7 October

First Session: Research Based Industry

Mr LePrince and Mr McCool made a presentation as follows:

http://www.who.int/intellectualproperty/events/en/R&D.pdf

They also submitted two additional documents on generic pricing in Canada:

www.who.int/intellectualproperty/events/en/R&Dpaper2.pdf

In the discussion the following points were made by RX&D:

- Private sector R&D in Canada is dominated by clinical trials rather than the discovery of new molecules. This is acknowledged. For a variety of reasons, including the patent and regulatory regime, the USA and Europe were more favoured for more fundamental research.
- India could be a strong competitor with Canada in the clinical trials market, in particular because of varied genetic populations and many people are not taking medicines already.
- Parallel trade was regarded as a threat to tiered pricing - Canada's internet pharmacies could be the tip of the iceberg.
- The internet pharmacy situation has raised a number of issues to do with health and safety and the security of the supply chain.
- Bill C-9 was OK but many uncertain legal issues and the provisions on diversion were considered rather weak.
- Regarding drug development, the "low hanging fruit had been plucked" - R&D on cancer, Alzheimers was more difficult. There was a need to identify failures earlier.
- There was a new paradigm for research developing with the biotech industry.
- It was considered that the generic industry was not very competitive, and prices were relatively high.
- There was scope for screening existing compounds for therapeutic effect in diseases affecting developing countries. The pool of knowledge could be made available to PPPs to work on.

Second Session: Biotech Canada

Janet Lambert made a presentation here:

• Patenting of research tools was not considered a big issue - could be overcome by collaboration
• The court decision on the Harvard Mouse sent the wrong message about IP protection in Canada
• Dr Bernstein of the Canadian Institutes of Health Research (CIHR) had set up a virtual organisation for stem cell research
• The issue of plant-made pharmaceuticals was raised (Pharmaplanta is an EU-funded project)
• Access to sources of funds was a big issue for biotech companies which are at an early stage of development in Canada

**Third Session: Canadian Generic Pharmaceutical Association**

Mr Keon made a presentation as follows:

http://www.who.int/intellectualproperty/events/en/CGPA.pdf

He also submitted an opinion piece on bill C-9:

www.who.int/intellectualproperty/events/en/CPGApaper.pdf

• The generic industry was not the proponent of bill C-9 - the NGOs were (similar to what happened internationally)
• They were not convinced they could make use of it
• It would take up to five years to get to marketing approval for a drug which was not currently produced
• There was a tension between the humanitarian purpose of the bill and the commercial objectives of companies
• The 25% rule on pricing was open to challenge by patent owners
• The system was too complex and litigation-prone
• Different markings, shapes etc added costs - normally the intention was to have similar formulation to originator drug to increase compliance
• How the list of products would be amended was unclear
• Most patents on ARVs expire in 2012-2015 - it was too early for generics to be considering development
• Given the length of the development period, a risk was that a current ARV would be therapeutically redundant by the time it got on the market
• A lot of litigation was now arising from trivial patents released at the end of the patent period

**Fourth Session: NGOs**

This session was attended by Richard Elliot (HIV/AIDS Legal Network), Rachel Kiddell-Monroe (MSF), Michelle Muno (CARE CANADA), Janet Hatcher Roberts (Canadian Society for International Health) and Michael O'Connor (International Coalition on AIDS and Development).

• It was confirmed that the generic companies did not seem interested in utilising C9 - MSF drew up a list of five drugs but evoked no response
• The withdrawal of WHO prequalification to ARVs produced by CIPLA and Ranbaxy had indicated how insecure the supply chain was for generic ARVs. More sources of supply and more competition would be desirable
• The C9 provisions for regulatory approval were similar to the FDA ones for potential PEPFAR products
• Could the WHO prequalification project play a role in providing differential risk/benefit assessments for developing countries
• It was noted that the problems of making bill C-9 operational may be as much the consequence of the nature of the WTO decision, as any specific deficiencies in the Canadian legislation

8 October

First Session: Eric Dagenais, Industry Canada

Eric Dagenais explained the process of implementing the WTO Decision in Canada. This involved consulting stakeholders and attempting to incorporate in national legislation both the letter and the spirit of the WTO decision. In doing so, various safeguards were introduced to satisfy the concerns of the different stakeholders. The initial list of eligible products consisted of all products on the WHO Essential Medicines List which were under patent in Canada. Others were listed during Committee hearings. All products need to be approved by Health Canada. Licences can be terminated if the licensee is demonstrated to have contributed to diversion of products. Compensation under the licence will be linked to the recipient country's Human Development Index ranking. Companies must participate in "good faith" and not for commercial purposes".

Draft Regulations have just been published and the law should come into force during 2005.

It was noted that negotiations on prices in Brazil and South Africa were said to have been assisted by the existence of the Canadian legislation.

Second Session: Doug Clark, Industry Canada

He explained that Canada's drug patent policy sought to achieve a balance between encouraging R&D while ensuring lower priced competitors can enter the market as soon as possible after patent expiry. Canada has increased its level of pharmaceutical protection in the last fifteen years, but not to the level of its main trading partners. Compulsory licences for import were introduced in 1969. In 1987, compulsory licensing was restricted, the patent term increased to 20 years from filing and the Patented Medicines Prices Review Board (PMPRB) was created. In 1993, compulsory licensing was eliminated, the PMPRB strengthened, early working and stockpiling exceptions introduced and Notice of Compliance (NOC) linkage regulations were introduced. Canada has no patent term restoration provisions as in many other countries, and stakeholders are of the view that Canada's data protection provisions are ineffective due to the manner in which generic medicines obtain regulatory approval in Canada.

