**MINISTRY OF HEALTH**
**INFORMATION BRIEFING NOTE**

**Cliff #**933448

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister-**FOR INFORMATION**

**TITLE:** BIO Conference with Pharmaceutical Companies in Boston - June 18-20, 2012.

**PURPOSE:** Additional background information to be included as part of the Minister's Briefing binder prepared by the Ministry of Jobs, Tourism, and Innovation.

**BACKGROUND:**
The Ministry of Jobs, Tourism, and Innovation (JTI) has prepared an Information Briefing Note for the Minister of Health (Appendix 1). Details on the health and life sciences sector, including investments in BC, are covered as well as additional information for each pharmaceutical company (Appendices 2-10). CETA/IP is covered in Appendix 11 and Drug Shortages is Appendix 12.

The following provides additional information of issues facing large pharmaceutical companies identified by the Pharmaceutical Services Division, Ministry of Health.

**DISCUSSION:**
**Threat of Generics** - Large pharmaceutical companies are facing a reduced business climate brought on by the loss of patent exclusivity to their "blockbuster" drugs, and the resulting generic competition, on widely prescribed, high sales volume drugs. Examples include atorvastatin in 2011 (Lipitor® from Pfizer) and rosuvastatin (Crestor® from AstraZeneca), both cholesterol lowering agents, and most recently antiplatelet agent clopidogrel (Plavix®from Bristol-Myers Squibb and Sanofi).

In response to the loss of business due to generic competition, brand name pharmaceutical companies have shifted focus to new therapeutic areas and more specialized medicine in which fewer patients may benefit from treatment, but the price and resulting sales margin is much higher than traditional prescription drugs. Some of these products are acquired through licensing or acquisition of biotech companies.

**Biologics and Increasing Product Prices** - Newer, more complex agents made from biological processes ("biologics") have replaced traditional small molecule drugs. Infliximab (Remicade® from Janssen), a biologic that treats rheumatoid arthritis and Crohn's disease has replaced atorvastatin as PharmaCare's highest expenditure drug, with 2011/12 expenditures of approximately $43 million.[1]

The availability of these new classes of expensive pharmaceuticals presents a challenge to public and private drug plans which must balance limited budgets and the need to maintain access and equity for all plan members. For comparison, some drugs considered Expensive Drug for Rare Diseases (EDRD) may cost $200,000 to more than $500,000 per patient per year, as compared to typical biologic products (which may cost $15,000 to $25,000 per patient per year) or other typical drugs which costs BC PharmaCare $1,000 per patient per year.

[1] Policy, Outcomes Evaluation and Research Branch, PSD June 12, 2012.

Another challenge for drug plan payers with biologic drugs is they are not easily replicated by competing manufacturers. For these products, called biosimilars or Subsequent Entry Biologics, payers cannot expect to see the same reduction in expenditures that occur when traditional prescription drugs lose patent protection and multiple manufacturers are able to sell identical product at lower prices.

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**BC Biotech Industry** - Business activity in the BC biotech sector in the late 1990's and early 2000's were funded initially through private venture capital and many maturing to public markets. However, since then, while there have been a few success stories (e.g. ID Biomedical, Inex Pharmaceuticals), many have underperformed (eg. QLT, Angiotech,and Cardiome), due to market competition, product development setbacks, and/or inability to attract funding.

**Investments in BC by Pharma** - The total public and private drug sales in BC in FY 11/12 was about $2.5 billion. Of this amount, sales from brand name companies was about 65 percent or $1.6 billion. JTI has reported some examples of how much investment from Pharma occurs in BC, however, care should be taken to differentiate how such “investments” actually benefit BC versus benefiting corporate executives and investors.

Unlike eastern Canada, very few profitable pharmaceutical or biotech companies have decided to establish research or manufacturing facilities in BC. Amgen is one of the few examples. Instead, “investments” may include business deals with local private and publicly traded biotech companies in the form of upfront payments or milestone payments for exclusive sales and marketing rights of biotech products in development.

**Research Spending in Canada** - With the adoption of the 1987 amendments to the Patent Act, Rx&D made a public commitment to increase their annual R&D expenditures to 10 percent of sales revenues by 1996. According to the 2010 Annual Report of the Patented Medicines Prices Review Board (PMPRB), the Rx&D ratio has been less than 10 percent for previous eight consecutive years. In 2010, the R&D-to-sales ratio for patentees was 6.9 percent of the total $17 billion sales in Canada. The proportion of R&D spending in Western provinces was 12.6 percent, versus 41 in Ontario and 45 percent in Quebec.

