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EDITORIAL

Ethics and Access to Medicine

BY SHEERIN KALIA, EDITOR

80% of the world's population does not have access to much-needed medicines – the same medicines that we take for granted in Canada. This lack of access leaves people vulnerable to disease and death caused by pneumonia, malaria, tuberculosis and AIDS. As Canadians, it is difficult to even grasp the reality of this issue. We do not, in our daily lives, come face to face with the human suffering that lack of access to medicine causes.

Without that visual, it is difficult to completely understand the implications of the statistic but, we can probably all agree that the statistic is alarming. Why is the number so high? The answer is complex and fingers really cannot be pointed in any one direction. As we discovered, the better question is perhaps: what can be and is being done about the problem by the business community and why? To understand the Canadian and global response to the problem, we sought the views of those who work in the area. In response, Dr. Roderick Slavcev (University of Waterloo's School of Pharmacy), Hugh O'Neill (President and CEO of Sanofi-aventis Canada), Dr. Sebbag (sanofi-aventis's Global VP of Access to Medicines), Glen Shepherd (President of Health Partners International Canada), and Dunniela Kaufman (Fraser Milner Casgrain LLP) and Chris Cochlin (Cassidy Levy Kent (Canada) LLP) agreed to provide us with their views.

For many industries, there can be a fundamental conflict between ethical and economic imperatives. In these industries, doing the morally right thing is strongly influenced by and even limited by economic and financial issues beyond a business' control. In the pharmaceutical industry, this is no less the case and in fact, in this industry, the tension is exacerbated by legal, political, regulatory and administrative issues that impact all aspects of a company's operations. In particular, the need to protect valuable patent rights attached to innovative pharmaceuticals can, on the surface and at first glance, prevent a company from allowing access to much-needed medicines, if that access will dilute valuable legal rights.

Given these obstacles, I assumed (and wrongly) that any efforts by the industry to provide medicines to those in need would be driven by either a desire to do what ought to be done or a utilitarian focus on producing the greatest good for the greatest number. But, as we started to take a closer look at this issue, we discovered that was not the case. Instead, some solutions being used by the industry appear to be borne out of a deliberate corporate social responsibility strategy that does recognize the inherent moral duty of providing medicines to those in need and to as many people as possible but, that does so because there is also a business case for doing so. That is, the industry recognizes to some degree that improved health in communities means increased markets. In that sense, on this issue at least, it appears that ethical and economic imperatives in fact converge.

What are the lessons that other industries can learn from this issue? The long-term viability of an organization may not be determined solely by its balance sheet (past and present) or how an organization views itself from the inside out. And sometimes, pursuing legal solutions to a problem with very human consequences leads to a less than satisfying result that creates even larger problems. Instead, as an organization is faced with new social, political and economic challenges, long-term viability may be influenced by recognizing that the health (financial or otherwise) of an industry may be better-served by increasing the size of the proverbial pie from which each organization partakes. Our hope is that the strong analysis and stories contained in this issue will resonate and provide a potential model for such value creation in other areas.

Moving Toward International Access to Healthcare: Aligning Ethics and Economics

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The health of a population is a highly complicated, emotional and multi-level issue that incorporates the stressors of living, working, aging, and access to pharmacotherapeutic and clinical services as well as education and prevention. Obviously, a well-functioning system requires financing necessary for such a large, multi-component undertaking. It is probably not surprising that low income countries have populations that possess the greatest disparity in socio-economic classes. In such countries, the poor that constitute the largest tier of the population endure the highest levels of environmental stresses and are also plagued by unavailable or inefficient deployment of finances toward health care access. Scarce access to healthcare for some basic, yet essential services can be as low as 10%, while the rich share similar service to that seen in developed countries[1]. The converse situation is the induction of poverty due to healthcare expenses, a situation that is estimated to force 100 million people annually, including those from developed countries, into poverty due to overwhelming individual health care costs.[2]

Access to health care is an extraordinary human need and priority and although many developing nations have made significant improvements toward this end over the past decade, this ethical imperative is far from universally implemented. Many envision limited access as specific to poorer nations, but this is hardly the case as there are a number of pathways by which access may be diminished that can make rich and poor countries

equally susceptible. The World Health Organization (WHO) notes that access is impeded internationally due to three fundamental problems: 1) the limited availability of resources and lack of immediate access to latest technology and treatment modalities; 2) overreliance on direct payments, whether completely or in part, that can lead to impoverishment; and 3) economic slack due to resource wastage.[3]

