explore novel approaches to stimulating such further R&D - within, of course, the limits of legal restrictions of various national competition laws and policies. Industry also continues to develop more than a hundred medicines for HIV/AIDS and malaria, including a number of vaccines. This is in addition to the research-based industry's efforts to address through innovation the growing threats worldwide of chronic diseases such as cardiovascular disease, diabetes, cancer, neurological diseases and other diseases.[10]

3. Conducting Research and Development for Pediatric Medicines

The use of medicines in children presents unique challenges. Clinical testing has evolved into a set of guidelines recognized worldwide by health authorities and the

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[8] For specific projects, see: http://www.ifpma.org/pdf/2007_11_02_Status_RnDforDDW.pdf

[9] See http://www.vaccineamc.org/

[10] See the extensive survey of medicines in the clinical development for a number of infectious and chronic diseases at http://www.phrma.org/medicines_in_development/

pharmaceutical industry, underpinned by the principles of good clinical practice.[11] Today there is greater appreciation of the physiological and psychological differences of children compared to adults and recognition of the need for children to be considered in their own right in drug development - not be treated as small adults. The pendulum is now swinging back towards protection of children's health through research, as documented in the international agreement on inclusion of children into the drug development process and a recently initiated WHO campaign in support of pediatric drug development.[12] The diagnosis of child cancer was almost a death sentence 50 years ago, against survival of around 80% today.[13]

Industry has already built up a considerable wealth of knowledge on the complexities of pediatric clinical trials and drug development. Industry has supported the introduction of pediatric legislation in the United States and the European Union.[14] In collaboration with the other key stakeholders in health care, industry is committed to letting children worldwide increasingly benefit from the therapeutic benefits of modern drug treatment. Industry has and will continue to encourage policies that will foster additional pediatric medicines development.

4. Supporting Sound IP Protection and Regulatory Conditions - Essential for Innovation to Address Unmet Needs of Patients

Intellectual property rights in both developed and emerging developing countries, supported by sound government regulatory processes and health care financing, are a critical enabling factor for industry's research and development efforts - its primary contribution to public health efforts. Without these enabling conditions, industry could neither provide innovative medicines nor be able to support partnership initiatives in developing countries. Effective intellectual property systems - including protection of patents, trademarks and proprietary data - are critical for stimulating R&D, because they provide some assurance that, if a new medicine is successfully approved, the innovator has a chance to generate revenues sufficient to justify the investments in R&D. The more than 20 current antiretroviral medicines were developed using the incentives provided by effective intellectual property protection in developed and many developing countries.

Thus, the research-based industry supports the strengthening of intellectual property rights in both industrialized and emerging developing countries in order to encourage and manage further innovation. As noted by former UN Secretary General Kofi Annan "Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people."[15] A

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[11] See provisions on the harmonization of technical requirement relating to children at http://www.ich.org

[12] See http://www.who.int/childmedicines

[13] See data for different types of children's cancer and survival rates at http://www.stjude.org/stjude/v/index.jsp?vgnextoid=5b25e64c5b470110VgnVCM1000001e0215acRCRD

[14] Industry's development of pediatric medicines is encouraged by specific pediatrics legislation in the United States (see: www.fda.gov/cder/pediatric/index.htm) and the European Union (see: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm).

[15] See http://www.who.int/inf-pr-2001/en/pr2001-19.html - The WTO TRIPS Agreement contains flexibilities that all countries may use (subject to being consistent with its provisions). A small number have made use of them (e.g., compulsory licenses) in their application of the Agreement. Such governments look to compulsory licenses (CLs) as a "solution" to their access problems. However, while compulsory licenses are possible under TRIPS, they are only an option; but they are certainly not a solution to access problems. Rather, frequent use of them could discourage introduction of new medicines where they could be used, and frequent use of CLs weakens the IP framework and thereby undermines the system that underpins the ability of the private sector to undertake essential R&D.

significant number of developed and emerging developing countries have progressed in improving their level of protection for intellectual property rights in the past two decades, and industry is committed to encouraging this positive trend for innovation and patient access to new medicines.[16]

B. Access

The Research-Based Pharmaceutical Industry is committed to:

5. Helping to Address Access Barriers through Partnerships

There must be clear global recognition of and priority attention placed on addressing the challenges to improving access to health care, including medicines. The most obvious and fundamental barriers to access to health care and medicines are poverty and the poor health infrastructure in developing countries, including a serious shortage of doctors, nurses and pharmacists. Compounding these shortcomings, in many developing countries there are also high medicine distribution costs because of the high import tariffs, port charges, importers' margins, value-added taxes on medicines, and high margins in the wholesale and retail components of the supply chain. These factors can inflate unnecessarily the costs of essential medicines, particularly in the least developed countries. A further critical issue around improved health care access is the need for supplementing the financing of health care, given the shortage of resources in poorer developing countries.[17] Industry has been supportive of innovative global financing mechanisms, including the Global Fund for AIDS, TB and Malaria, GAVI for vaccines, national programs (e.g., PEPFAR for HIV/AIDS) and advanced market commitments to purchase new medicines tailored to the needs of developing countries. Without these mechanisms - and more are needed - medicines from whatever sources cannot be supplied on a sustainable basis for diseases that are the most important threats to the well-being of patients in developing countries.

While the role of governments is primary, public-private partnerships enable each stakeholder to use its expertise in a concerted manner - through joint efforts making effective far-reaching and beneficial undertakings for patients that improve patient access in developing countries. Poor people who lack education in health matters and have limited or no access to adequate nutrition, safe water, and sanitation are also not likely to have the ability to buy even basic health products and services. In these circumstances, it is rarely high-tech solutions, but rather primary care interventions, that

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Meanwhile, a number of developing and developed countries have placed strict limits on, or have indicated that they will completely forego the use of the flexibilities of the TRIPS "Paragraph 6" amendment. Furthermore, either unilaterally or as part of trade agreements, a number of developing and developed countries have made use of another type of flexibility – i.e., the flexibility in TRIPS Article 1 to "implement in their law more extensive protection than is required by this Agreement".

[16] For example, a number of developing and developed countries have elaborated on the provisions of TRIPS Article 39 in specifying up to 10 years of data exclusivity related to performing work on clinical trials. Data exclusivity provides an important incentive for the development of new medicines, but also can encourage the development of new indications for older, even off-patent, medicines.

[17] In May 2000, "The Joint Statement of Intent" between the WHO, UNICEF, UNFPA, UNAIDS and the World Bank and five (now eight) pharmaceutical companies identified national political commitment, national infrastructure capacity, societal mobilization, secure distribution systems, significant additional funding and continued industry R&D - along with pharmaceutical company access initiatives - as the key elements in efforts to address the need for expended AIDS treatment with ARVs. This statement has lessons for other priority disease campaigns. See the Joint Statement in Annex 1 of: http://www.who.int/hiv/pub/prev_care/en/isbn9241210125.pdf

are needed to combat typical poverty-related diseases. Poverty alleviation in general and especially targeted interventions - better nutrition for mothers, mass vaccination campaigns, access to basic antibiotics, bed nets for malaria prevention, and condom use programs to prevent the spread of HIV/AIDS and other sexually transmitted diseases - are highly effective in reducing preventable mortality. The combination of these with well-known, inexpensive basic health interventions would have a dramatically positive impact on the health of the poor. In this regard, industry's contributions go beyond the supply of medicines and include, for example, training, know-how in supply-chain management and the use of innovative medicines.[18]

Other major barriers to access that need to be addressed concern tariff barriers and indirect taxes. Tariffs and taxes levied on medicines increase the price of medicines, and are under the direct control of national governments. Where most patients have low incomes and must buy health products out of their own pocket, high tariffs and taxes further impoverish them and make their ability to access these products more difficult. If such taxes went directly towards helping to finance better health care access and infrastructure, they might be defensible. They generally do not, and instead often simply protect local producers or contribute funds to non-health programs. Tariffs should be substantially reduced or eliminated along with high internal taxes on medicines, and industry is committed to work with relevant international agencies to overcome this problem.[19]

6. Making Individual Company Efforts to Make Treatments Available and Accessible

Research-based companies take many initiatives to improve access through practical measures. These include, but are not restricted to, training in clinical trials and manufacturing, training of health care professionals, providing educational grants, and supporting regulatory and health care infrastructure development. They also work, in partnerships with other stakeholders, to make their products more accessible in poor countries via donations of high quality medicines or through subsidized, individual differential pricing schemes - as each company chooses to do, based on its own circumstances.[20] Also, a number of companies are committed to licensing their technologies to quality generic producers, while many others commit to expanding their own production and distribution capacities to meet the needs of patients. There is an important role for the generic industry, since more than 95% of the World Health Organization's designated list of essential medicines consists of off-patent, generic products.[21] Under competitive conditions, the generic industry's products can reflect

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[18] See company programs identified in the reference in footnote 5 supra and in the Annex below. For example, in addressing access to HIV/AIDS anti-retroviral treatments, seven companies have worked with international agencies to scale up AIDS treatments in the poorest and low-income developing countries, under the "Accelerating Access Initiative", and worked to overcome infrastructure barriers with partners.