**ADVICE:**
These meetings will provide an opportunity for industry to showcase new and innovative drugs in the product pipeline, as well as investment opportunities in BC. If the Minister is requested to comment on specific drugs that Health Canada has approved, kindly direct company representatives to contact PSD staff directly.

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Appendix 1

MINISTRY OF JOBS, TOURISM AND INNOVATION

**INFORMATION NOTE**

Cliff #: 67994

Date: June 13, 2012

**PREPARED FOR:** Honourable Michael de Jong, Minister of Health

**ISSUE:** B.C.'s Pharmaceutical Industry and Investments

**BACKGROUND:**

The health and life sciences sector includes medical devices, biopharmaceuticals, bio-products and process innovations. B.C. has the highest concentration of biotechnology companies in Canada, a strong industry association in LifeSciences BC, well-respected research and commercialization organizations, globally linked academic and research programs, and a supportive tax and regulatory environment.

Specific to the pharmaceutical industry, B.C.'s biopharmaceutical cluster is the seventh largest in North America, with more than 90 biopharmaceutical companies providing 2,200 jobs. Its commercial success has been impressive, with the highest growth in number of companies in Canada and revenue in the range of $800 million annually.

B.C.'s delegation to 2012 BIO International Convention in Boston will have the opportunity to meet with representatives of Canada's leading pharmaceutical companies. Meetings with Rx&D's Board of Directors and individual pharmaceutical companies, as well as networking events will all provide the opportunity to raise the profile of B.C.'s life sciences and pharmaceutical industries, and encourage investment and new partnerships with our research organizations and B.C. companies.

**DISCUSSION:**

The B.C. government has made significant investments in the life sciences sector, helping to create an attractive environment for private investment. Examples include:

- **Michael Smith Foundation for Health Research** – this world-class health research institution was established by the provincial government in 2001. Since then over $322 million has been invested to build research capacity and excellence, mobilizing the health research community to identify critically needed evidence and fast-track the development of solutions.
- **Centre for Drug Research and Development (CDRD)** – $33 million in provincial investment has leveraged a further $14.95 million from the federal government to create this national not-for-profit drug development and commercialization centre. CDRD provides expertise and infrastructure that allows global industry and research partners to "de risk" and advance promising early stage drug candidates and accelerate their commercialization. To date, CDRD has undertaken work on 80 novel health technologies (over 100 research projects), with 40 of those being successfully advanced toward commercialization.

- **Genome BC** – Genome BC is one of five Genome Centres established by Genome Canada, the primary federal funding and information agency for genomics and proteomics in Canada. The B.C. government has provided $177.5 million since 2001 to Genome BC, leveraging three times that amount in external funding and securing over 25 percent of Genome Canada's total funding. This non-profit research organization invests in and manages large-scale genomics and proteomics research projects and enabling technologies in areas of strategic importance such as human health, forestry, fisheries, bioenergy, mining, agriculture and the environment. Its research projects have attracted over 100 major international co-funders and partner organizations, including many multinational corporations, pharmaceutical and biotechnology companies, worldwide charitable foundations and top-tier research institutions. Genome BC research projects are carried out in partnership with key health provincial organizations including the BC Cancer Agency and Centre for Molecular Medicine and Therapeutics. Genome BC's objectives include developing a strategy for a strong genomics cluster in B.C. and helping to commercialize intellectual property from the projects and platforms they manage.
- **Wavefront** – an initial provincial investment of $5 million in 2007 launched this National Centre of Excellence dedicated to accelerating the growth and success of wireless companies. Wavefront is headquartered in BC and has a mandate to accelerate the commercialization of new technology in all sectors including health, mining, transportation, forestry, new media and clean technology. Wavefront is unique in North America as it provides physical testing environments for networked devices in global markets through its infrastructure partnerships. Wavefront also has relationships with the world's largest telecommunications companies. Wavefront is currently building its focus on machine to machine opportunities for wireless applications and is seeking new partnerships from medical device, pharmaceutical and natural resource industries to do so.