While citizens of the poorest countries suffer from little access to any health care, no country can claim universal access to the best treatment options, and most developed countries fall short to some extent by requiring direct payments, even where these costs may eventually be reimbursed.[4] While the first two points diminish the size of an individual's "slice" of access to healthcare arising from a lack of resources, wastage accounts for 20 to 40 percent globally. Such economic appropriation is particularly insidious in that it diminishes the size of the entire healthcare pie, but if corrected could confer the greatest impact and even aid in remedying resource scarcity and the need for direct payments. Building an efficient system thus minimizes the losses associated with raising and disbursing revenue and facilitates the development of a progressive system that can redistribute resources with equality among rich and poor alike.

The practice of ethics and ethical decision making has to do with values, and values can and are more likely to conflict when one necessary part of a system doesn't know the values that motivate the other parts. While we may look to some countries as ethical benchmarks of equity, and for good ideas along the road to effective and universal healthcare access, the political and economic environment of each country is different and impacts its value system differently. That being the case, the path to universal healthcare will evolve uniquely for each country. In the 49 lowest income nations, there are fewer stakeholder and access points in the healthcare continuum to accumulate slack and resource wastage, but here resources are also very scarce and the role and power of a stakeholder such as government may be highly unstable, whereby its economic imperatives and values are often not directed appropriately toward universal healthcare.[5] Change here will of course need to come from within and while a few governments have honoured agreements and allocated the agreed upon double digit percentages of their GDP to healthcare, others have either fallen short or decreased access.[6] However, for more than 80% of these poor nations, even these changes will not suffice. Per capita spending will essentially need to double—an endpoint that cannot be achieved by internal strategies alone.[7] Thus, while these countries may look to universal health care providers like Canada, which allocates 11% of its GDP to healthcare provision, as a benchmark of ethics and equality, the true test of ethics will need to occur on a global scale, whereby the industrialized world makes good on its global commitment to both guide and support poorer nations toward this end.



Undeniably, some industrialized countries, particularly in Europe, are far closer to attaining sustainable, universal (timely) healthcare access than others and yet, no country can claim perfection. In Canada, we arguably enjoy reasonable equality of access to healthcare. Whether to medication or vital clinical services, access is perhaps our greatest national and internationally recognized landmark achievement. It differentiates us from our southern neighbour despite that it spends more per capita then we do (17% vs. 11%).[8] While the ethical imperative demonstrated in Canada is strong in its pursuit of equity and is very fit to serve as an international model, its implementation is compromised by high bureaucratic costs and ethical disparities that, particularly in light of a massive aging population and reduced work force, may quickly diminish the underlying goal. To this point, while Canada is recognized as the nation with the fairest mechanism of health system finance in North America, we still ranked 30th in the world in health systems, and that was over a decade ago.

"IN THE 49 LOWEST INCOME NATIONS, THERE ARE FEWER ACCESS POINTS IN THE HEALTHCARE CONTINUUM TO ACCUMULATE SLACK AND RESOURCE WASTAGE, BUT RESOURCES ARE ALSO SCARCE AND THE ROLE AND POWER OF A STAKEHOLDER SUCH AS GOVERNMENT MAY BE HIGHLY UNSTABLE."

The ethical imperative of equal access is thus hindered by varying value drivers of each player in the healthcare mix. This access framework from bench (drug discovery) to bedside (clinical service) consists of various participants, including drug manufacturers, health providers, policy makers, and public/private payers, and embodies an evolved and integrated collaboration between its many phases for what can be best described as a continuum of access. The stakeholders, each of whom controls access in its own way, are driven by their own set of values and economic drivers, in both decision making and operation.