[19] Tariffs, taxes and other "mark-ups" in the supply chain are a part of an analysis and initiative being undertaken via the "MeTA Project" by the UK Department for International Development. See http://www.dfidhealthrc.org/meta/index.html

[20] These actions are done within the framework of the respect for competition policies, laws and regulations worldwide. As in the case other industries, medicines prices reflect market-based competition - i.e., competition among patented products, and between patented products and off-patent products, and competition with other medical technologies.

[21] UK Department for International Development (DFID) report "Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry", March 2005, page 20. This DFID report also contains a number of other constructive observations and recommendations related to the overall topic of this paper.

their relatively lower cost structure, as generic companies do not need to recover the originator's significant R&D costs in the sales of generic products.[22]

It is critical, however, to secure needed supplemental financing from international donors or national governments: e.g., in the absence of intellectual property protection or enforcement by rights-holders in certain developing countries (a number of which are relieved of any TRIPS obligations until 2016), both originator and generic producers can make their products available there; but, in the absence of additional financial support, neither discounted original nor generic-copy medicines can be afforded by patients, given the very low per capita income levels and poverty conditions prevailing in many developing countries around the world.

The combination of these various industry actions maximizes the opportunity for patients in developing countries to access originator or qualified generic producers' products via partnerships. This can help to ensure sustainable access. From this perspective, intellectual property rights are essential for patients' access to innovative medicines - as they permit industry to conduct research and development on a sustainable basis.

C. Corporate Good Governance

The Research-Based Pharmaceutical Industry is committed to:

7. Complying with and, when appropriate, Going beyond National Health, Safety and Economic Regulations

Research-based pharmaceutical companies commit to comply with all laws and regulations concerning healthy workplaces, environmental protection, and the safety and effectiveness of products and services. Under constructive political and social conditions (i.e., "good governance" conditions), these corporate contributions are of major value in enabling individuals to lead a healthy life as well as the state to bear its duties - i.e., through the wages paid to staff, employees are empowered to fulfill their economic, social, and cultural rights, and through taxes paid, the state is enabled to improve public health conditions. Research-based companies are committed to having appropriate corporate responsibility guidelines and responsible business policies in place. Indeed, companies' self-imposed corporate responsibility norms are frequently standards set by local laws and regulations.

8. Ethically Performing Clinical Trials and Promoting Medicines

Industry has, in dialogue with clinical researchers and the regulatory authorities, developed a system of good clinical trial practices to test safety and efficacy of innovative medicines. These allow an accurate depiction of short and long-term results to peer reviewers, regulators and the general public. Recently, companies have furthermore committed to making their ongoing trials and results publicly accessible in

[22] The existence of the generic industry and its products are an important consequence of an effective global IP system, which yields not only innovative medicines but also, after the expiry of IP rights, an ever growing supply of "new" generic products, which do not have to recoup R&D and other costs that originators support.

a timely manner. They accomplish this goal by publishing results of trials through official and private sources. Industry has in fact created an Internet portal so that the public can easily access ongoing clinical trials and results of these trials, whether positive or negative.[23]

A critical part of the process of the discovery, clinical development and marketing of medicines for the benefit of patients is the promotion of innovative medicines - essential for informing health care professionals about new medicines and approved new uses for existing medicines. The research-based pharmaceutical industry is the primary source of information about its own products and recognizes its major responsibility for helping to ensure that product information is accurate and is not misleading. Every company in membership of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) - either directly or through its member associations - must adhere to the principles laid out in the IFPMA Code of Pharmaceutical Marketing Practices.[24] This Code, supplemented by member association and company codes, and respectful of national laws and regulations, sets forth the global standards for the ethical promotion of medicines to healthcare professions by industry - in every country around the world where companies are operating via sales and promotional activities. The basis of those activities rests on the principle that member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine.