Notable investments by Rx&D member companies for pharmaceutical research in B.C. since January 2011 include:

- Lundbeck made a donation of $2.7 million to fund the establishment of the Canadian Depression Biomarker Network, a Canada-wide research study into the biomarkers of depression that will involve six academic centres across Canada, including the University of British Columbia.
- Merck provided a $1.4 million donation to Simon Fraser University, including equipment, to support research in a number of areas affecting human health.
- Merck is collaborating with Zymeworks, a privately held Vancouver biotechnology company, to develop potentially novel antibodies.
- Janssen provided $1 million in support for the *Treat to Prevent* initiative being spearheaded by Dr. Julio Montaner from the BC Centre for Excellence for HIV/AIDS. This initiative was recognized in the Globe and Mail as one of the top innovations in Canada in 2012 and is focused on an approach to HIV/AIDS treatment aimed at eradicating the illness.
- Johnson & Johnson provided $1.3 million to establish a business partnership with the provinces of Alberta and B.C. on early stage compounds in R&D.

- GlaxoSmithKline (GSK) is collaborating with CDRD and CDRD Ventures Inc. to advance the development and commercialization of Canadian health research.
- Pfizer Canada has provided several million to CDRD to establish a fund designed to accelerate the commercialization of some of Canada's most promising academic research projects into high-value medicines.
- The Western Canada Innovation Fund is a partnership with Johnson & Johnson (COSAT) which also includes investments from BC/CDRD and Alberta. The Western Canada Innovation Fund is co-managed by a joint steering committee that oversees a seed fund to enable early-stage innovative discoveries within the health sciences to advance toward commercialization.

**CONCLUSION:**

Bilateral meetings with representatives of leading pharmaceutical companies at BIO 2012 present an opportunity to encourage additional health research and commercialization investments in British Columbia and explain B.C.'s value proposition for future pharmaceutical investments.

Attachments 1 - 9 follow.

**ATTACHMENTS:**

Attachment 1 – Pharmaceutical Services Division (PSD) Information Briefing Note
Attachment 2 – Novartis Corporate Summary
Attachment 3 – Merck Corporate Summary
Attachment 4 – GlaxoSmithKline Corporate Summary
Attachment 5 – Pfizer Corporate Summary
Attachment 6 – Janssen Corporate Summary
Attachment 7 – Sanofi Corporate Summary
Attachment 8 – Versant Corporate Summary
Attachment 9 – Lumira Corporate Summary

Prepared by: Tim Ewanchuk, Director, Knowledge Transfer and Commercialization
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| Reviewed by: | | | | |
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| Dir: | ED: | ADM: | DM: | MIN: |

## Appendix 2 - Novartis Pharmaceuticals Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** Tuesday, June 19, 2012 (Time TBD)

**ATTENDEES:** Dr. Riad Sherif B., President, Novartis Pharmaceuticals Canada Inc.

**BACKGROUND:**

- Novartis is a multinational pharmaceutical company based in Basel, Switzerland; it ranked number two in sales ($46.806 billion US) among the global pharaceutical industry in 2010.
- Novartis develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, central nervous system, cancer, ophthalmics, organ transplantation and respiratory areas.

**CANADA PRESENCE:**

- Novartis Pharmaceuticals Canada is headquartered in Dorval, Quebec; it employs 550 people and invested almost $100 million in R&D in Canada in 2011.
- Novartis Pharmaceuticals Canada conducts clinical trials at hundreds of sites across the country, involving thousands of patients, researchers, and investigators.
- Notable among these studies include: cardiovascular and metabolic diseases; respiratory diseases; Multiple Sclerosis; organ transplantation; bone and arthritic diseases; glaucoma and retinal disease; different types of cancer; and Alzheimer's Disease.
- The Novartis Group of companies in Canada consists of Novartis Pharmaceuticals Canada Inc., Novartis Animal Health Canada Inc., Novartis Consumer Health Canada Inc., Alcon Canada Inc. and Sandoz Canada Inc; together, they employ approximately 2,300 employees.
- Similar to other members of Canada's Research-Based Pharmaceutical Companies (Rx&D), Novartis Pharmaceuticals Canada Inc. has greatly increased its R&D activities in Canada following the modernization of the nation's pharmaceutical patent laws in 1987 and 1993.
- A major international study of 11,000 elderly persons with high blood pressure (hypertension) will be led and managed by the Population Health Research Institute (PHRI) of Hamilton Health Sciences and McMaster University, thanks to a $40-million investment in Ontario by Novartis.