Healthcare must be thought of as a continuum from bench to bedside, and while each phase is motivated by different economic incentives, a bottleneck anywhere along the way accumulates economic slack and compromises downstream healthcare access. On a global scale, despite having fewer access points, these bottlenecks are magnified, given the differences in values of global players, economic incentives and mandates of the primary stakeholders, regulatory approaches (if any), and the situational economic complexities involved in providing healthcare.[10]

Ethical practices or ethically-informed decisions may only relieve such bottlenecks if we can first agree on a universal set of stakeholders' values and align economic incentives— a difficult challenge intra-nationally, let alone internationally. This will require global solidarity and the understanding that ethics and economics cannot be separated. Canada is a world leader, alongside the U.K. and Australia, in health economics, a discipline that is quickly developing and ever improving as a universal language of ethical economics to help policy makers decide who is eligible to what therapeutics, and at what cost, based on incremental value/cost ratio. Health economics is arguably still in its infancy, subject to substantial ethical debate unto itself and certainly not (yet) globally accepted as an economic/ethical paradigm of policy making and it may never be. However, as this outcomes-based system continues to evolve, it benchmarks ethical practice toward universal drug access (pharmacoeconomics), including clinical access and therapeutic modalities in totality (health economics) that could serve to remove slack from the system. It may even serve as a tool to wield ethical and gaugeable taxation of commercial firms (cigarettes, alcohol, junk food[11], etc) that profit, while taxing healthcare systems.



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Sanofi-aventis and the Economic Imperative of Corporate Social Responsibility

BY HUGH O'NEILL PRESIDENT AND CEO OF SANOFI-AVENTIS CANADA
AND DR. ROBERT SEBBAG GLOBAL VICE PRESIDENT, ACCESS TO MEDICINES, SANOFI-AVENTIS GROUP

Sanofi-aventis is one of the world's leading diversified healthcare companies with more than 100,000 employees in 100 countries. Our mission is: "to improve the lives of everyone". To strengthen our commitment to the patient who is at the center of our focus, we created a new Corporate Social Responsibility (CSR) Direction. The goal was to bring together all of sanofi-aventis' major initiatives in the economic, social and environmental fields, access to medicines, diversity and humanitarian partnerships.

Our CSR Direction is emblematic of our desire to be a true global healthcare partner with a responsibility to patients, governments, insurers and the general public, as well as a desire to create sustainable solutions that create win-win situations. Given that our CSR approach places the patient at the centre of sanofi-aventis' business activities, one of our main objectives is to ensure patients have the right to health and therefore access to healthcare. This is a sizeable challenge, when you consider that 80% of the world's population has little or no access to the medicines they need.

THE HISTORICAL CONTEXT FOR ACCESS TO MEDICINES AT SANOFI-AVENTIS

The general awareness of the need for better access to medicines emerged at the end of the 1990s and was driven by society's awakening to the desperate need for better access to HIV drugs in developing countries, especially in the southern hemisphere. Nothing epitomized the world's awakening social consciousness to this access issue better than when 40 of the largest pharmaceutical companies sued South Africa over their Medicines Act, which would allow the import and generic production of cheap AIDS drugs.

SANOFI-AVENTIS IN ACTION

One of our responses to the global access challenge was the establishment of the Access to Medicines Division, which focuses on six serious public health threats in the southern hemisphere and in which our company has a history of pharmaceutical expertise: malaria, tuberculosis, leishmaniasis (skin sores and organ damage caused by sand fly bites), sleeping sickness (sleep disorders, dementia, convulsions, paralysis and eventually coma caused by tsetse fly bites), epilepsy, mental health and vaccine-preventable diseases.

Our Access to Medicines Division has four priorities:

PRIORITY 1
education and information for comprehensive disease management, at every link in the healthcare chain

PRIORITY 2
pricing and distribution policies that help facilitate access

PRIORITY 3
research and development to meet current and future needs

PRIORITY 4
best possible use of our industrial skills in developed and developing countries

These priorities stem from the company's business model which we have clearly aligned with what we do at a humanitarian level.

MAKING GOOD ON OUR PRIORITIES

If you look at our Impact Malaria program, you'll see that our company mobilizes its expertise, antimalarial product portfolio and other resources in the fight against malaria. Malaria is a parasitic disease, transmitted among humans via the Anopheles mosquito. Every year approximately 500 million people will suffer an attack and more than half of all deaths from the disease will be children under the age of five. In many sub-Saharan African countries, malaria is the largest single health expenditure.