9. Ensuring Product Quality: Good Manufacturing Practices and Bio-Equivalence Standards are Critical

The research-based industry is committed to manufacturing products of the highest quality and to considering the practical needs of resource poor environments (e.g., heat stable products). The industry also supports the strengthening of national regulatory systems and the global promotion of Good Manufacturing Practices (GMPs) to improve the availability of good quality originator, bio-equivalent generic medicines worldwide. The commitment to quality is very important, and there is a need to focus attention to addressing the problem of substandard medicines manufactured where adequate standards for GMPs do not exist or are not enforced. Additionally, even where GMP standards exist, there remains the problem of non-bioequivalent copied products being produced and approved by some regulatory authorities, and thus putting patients' health at risk. Failure to ensure that patients receive bioequivalent generic products can lead to drug resistance, death, and to the spread of epidemics. Industry is committed to support regulations requiring GMPs and effective bioequivalence standards, and companies are committed to helping to assure that these standards are effectively implemented by any of their licensees. Industry is also committed to support a regulatory framework adapted to the special characteristics of similar biological medicinal products ("biosimilars") made by manufacturers other than the original manufacturer.[25]

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[23] See the IFPMA Clinical Trials Portal at http://www.ifpma.org/clinicaltrials

[24] More Code information is at http://www.ifpma.org/ethicalpromotion/

[25] Due to the complex nature and diversity of biological products, the benefit/risk profile of "biosimilars" must be carefully evaluated and monitored, a specific, well-defined and transparent regulatory framework covering development, approval and post-authorization procedures must be in place (see http://www.ifpma.org/Issues/Biologicals). The EMEA notes that: "The standard generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate bioavailability studies) is normally applied to chemically-derived medicinal products. Due to the complexity of biological/biotechnology-derived products the

10. Fighting against Counterfeit Medicines

The industry is deeply committed to counter the growing public health threat of counterfeit medicines, which is most prevalent among the most vulnerable, poor populations in countries with weak legal and regulatory structures. The counterfeiting of medicines in developing countries ranges between 10 and 30 % of all medicines sales, and the problem of counterfeits is widespread among generic drugs and vaccines, as well as among originator products.[26] The making of counterfeit medicines is a criminal act, and there is no such thing as a "good quality" counterfeit medicine, since the manufacture of counterfeit medicines is unlawful and therefore unregulated, in contrast to the case of legitimate prescription medicines. Frequently, counterfeit medicines do not contain the proper quantity, or even any amount, of the active ingredient. The principal global and national health agencies, as well as law enforcement agencies, must lead efforts to reduce the circulation of fake meningitis vaccines, antibiotics, antimalarial and antiviral AIDS drugs, as well as other essential medicines identified by the World Health Organization or national governments. Industry is working closely with the WHO International Medical Products Anti-Counterfeiting Task Force (IMPACT) and other institutions willing to take a leadership role. Industry itself has taken a leadership role and in 2002 formed the Pharmaceutical Security Institute to coordinate anti-counterfeiting efforts among 27 companies and work with governments and their health and law enforcement agencies.

11. Fighting Corruption in the Health Care System

Patients are subject to the decisions of others in the selection of health care interventions, and especially in poorer economic settings. They are thus vulnerable to decisions being made based on bribes, cronyism, nepotism or other fraudulent behavior. This is made possible by inadequate transparency and controls over transactions, and the lack of adequate enforcement of rules designed to make the patient the beneficiary of the health care system. Use of scarce funds to purchase substandard or fake medicines harms patients, and reduces the effectiveness of disease eradication programs. The industry gives a priority to efforts to fighting corruption individually and collectively with other stakeholders.