**BC PRESENCE:**

- Novartis Ophthalmics partnered with Vancouver based QLT Inc. to develop Visudyne therapy, for the treatment of wet age-related macular degeneration (AMD), to treat approximately 150,000 patients worldwide. The use of Visudyne has now largely been replaced by more effective intravitreal treatments of bevacizumab (Avastin) and ranibizumab (Lucentis).

**ISSUES IN BC:**

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- Lucentis has a new approved use in diabetic macular edema, which is currently under review by the Ministry. Like AMD, Novartis will strongly discourage the off-label use of Avastin for this indication.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Clozapine (Clozaril): $4.8 million
- Deferasirox (Exjade): $2.7 million
- Rivastigmine (Exelon): $1.6 million

Current Submissions with the Pharmaceutical Services Division under review for inclusion as a benefit under the PharmaCare program:

- Zoledronic acid (Aclasta) for osteoporosis, Ranibizumab (Lucentis) for diabetic macular edema, Fingolimod (Gilenya) for multiple sclerosis, Zoledronic acid (Zometa) for cancer-related bone pain.

Reviews Pending:

- Indacaterol (Onbrez) for chronic obstructive pulmonary disease, Ranibizumab (Lucentis) for retinal vein occlusion.

## Appendix 3 - Merck Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** TBD

**ATTENDEES:** Cyril Schiever, President and CEO, Merck Canada Inc.

**BACKGROUND:**

- Merck is a leading global pharmaceutical and chemical company with a diversified portfolio of prescription medicines, vaccines, consumer and animal health products; it currently markets over 530 pharmaceutical products in areas such as cardiology, immunology, infectious diseases, respiratory, and women's health.
- Merck had total global revenues of €10.3 billion in 2011; it employs more than 40,000 people in 67 countries.
- The Merck family holds an approximately 70% interest in the company, and public shareholders own the remaining 30%.

**CANADA PRESENCE:**

- Based in Montreal, Quebec, Merck employs over 1,600 people across Canada; it is one of the top 25 R&D investors in Canada, investing $95.4 million in 2009.
- Merck has a large manufacturing facility in Quebec dedicated to the annual production of some 35 million units including the Claritin® and Aerius® brands; it is committed to maintaining a strong presence in the life sciences and innovation sector in Québec and Canada, and continues to invest in academic, biotechnology and clinical R&D collaborations to advance its internal research programs globally.
- Merck announced that, starting in 2010 and continuing over the next five years, it would invest an additional $100 million in biopharmaceutical R&D collaborations with Québec-based companies and academic institutions.

**BC PRESENCE:**

- In February 2010, Merck entered into a $1.5 million funding commitment and partnership over three years with the BC Centre for Excellence in HIV/AIDS in support of its research program entitled "Seek and Treat for Optimal Prevention of HIV/AIDS", focusing on HIV treatment and care for hard-to-reach residents in Prince George and Vancouver's Downtown Eastside.
- Merck recently provided a $1.4 million donation to Simon Fraser University, including equipment, to support research and teaching in a number of areas affecting human health.
- Merck is collaborating with Zymeworks, a privately held Vancouver biotechnology company, to develop potentially novel antibodies.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Carbidopa/levodopa (Sinemet): $4.7 million
- Losartan (Cozaar): $3.6 million
- Nitroglycerin (Nitro-Dur): $2.6 million

Current Submissions with the Pharmaceutical Services Division for under review for inclusion in the PharmaCare formulary:

- Mometasone furoate (Asmanex) for asthma, mometasone-formoterol for asthma (Zenhale CR).

In March 2012, BC PharmaCare added coverage of boceprevir (Victrelis) for chronic hepatitis C. Expanding coverage to include boceprevir represents an investment of up to $50 million over the next three years.

## Appendix 4 – GlaxoSmithKline Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** TBD

**ATTENDEES:** Peter Simpson, Senior Manager

**BACKGROUND:**

- Headquartered in the UK, GSK is a global organisation which employs over 97,000 people in over 100 countries, with approximately 12,500 people working in research teams in the UK, USA, Spain, Belgium and China.
- GSK invested nearly £600 million in vaccines R&D in 2011 and have more than 1,600 scientists working on the development of new vaccines. GSK is researching both medicines and vaccines for the World Health Organization's three priority diseases – HIV/AIDS, tuberculosis and malaria. They produce medicines that treat major disease areas such as asthma, anti-virals, infections, mental health, diabetes, cardiovascular and digestive conditions, as well as consumer products.
- Overall the company grew about 2% in 2011; sales to China were up 27% to £163 million.