To implement our 1st Priority, Impact Malaria developed numerous programs including an educational manual for prescribing physicians, certificate courses on the disease for African physicians, the Web site impact-malaria.com, local malaria awareness building tools, pictograms that can be understood by everyone, as well as a Practical Guidebook for the Corporate Fight against Malaria to help companies organize care for employees and their families. Sanofi-aventis also initiated a "School Children Against Malaria" program that has helped raise awareness in 200,000 children in Côte d'Ivoire, Ghana and Burkina Faso since 2008.

For Priority 2, the company established no-profit, no-loss pricing for the most underprivileged in malaria-stricken regions. In private-sector pharmacies, in affected countries, the sanofi-aventis brand is available at normal price but it is also available under a different brand name at a preferential price for the needy through public-sector facilities since sanofi-aventis offers treatments at the lowest possible price to public health systems.

For Priority 3, in order to fight against the emergence of drug resistant parasites, the company worked closely with Montpellier II University, Palumed in Toulouse and USTL in Lille on various compounds that led to several new drug candidates.

For Priority 4, sanofi-aventis developed treatments composed of two modified antimalarial compounds in the same packaging: the co-blister format. The artesunate-amodiaquine fixed-dose combination, produced in one of the Group's plants in Morocco, is now available in more than 20 African countries, and over 80 million treatments have been distributed since its launch in 2007.

PARTNERSHIPS TO IMPROVE PATIENT HEALTH OUTCOMES

Another program, which was created to complement the Access to Medicines Division and broaden sanofi-aventis' CSR scope, was the Sanofi Espoir Foundation. Created in October 2010, this foundation aims to reduce health inequalities by focusing on prevention, training and access to care. It was founded on the belief that humanitarian partnerships are needed to achieve a more equitable human environment.



My Child Matters is another example of a program developed in partnership with the Union for International Cancer Control to combat childhood cancer in developing countries. My Child Matters aims to improve cancer cure rates in resource-poor countries by improving access to early diagnosis, information and care. The initiative has already supported 40 field projects in 26 countries.

On a local level, in Canada, sanofi-aventis and sanofi pasteur, (the vaccines division of sanofi-aventis Group), have a long history of working with Health Partners International of Canada (HPIC) to donate vaccines and medicines to the most underprivileged populations. Since 1991, the Canadian affiliate has donated over $60 million worth of vaccines and medicines to HPIC for health programs around the world.

Sanofi-aventis is proud of its CSR work and recognizes its business value, but there are obstacles to CSR. Innovative medicines are often viewed by governments as costs as opposed to economic investments — drug-approval processes are slow, too many innovative drugs are not reimbursed and sub-par intellectual property serve as a disincentive to investments. These challenges need to be addressed in many countries.

Despite these CSR challenges, sanofi-aventis' mission remains patient-focused. We are committed to improving access to medicines for everyone. We believe in creating economically-sustainable models that enable us to supply important medicines to those in need without making a profit, while creating precious goodwill for our company that is difficult to measure but appreciated by all our employees and stakeholders.



HUGH O'NEILL

President and CEO of Sanofi-aventis Canada



DR. ROBERT SEBBAG

Global Vice President, Access to Medicines, Sanofi-aventis Group



Increasing Access to Medicine and Improving Health in the Developing World

BY GLEN SHEPHERD
PRESIDENT, HEALTH PARTNERS INTERNATIONAL OF CANADA

The World Health Organization (WHO) estimates that each year, nearly three million children under five years old die because of diarrhea and pneumonia. In addition, only half of mothers in Africa and Asia have a skilled health worker attend the birth of their babies. This puts these mothers and children at risk for many complications. Health Partners International of Canada (HPIC), a not-for-profit relief and development organization based in Montreal, works with a network of partners, including pharmaceutical and healthcare products companies in Canada, to increase access to medicine and improve the health of people in the developing world, with a special focus on the needs of women and children.

Through HPIC's efforts last year, over one million patients in the developing world were treated with medicine provided by HPIC. HPIC was able to accomplish this because of successful partnering efforts with dozens of pharmaceutical and healthcare products companies in Canada, signalling a serious commitment by the industry to combat the health issues related to access to medicines and health care. In turn, the industry has made HPIC its charity of choice for international development by making it the main channel in Canada for gift-in-kind donations of medicine and medical supplies. These donations are accepted according to the World Health Organization's Guidelines for Drug Donations, which means that donated medicines must meet identified needs in the destination community, have minimum dating and be appropriate.