12. Contributing to Pandemic Influenza Preparedness

Industry is committed to preparedness against the threat of a pandemic influenza outbreak, and research-based vaccine companies have made tremendous R&D investments in pandemic vaccines; have expanded seasonal influenza vaccine manufacturing capacity as a necessary step in building capacity against the threat of a pandemic influenza outbreak; invested in dose-sparing technologies; donated pre-pandemic vaccines and antiviral medicines to WHO stockpiles for developing country use; have offered appropriate and feasible technical assistance to developing country vaccine producers; and have taken a number of other responsible measures. Industry has also prepared a guidance manual for health care companies to assist in the

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generic approach is scientifically not appropriate for these products." See http://www.emea.europa.eu/pdfs/human/biosimilar/043704en.pdf

[26] See the WHO International Medical Products Anti-Counterfeiting Task Force (IMPACT) fact sheet at http://www.who.int/impact/news/en/

development of business continuity planning to maintain the supply of essential health care products in the face of a potential pandemic.[27] This manual has been translated into 7 languages (English, French, German, Italian, Japanese, Portuguese and Spanish). Industry is committed to work in advance with various stakeholders to continue delivering healthcare services and medicines in the event of a pandemic.

Conclusion: A Partnership Approach Must Be the Central Focus of Global Efforts

Industry is committed to its prime function of discovering and developing new medicines, vaccines and, increasingly, products of biotechnology for patients worldwide. The enormous mortality and morbidity burden in the poorest developing countries can only be addressed by improving access to health care via a *concerted, partnership-oriented strategy* that is supported globally with financial resources as well as know-how about good practices, and with national and community efforts to increase poor people's access to essential health services, regardless of where they live.

It is obvious that single actors on their own will have a limited impact on global development and health problems. All actors in society - state and non-state - must contribute to solutions according to their obligations, abilities, and enlightened self-interest. All societal actors must make resources available and cooperate in a creative way in order to meet all the Millennium Development Goals. Industry commits to continue to act responsibly in its sphere of capability and is committed to work collaboratively to make its novel preventative and therapeutic products available and accessible to the global patient community.

Annex:

R&D Pharmaceutical Companies Involved in Access, Capacity-Building and R&D Public-Private Partnerships (PPPs) to Improve Health in the Developing World

HIV / AIDS – Antiretroviral Access PPPs

Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Merck & Co., Inc. and Roche

HIV/AIDS – Mother & Child Programs PPPs

Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, Johnson & Johnson, Novartis and Roche

HIV/AIDS – Capacity Building PPPs

Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Johnson & Johnson, Japan Pharmaceutical Manufacturers' Association, Merck & Co., Inc., Pfizer and Roche

HIV/AIDS – R&D PPPs

Abbott, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., Novartis and sanofi-aventis

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[27] See http://www.ifpma.org/Influenza/index.aspx?48

Malaria – Access & Capacity Building PPPs

GlaxoSmithKline, Novartis, Pfizer and sanofi-aventis

Malaria – R&D PPPs

GlaxoSmithKline, Novartis, sanofi-aventis and Sigma-Tau

Tuberculosis – Access & Capacity Building PPPs

AstraZeneca, Eli Lilly, GlaxoSmithKline, Novartis and sanofi-aventis

Tuberculosis – R&D PPPs

AstraZeneca, Bayer HealthCare, GlaxoSmithKline, Novartis and sanofi-aventis

Tropical Diseases – Eradication or Elimination Programs PPPs

Bayer HealthCare (sleeping sickness), GlaxoSmithKline (lymphatic filariasis), Johnson & Johnson (Guinea worm), Merck & Co., Inc. (lymphatic filariasis, onchocerciasis), Novartis (leprosy), Pfizer (trachoma) and sanofi-aventis (sleeping sickness)

Tropical Diseases – Access, Capacity Building PPPs

Bayer HealthCare, Gilead, Johnson & Johnson, Merck KGaA, sanofi-aventis and Schering-Plough

Tropical Diseases – R&D PPPs

GlaxoSmithKline, Novartis, Pfizer, Schering-Plough and Wyeth

Vaccine-Preventable Diseases – Access & Capacity Building PPPs

Bayer HealthCare, Crucell, GlaxoSmithKline, Merck & Co., Inc., Novartis, sanofi-aventis and Wyeth

Vaccine-Preventable Diseases – R&D PPPs

GlaxoSmithKline, IFPMA Influenza Vaccine Supply ITF, Merck & Co., Inc., Novartis, sanofi-aventis and Wyeth

Child & Maternal Health PPPs

Abbott, AstraZeneca, Bayer HealthCare, GlaxoSmithKline and Johnson & Johnson

Chronic Diseases PPPs

Abbott, AstraZeneca, Novartis, Novo Nordisk and sanofi-aventis

For more information on these programs, please go to:

http://www.ifpma.org/healthpartnerships