**CANADA PRESENCE:**

GSK has made substantial investments in research and infrastructure in the Province of Quebec. Other Recent Canadian investments include:

- In 2005, GSK acquired BC-based ID Biomedical for $1.7 billion. ID Biomedical was a biotechnology company dedicated to the manufacturing and development of innovative vaccine products, including influenza vaccines.
- Launch of the new $50 Million GSK Canada Life Sciences Innovation Fund.
- $300,000 for collaboration with AngioChem in Montreal to discover, develop, and commercialize treatments for lysosomal storage diseases.
- $12 million in Canada for Influenza Research. Funding ensures key infrastructure will continue as surveillance research will be conducted in 40 hospitals across Canada
- $1.8 million Rotavirus surveillance investment in Quebec to enable implementation and sustainability of a "gold standard" in surveillance, demonstrated value of rotavirus vaccination, and apply learnings towards future disease targets.
- $300,000 Investment in the Quebec Consortium for Drug Discovery (CQDM) to strengthen innovative research in Quebec
- $750,000 to create the GSK-MaRS Innovation Fund that will support and fast-track the commercialization of some of the country's most promising translational research coming from 16 leading academic health sciences centres, hospitals and universities.

- GSK's Pathfinders Fund is providing $1.5 million toward the establishment of Manitoba's first-ever research chair in the immunobiology of infectious disease at the University of Manitoba.

**BC PRESENCE:**

- The GlaxoSmithKline Foundation, in partnership with ViiV, provided the Vancouver Native Health Society with $13,000 for the Dude's Club pilot project. The Society's mandate is to improve and promote the physical, mental, emotional and spiritual health of individuals, focusing on the Aboriginal community residing in Greater Vancouver. (2010).
- Each year, GlaxoSmithKline donates $100,000 to the HIV/AIDS Community Innovation Program that promotes innovative projects that use multi-dimensional approaches to optimize the health and well-being of people living long-term with HIV/AIDS and antiretroviral therapy. Recipients in 2009 included AIDS Vancouver.
- GlaxoSmithKline is collaborating with the Centre for Drug Research and Development (CDRD) and CDRD Ventures Inc. to help advance the development and commercialization of health research.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Fluticasone/salmeterol (Advair): $14.2 million
- Fluticasone (Flovent): $6.6 million
- Salbutamol (Ventolin): $1.7 million

Current Submissions with the Pharmaceutical Services Division for under review for inclusion in the PharmaCare formulary:

- Belimumab (Benlysta) for the treatment of lupus.

## Appendix 5 - Pfizer Canada Inc. Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** Wednesday June 20, 2012, morning [time TBD]

**ATTENDEES:** Bob Dawson, Director, Pfizer Canada Inc.
John Helou, President, Pfizer Canada Inc.
Dr. Bernard Prigent,Vice-President, Pfizer Canada Inc.

**BACKGROUND:**

- Pfizer Canada Inc. is the Canadian operation of New York-based Pfizer Inc. The company has a diversified health care portfolio that includes biologic and small molecule medicines, vaccines for humans and animals, and consumer products. Pfizer invests in a range of therapeutic areas including arthritis, cardiovascular disease, endocrinology, infectious disease, neurological disease, oncology and ophthalmology and smoking cessation.

**CANADIAN PRESENCE:**

- Pfizer Canada Inc. employs close to 3,000 people.
- The Canadian headquarters of Pfizer Bio-Pharmaceuticals and Animal Health are in Kirkland, Quebec; the Consumer Healthcare business is based in Mississauga, Ontario; and the Vaccines Research Unit is located in Ottawa, Ontario.
- Pfizer operates distribution facilities in Ontario and Alberta, Global Supply and Distribution Centres in Quebec and Manitoba, and an Animal Health Vaccines Research Unit in Victoria, British Columbia.
- Pfizer Canada has invested an average of $150 million per year in Canadian health care research and development activities, contributions and partnerships; the company has invested more than $1 billion in R&D since 2000.
- Recent investments by Pfizer Canada in pharmaceutical research in Canada include:
    - $5 million for the Pfizer-FRSQ-MSSS Chronic Disease Fund: this FRSQ-coordinated research grant program is aimed at evaluating chronic disease prevention and management initiatives.
    - $130,000 for the Nova Scotia Chronic Pain Collaborative Care Network (NSCPCCN).
    - $500,000 to the Alberta Pfizer Collaboration Fund, now a $2.5 million initiative, to identify and support promising health care innovations with market potential.