OUR HISTORY

As with most not-for-profits, our efforts began with one project and, with support, we grew from there. That first project was geared towards helping the survivors of the earthquake in Manjil-Rudbar, Iran, in 1990. That earthquake resulted in an estimated 40,000 fatalities, and left 60,000 people injured. In response, HPIC rallied the pharmaceutical industry and was able to assemble more than $1 million in medicines to respond to the needs on the ground.

In the beginning, partner companies came exclusively from the research-based pharmaceutical industry. While this segment remains a key partner in our mission, other partners have come on board in a significant way. Today HPIC counts on the active partnership of 50 companies from the research-based and generic

pharmaceutical industries, the manufacturers of over-the-counter medicines, the biotechnology sector, and the makers of medical supplies. HPIC's donors are in competition with each other and have very different viewpoints on many issues. By working through HPIC, companies can together provide a better assortment of needed medicines. They also save time and money by referring all requests for donated medicines to HPIC. HPIC has its own projects and a large global network of NGO partners. HPIC's partners must agree to distribute medicines without discrimination or preference. There is a screening and accountability process to ensure that donated medicines and supplies are used as promised. Partners must submit applications and file project reports. In addition, HPIC conducts random audits.

AN INDUSTRY RESPONSE - $340 MILLION IN DONATED MEDICINES AND MEDICAL SUPPLIES

Since 1990, our donor-partners have made it possible for HPIC to provide more than $340 million in needed medicines and medical supplies to vulnerable communities in 110 countries.

Many of HPIC's donor companies view their partnership with HPIC as a key commitment in their corporate social responsibility programs. Additionally, our donor-partners come from different segments of the industry, reflecting a common concern for the health of those who cannot access medicines and health care.

HPIC'S PROJECTS

Emergency response operations show the strength of HPIC's partnerships and the compassion of its partners. However, there are other projects that run throughout the year to bring hope and healing all over the world.

Hundreds of Canadian healthcare workers and smaller NGOs travel to communities in the developing world every year to provide primary health care. HPIC equips each of these volunteers with a Physician Travel Pack — a mobile medical kit that has enough medicines and supplies to treat about 600 children and adults. HPIC also has a modified dental pack for dental missions.

The largest project that HPIC is managing at this time is our Capacity Building and Access to Medicines project in Afghanistan. Funded by the Canadian International Development Agency, the multi-year project's goal is to support Afghanistan's Ministry of Public Health to ensure greater and more equitable access to priority medicines and medical supplies. The needs of women and children in Afghanistan are a special focus of the project.

HPIC is committed to providing $25 million in medicines and hospital supplies to partner public hospitals in Kabul. We are working with the Pharmaceutical Donations Office in Kabul to help them improve the coordination of donations, improve the operational efficiency of the Central Medical Stores, improve the efficiency and efficacy of national drug quality control procedures and systems, and undertake an assessment study about the development of a pharmaceutical manufacturing industry in the country.

HPIC approaches donors of medicines and medical supplies on an annual basis to present the needs of various projects. These projects are possible in large part because of the commitment of HPIC's top donors from the pharmaceutical and healthcare industries: Abbott Laboratories Limited, AstraZeneca Canada Inc., Bayer Inc., GlaxoSmithKline Inc., Pharmascience Inc., Pfizer Canada Inc., Ranbaxy Pharmaceuticals Canada, Roche Canada, sanofi-aventis Group, and Teva Canada.

LOOKING AHEAD

HPIC has evolved over the decades it has been in operation to better respond to needs in the developing world and to adjust to changes in the environment of our partners. Our model of operation used to be exclusively based on gift-in-kind donations. Over the last decade, HPIC has made significant progress in adding development projects while continuing to distribute medicines in response to needs identified by partner organizations. One of the challenges that HPIC faces is that dealing with industry partners increasingly means developing relationships with global headquarters outside of Canada. Globalization has also led HPIC to build an alliance with similar organizations in other countries in order to tap into greater resources and together coordinate projects and respond jointly when emergencies strike.