The NOC regulations are inspired by Hatch-Waxman legislation in the USA, balancing patent enforcement with timely generic entry. A WTO case confirmed the TRIPS compliance of early working, but not of stockpiling (which was then repealed in national legislation). The regulations provide for patents on drugs to be added to a register at Health Canada (after checking). A generic producer of an equivalent must
either await patent expiry or challenge the patent. In the latter case, the brand-name producer may contest the challenge, which triggers a 24 month stay on patent expiry.

The generic industry complains that brands "are using Regulations to delay generic entry beyond basic patent expiry through the timed addition of irrelevant and insubstantial patents". The brands claim that the regulations are essential to prevent generic entry prior to patent expiry, and that subsequent patents are necessary to protect "incremental innovation" and are not a barrier to generic entry on the original drug.

As a part of the 1987 reform of patent law, the brand name companies made a public commitment to raise R&D expenditures as a proportion of sales from 5% to 10%. This was reached in 1996, but is now declining as sales growth outstrips R&D growth. Prior to the inception of the PMPRB, Canadian brand name prices were 23% higher than the international median (2nd only to the US): now prices are 5-12% below median, and 40% below the US. Nevertheless, drug costs are the fastest rising component of health care costs (9.5% of total in 1985, now 16%). Total sales of patented drugs are increasing by 14.5% annually.

Currently, brand name producers advocate patent term restoration as in the US or Europe, enhanced data protection, stronger NOC linkage regulations, less stringent application of PMPRB guidelines and faster drug approval times. The generics want the repeal of NOC regulations, introduction of an export exception and a 180-day initial exclusivity (as in Hatch-Waxman).

Reference was also made to the annual report of the PMPRB (http://www.pmprb-cepmb.gc.ca/). This report provides more detailed information on sales, compliance with the regulations, prices and R&D expenditures.

Other issues noted were the debate on patenting life forms and genes. A report on gene patenting by the Biotechnology Advisory Committee (http://cbac-ccc.ca/epic/internet/incbac-ccc.ca.nsf/en/Home) is due in April next year. The rejection of the Harvard Mouse patent by the Supreme Court was indicative of the concerns felt in Canada in this area. On data protection, US companies were pressuring the US government to challenge Canadian data protection provisions in the WTO, and Canada is also listed on the US Special 301 watch list for this reason.

**Third Session: David Lee, Health Canada**


This report provides a wealth of information on the workings of the NOC regulations. It examines the numbers of patents accepted for the Register, and those rejected with reasons. It lists court cases concerning patent eligibility for the Register. A table shows the number of patents per medicine. As of 23 March 2004, 94% had four patents or less, but the remainder had between 5 and 13 patents each. Those in the latter category tended to be "blockbusters". There are also details of the number of court cases related to the NOC regulations, and of the time taken to resolve them.
Fourth Session: Dr John Frank, Institute of Population and Public Health

Dr Frank gave a presentation as follows:

www.who.int/intellectualproperty/events/en/GHRI.pdf

He outlined the working of the Global Health Research Initiative set up in 2001 to bring more coherence to the work of different agencies in this field (IDRC, CIDA, Health Canada and the Canadian Institutes of Health Research). It has committed nearly $8 million to different projects in the last two years. More information is at:

http://www.cihr-irsc.gc.ca/e/13249.html

Fifth Session: Dr James Orbinski, University of Toronto

Dr Orbinski reviewed the issues that confronted the Commission - in particular the lack of R&D for neglected diseases, not R&D overall. TRIPS and the regulatory framework tended to focus R&D on non-priority health needs. The problem needed to be viewed in a human rights perspective. An alternative framework for health R&D was required which reflected global health priorities and the human right to have access to appropriate health care. WHO should play a much more active role in bringing this about. There were several precedents (e.g. the landmines treaty and the tobacco control convention), which could form the basis for an international agreement on health R&D. There were many technical and political challenges in pursuing this agenda but there were some hopeful signs in the change in the terms of the debate in the last five years. Most recently the adoption by WIPO of a resolution supporting a development agenda was indicative of a change in thinking. Again, WHO should take the lead in the political debate on health care technologies.

In discussion the following points were noted:

- the problem of paediatric medicines, in particular ARVs
- a difficult problem because of the six juvenile categories
- in that context the issue of the age distribution of the disease burden was important - the young, the old and women were often neglected
- the issue of regulation and varying risk/benefit but need not to "weaken" regulation at the same time
- IP could be an obstacle to the scientific enterprise or be misused for revenue generation not innovation
- Me-too drugs - no one denies that 20 ARVs are a good thing but there are issues about minor variations on the same drug in terms of patenting, reimbursement or regulatory policy

Sixth Session: Nancy Connor, CIDA and Christopher Armstrong, Foreign Affairs

Nancy Connor noted Canada's $100 million donation to WHO for the 3 by 5 initiative, a contribution to the World Bank Institute for training of government officials involved in the procurement and distribution of ARVs, and its $30 million contribution to the Global Fund.
Points made included:

- The trend in patenting minor variations of old medicines needed examination
- The medicines list in bill C-9 needs expansion
- Ideas about extending patent terms for drugs for neglected diseases
- Or relaxing advertising restrictions
- The IP system might not stimulate breakthrough medicines - a reward mechanism might be considered as a supplement.

In conclusion Madame Dreifuss thanked Ian Shugart, ADM, Health Canada, for the very excellent sessions organised by Health Canada and said the visit had been very successful.