**BC PRESENCE:**

- Pfizer Canada has an Animal Health Vaccines Research Unit in Victoria, British Columbia.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Donepezil (Aricept): $5.4 million
- Dalteparin (Fragmin): $3.3 million
- Quinapril (Accupril): $3.2 million

Current Submissions with the Pharmaceutical Services Division for under review for inclusion in the PharmaCare formulary:

- Celecoxib (Celebrex) for pain control

Submission expected later in 2012, in partnership with Bristol-Myers Squibb:

- Apixaban (Eliquis) for prevention of clots after hip or knee surgery

## Appendix 6 - Janssen Inc. Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** [time TBD]

**ATTENDEES:** Chris Halyk, President, Janssen Inc.

**BACKGROUND:**

- As a member of the Johnson & Johnson Companies, Janssen Inc. is a Toronto based pharmaceutical company that develops treatmenst for pain management, psychiatry, oncology, psoriasis, virology, anemia, attention deficit hyperactivity disorder, dementia, gastroenterology and women's health.

**CANADIAN PRESENCE:**

- Janssen recently invested $200,000 in COSAT – MaRS Co-Managed Fund. This partnership between the Corporate Office of Science and Technology of Johnson & Johnson and the MaRS Discovery District in Toronto establishes a working agreement to support the development of early stage medical innovations.
- Janssen Inc. employs approximately 700 across Canada.

**BC PRESENCE:**

- In November 2010, the Centre for Drug Research and Development (CDRD), based at UBC, announced the "Western Canada Innovation Agreement" (WCIA), which brings together CDRD, the Province of British Columbia, the Province of Alberta, and Johnson &Johnson Corporate Office of Science and Technology (COSAT) to jointly develop and manage a fund to support innovative health research programs in the life sciences sector.
- WCIA provides for a joint steering committee that will oversee a co-managed seed fund to enable early-stage, smart discoveries within the health sciences so that they may advance along a pathway to commercialization. Representatives from Alberta, British Columbia/CDRD and COSAT will jointly assess opportunities for the collaboration, funding, management, and commercialization of innovative health research projects.
- Janssen Inc. provided $1 million to the “Treat to Prevent” initiative at the BC Centre for Excellence for HIV/AIS. The initiative pioneers HIV/AIDS treatments aimed at eradicating the illness.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Infliximab (Remicade): $43.0 million
- Risperidone microspheres (Risperdal Consta): $8.7 million
- Codeine/Acetaminophen/Caffeine(Tylenol with Codeine): $4.4 million

## Appendix 7 - Sanofi Canada Inc. Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** June 19, 2012 [time TBD]

**ATTENDEES:** Jon Fairest, CEO, Sanofi Canada

**BACKGROUND:**

- Sanofi Canada is a subsidiary of Paris based Sanofi, one of the world's largest health-care providers. Sanofi Canada is based in Laval, Quebec.
- Sanofi Canada specializes in developing treatments in several therapeutic areas, mainly diabetes, oncology and cardiovascular disease.
- Sister companies in Canada include, Sanofi Pasteur, based in Toronto, one of the world's largest vaccine producers; Sanofi Consumer Health (health and beauty products); Genzyme (treatments for rare diseases); and Meriel (animal health).
- Together, the Sanofi group of companies in Canada employ approximately 1,800, mainly in the greater Montreal and Toronto areas.
- In 2011, Sanofi companies invested $152 million in R&D in Canada.

**CANADIAN PRESENCE:**

- Opened a new $101 million vaccine research and development facility at Sanofi's Connaught Campus in North Toronto. Ontario contributed $13.9 million to the project through the Biopharmaceutical Investment Program.

**BC PRESENCE:**

- In April 2011, Sanofi Canada's funding for BC's Genetic Pathology Evaluation Centre (GPEC) surpassed $2 million.
- Sanofi Canada has a 10 year research collaboration agreement with GPEC, which was formed in 2001, as a collaborative research venture of the Pathology Department at Vancouver General Hospital, Vancouver Prostate Centre, and the BC Cancer Agency. GPEC research has developed protocols for cancer diagnosis and treatment.