In the spring of 2010, HPIC went through a reflection and discernment process called Appreciative Inquiry. One of the things that emerged from the process is the level of support and commitment of HPIC's partners. We intend to continue to deepen our relationships, seek the input of partners and involve them directly in our work. An example of this is PULSE, a Volunteer Partnership Program of GlaxoSmithKline. HPIC was loaned a GSK employee full-time for a six-month term to work on special assignments. We will be actively seeking more of these kinds of specialized volunteers and will not hesitate to ask for help and input from our partners.

In our third decade we are enthusiastic about the present as we look forward to what the future will bring.

More info: www.hpicanada.ca



GLEN SHEPHERD
President, Health Partners International of Canada

The Regulation of Global Trade in Pharmaceuticals

BY DUNNIELA KAUFMAN FRASER MILNER CASGRAIN LLP
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Pharmaceutical innovations are protected by patents granted under national laws. When pharmaceuticals are commercialized internationally, patent protection must be sought in each country of sale or intended destination. Historically, this legal framework led to inconsistent and unpredictable protection, which in turn created barriers to trade, given the differences in legal rules regarding what is patentable, how long patent protection would last and disparities in or lack of enforcement mechanisms.

Today, the intellectual property (IP) regimes of over 150 countries share a single, comprehensive treaty-based governing framework: the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS").[1] TRIPS entered into force on January 1, 1995 following unprecedented trade negotiations between 123 countries, who were the signatories to the General Agreement on Tariffs and Trade ("GATT")[2] at that time. TRIPS is the first multilateral agreement to establish common rights and obligations across the range of IP subject matter in a vast number of individual national IP regimes. While TRIPS does not fully harmonize laws with respect to the definition of what is patentable, it does establish that patent protection must last for a minimum of 20 years once granted and, in cases of non-compliance, allows signatory States to make use of the dispute resolution process of the World Trade Organization ("WTO"), which administers the agreement.

In this way, TRIPS is both unprecedented and cutting-edge: governments from around the world recognized that the protection of IP was as fundamental to the future prosperity of the global economy as was the continued push towards fuller and freer trade in goods and services.

BASIC LEGAL PROTECTIONS

As the first multilateral agreement to require minimum standards of IP protection through the implementation of a comprehensive domestic IP regime based on agreed principles, TRIPS establishes the framework for patent protection of and trade in pharmaceutical products. Article 7 of the Agreement recognizes that IP protection is a key element for further innovation by private interests that benefit the broader public, and recognizes that the broader public good must always be taken into account in balancing private interests. This is particularly true in the area of public health care and patent protection for innovative pharmaceutical products. Article 8 of the Agreement goes on to provide a statement of principle that confirms the legitimacy of pursuing all manner of public health-related policies within this balance.

Article 28 of TRIPS sets out the rights that all Member countries agree are to be conferred by a patent, which are to prevent third parties from making, using, offering for sale, selling, or importing a patented product, without the right holder's consent.

TRIPS AND PUBLIC HEALTH

Articles 30 and 31 of TRIPS provide for exceptions to these fundamental rights for certain limited public policy reasons. Article 31 in particular sets out the specific circumstances in which a patented product may be used without the authorization of the patent holder, commonly referred to as "compulsory licensing." The provision enumerates agreed conditions for compulsory licensing, including:

1. that the Member issuing the license must first attempt to obtain a voluntary license from the patent holder (paragraph (b)),
2. that the license must be primarily for domestic use (paragraph (f)), and
3. that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization (paragraph (h)).

Through inclusion of these exceptions, TRIPS sets out to achieve a balance in the area of public health and the promotion of new and innovative medicines. On one hand, its provisions reflect an agreement that innovators must be provided with the exclusivity needed to recover the significant research and development costs and investments involved with bringing new medicines to market (often in excess of USD 1 billion per medicine). On the other hand, its provisions also reflect agreement that Member countries must have flexibility to address domestic public health urgencies.

"IN THE YEARS FOLLOWING THE CREATION OF TRIPS, UNCERTAINTY WAS EXPRESSED WITHIN THE WTO MEMBERSHIP REGARDING THE FLEXIBILITY OF TRIPS TO ACCOMMODATE DOMESTIC HEALTH URGENCIES AND DOMESTIC MANUFACTURING LIMITATIONS IN PARTICULAR."