**PHARMACARE EXPENDITURES:**

Top PharmaCare Expenditure Drugs in 2011/12, Chemical Name (Brand Name):

- Clopidogrel (Plavix): $13.8 million
- Insulin glargine (Lantus): $7.5 million
- Felodipine (Renedil): $0.5 million

In the Spring of 2012, generic competition was launched for Sanofi's clopidogrel

## Attachment 8 - Versant Ventures Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** [time TBD]

**ATTENDEES:** Bradley Bolzon, Managing Director, Versant Ventures
Jerel Davis, Investment Professional, Versant Ventures

**BACKGROUND:**

- Versant Ventures was founded in 1999, and is a San Francisco based leading venture capital firm that specializes in investments in medical devices, biopharmaceuticals and other life science opportunities.
- One of its founders, Brad Bolzon, is Canadian and studied at the University of Toronto.
- Versant has $1.6 billion USD under management. They are currently investing their latest $500 million fund, raised in July 2008.
- Versant is composed of 13 Managing Directors and three Investment Professionals.
- Versant has over 75 companies in its portfolio.
- Initial Versant investments have been as small as $250,000, and as large as $30 million.
- Versant primarily invests in the United States; however, they hold investments in Australia, and in several European countries, including Finland, Italy and Switzerland.

**BC PRESENCE:**

- Versant Ventures currently has no investments in B.C.

**OPPORTUNITIES FOR BC**

- Versant backs a top-tier drug discovery team in San Diego known as Inception Technologies, headed by a Canadian from Montreal. Inception specializes in neurology and oncology research.
- This 12 person team has been responsible for licensing $37 billion worth of pharmaceutical platforms in the past 5 years. Their partners in this group include Merck Laboratories and GSK Pharmaceuticals. Both partners have now ceased funding the group and Versant is intending to relocate the team to Vancouver.
- Versant's rationale for relocating to Vancouver is that B.C. has significant research talent and institutions in neurology and oncology, as well as research entrepreneurs. JTI is helping Versant to find 12,000 square feet of lab space.
- Versant is also looking for the BC Renaissance Capital Fund to be part of its next Life Sciences Fund.
  Versant's interest in B.C. has been referred to PriceWaterhouseCoopers, which is investigating how Inception can attain tax efficiencies using federal SR&ED program tax incentives.

## Attachment 9 - Lumira Capital Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** [time TBD]

**ATTENDEES:** Peter van der Velden, President and CEO, Lumira Capital Corporation
Daniel Hetu, Managing Director, Lumira Capital Corporation

**BACKGROUND:**

- Lumira Capital Corp. is a venture capital firm specializing in investments in emerging, mid and late stage companies. Lumira's investment focus is in life sciences, particularly pharmaceuticals, biotechnology, medical services, health information technology and health care products.
- Lumira Capital was founded in 1988 and is based in Toronto, with additional offices in Montreal, Quebec, Cambridge, Massachusetts, and Palo Alto, California. It has approximately 15 staff among the offices.
- Lumira Capital manages a number of funds, including Lumira Capital II, Lumira Life Sciences Capital Fund II, and in March 2012, Merck and Lumira jointly announced the creation of the Merck Lumira Biosciences Fund, a $50-million capital pool, that will invest primarily in Quebec companies.

**BC PRESENCE:**

Lumira Capital's investments in B.C. companies have included:

- In 2002 and 2003, $8.7 million and $32 million investments, respectively, in Neuromed Pharmaceuticals, developers of a next generation of chronic pain drugs.
- In 2001, a $14.5 million investment in Protiva Biotherapeutics Inc., a nucleic acid based pharmaceutical company developing products to treat human diseases such as cancer, influenza, Ebola, inflammatory diseases and chronic viral infections.
- In 2001, a $750,000 investment in Synapse Technologies Inc., a company developing techniques to deliver therapeutic drugs across the blood/brain barrier and new drugs targeting neurodegenerative disease.

**OPPORTUNITIES FOR BC**

- Lumira Capital is in the process of closing a $125 million fund in the next six months and is interested in the BC Renaissance Capital Fund's participation in this new fund. Given Lumira's previous presence in B.C. and the contribution B.C.'s key research centres have made to their portfolio companies, Lumira has indicated a renewed interest in B.C.'s life sciences centres and pipeline.

## Attachment 10 - AstraZeneca Corporate Summary

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** June 18, 2012, 1:45 – 2:15 p.m.