THE WTO'S RESPONSE TO PUBLIC HEALTH ISSUES

On November 14, 2001, the WTO Ministerial Conference issued the "Declaration on the TRIPS Agreement and Public Health" (the "Declaration"). The Declaration served to recognize the public health issues confronting many developing countries (e.g. HIV/AIDS, tuberculosis, and malaria) and to underscore that the TRIPS Agreement should be interpreted to form part of the solution to these circumstances.[3]

Most notably, the Declaration reiterated the right of every Member country to grant compulsory licenses and acknowledged the limitations of this right in circumstances where a country does not have the domestic manufacturing capability to produce generic versions of a patented medicine. Under paragraph (f) of Article 31, compulsory licenses are to be granted "primarily for domestic use." The Declaration therefore called upon the Council for TRIPS to find a solution to this problem.

In response, the TRIPS Council issued a Decision in 2003, which established a framework pursuant to which Member countries that do not have domestic production capability could import generic versions of patented medicines produced elsewhere (the "TRIPS Waiver").[4] The TRIPS Waiver did the following:

1. waived Members' obligations under paragraph (f) of Article 31 on exports of products;
2. clarified that adequate remuneration is to be paid by generic manufacturers in the exporting country alone; and
3. waived other exporting impediments for developing and least-developed countries operating within a regional trade agreement (e.g. the Mercosur countries of South America).

Further, specific conditions were agreed to, in order to prevent generic manufacturers from diverting shipments to richer markets where the public heath urgencies and domestic manufacturing challenges did not exist.

In 2005, the TRIPS Waiver was transformed into an amendment to the TRIPS Agreement, which is currently set for acceptance by the WTO Membership by December 31, 2011.[6] While debate may continue over the effectiveness of the TRIPS Waiver, the creation of the Waiver proves beyond debate that it is possible to reconcile meaningful and effective IP protection with difficult public health challenges that may arise.



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3 Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November, 2001.
4 Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, 1 September, 2003.
5 This was announced on December 6, 2005 http://www.wto.org/english/news_e/pres05_e/pr426_e.htm. Once the amendment is adopted, it will formally become part of the TRIPS agreement and negate the 2003 waiver.

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Robert Yalden, Osler, Hoskin & Harcourt LLP

STAFF

Hélène Yaremko-Jarvis, B.C.L., LL.B., Executive Director

Lois Marsh, Administration

CALENDAR OF EVENTS

BREAKFAST EVENTS

Tuesday, April 5
Chris MacDonald, Ph.D., Visiting Scholar, Clarkson Centre for Business Ethics & Board Effectiveness, Rotman School of Management
Conflict of Interest: What Is It and Why Does it Matter?

Wednesday, May 11
Todd Hall, Director - Sustainable Development, Ontario Power Generation Inc. and
Bob White, President, B.R.I. International Inc.,
Credibility in Social Responsibility and Sustainability Performance Reporting

LUNCHEON EVENTS

Thursday, April 28
Madame Louise Fréchette, Distinguished Fellow at the Centre for International Governance Innovation of Waterloo, Former Deputy Secretary-General of the UN
Responsibility to Protect - a Challenging Concept

Wednesday, October 12
Bruce March, Chairman, President & CEO, Imperial Oil

NEW ETHICSCENTRE MEMBERS

KINROSS

Kinross is a Canadian-based gold mining company with mines and projects in Canada, the United States, Brazil, Chile, Ecuador, Russia, Ghana and Mauritania, employing approximately 7,000 people worldwide. Kinross' core purpose – to lead the world in generating value through responsible mining – embodies a commitment to corporate responsibility in all our relationships with employees, partners, governments and the communities affected by our operations.

Guelph Hydro Electric Systems Inc.

Guelph Hydro Inc. provides electricity to 50,000 customers in Guelph through Guelph Hydro Electric Systems Inc. and alternative energy through Ecotricity Guelph. By promoting energy conservation and developing alternative energy projects, the company is moving Guelph towards a sustainable energy future and a cleaner environment. In 2011, Guelph Hydro will be one of Ontario's first utilities to publish a Sustainability Report measuring its performance against the Global Reporting Initiative (GRI).

MANAGEMENT ETHICS

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