**ATTENDEES:** TBD

**BACKGROUND:**

- AstraZeneca is one of the world's largest pharmaceutical companies, employing more than 66,000 people in over 100 countries and spending approximately US$3.5 billion annually. Some 13,000 R&D personnel are employed at research centres located in Canada, the United States, the United Kingdom, Sweden, France, India and Japan.
- AstraZeneca's extensive product portfolio spans six main therapeutic areas: cardiovascular, gastrointestinal, oncology, respiratory, neuroscience and infection.

**CANADIAN PRESENCE:**

- Most of AstraZeneca's 1,050 Canadian employees work at its high-tech facility in Mississauga, Ontario, headquarters for clinical research, corporate affairs, sales and marketing, while over 120 scientists work at a pain research centre in Montreal, Quebec.
- The AstraZeneca Research Award program funds basic research by up-and-coming scientists at universities and medical institutions across Canada. The company also sponsors Chairs in organic synthesis, asthma, biotechnology, respirology, cardiovascular research and respiratory disease management at universities across Canada.
- AstraZeneca funds a disease management program in mental health called Prends Soin de Toi. In 2011 and 2012, the company invested $5.7 million in the program, which is aimed at funding locally initiated projects with the goal to improve knowledge, health care delivery, disease prevention and patient treatment in mental health.

**BC PRESENCE:**

- AstraZeneca has no significant corporate presence in BC.

**PHARMACARE EXPENDITURES:**

Top PharmaCare expenditure AstraZeneca drugs in 2011/12, chemical name (brand name):

- Rosuvastatin Calcium (Crestor): $24.1 million
- Esomeprazole Magnesium (Nexium): $8.0 million
- Quetiapine Fumarate (Seroquel): $6.6 million
- Budesonide/Formoterol Fumarate (Symbicort): $4.4 million
- Budesonide (Rhinocort): $1.7 million
- In the Spring of 2012, generic competition was launched for AstraZeneca's rosuvastatin.

Current submissions with the Pharmaceutical Services Division under review for inclusion as a benefit within the PharmaCare program:

- Ticagrelor (Brilinta) for Acute Coronary Syndrome

**Attachment 11 – Comprehensive Economic and Trade Agreement (CETA) / Intellectual Property (IP)**

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** TBD

**ATTENDEES:** TBD

**BACKGROUND:**

- As part of the Comprehensive Economic and Trade Agreement negotiations, the European Union (EU) has tabled proposals that would alter Canada's intellectual property regime for pharmaceuticals.

- Each of the following three proposed changes by the EU would delay the launch of generic products in Canada which would have significant economic implications for public drugs plans and other payers:

    1. The EU is requesting the establishment of a patent term restoration or extended patent term (currently 20 years) - IMPACT: up to five years of automatic additional protection after a patent expires (plus six months if paediatric studies have been carried out) for drug products requiring marketing approval.

    2. The EU is proposing data exclusivity changes - IMPACT: Canada would be required to provide a minimum of 10 years data protection (currently eight years) against reference by generic drug manufacturers to clinical trial data that was used for the initial approval of a pharmaceutical product. The proposal also extends the timeframe for when Health Canada could receive an application for approval of a generic product from six to eight years after the brand receives initial marketing approval.

    3. The EU is also seeking to change legislation to provide patent holders the right to appeal Federal Court rulings that rule infringement on a valid patent has not occurred - IMPACT: successful or not, would have the effect of delaying the launch to the market of the generic pharmaceutical product at issue. Patent holders' existing right to pursue separate patent infringement action would not be impacted.

- s.13,s.16,s.17

**CURRENT STATE – CANADA & BC:**

- In Canada, international trade, and intellectual property legislation fall within the sole jurisdiction of the federal government.

- The patent regime for pharmaceuticals was amended in 1987 and extended significant monopoly protections to manufacturers of patented drugs in exchange for commitments regarding domestic research and development expenditures. At that time, Rx&D member companies pledged to spend at least 10 percent of domestic revenues on research and development. For 2010, the Patented Medicine Prices Review Board reported that Rx&D member companies spent only 8.2 percent of their Canadian revenues on research and development, marking the eighth consecutive year that Rx&D member companies have failed to meet their commitment in this respect. The corresponding investment-to-sales ratio for all brand companies (including Rx&D member companies) in 2010 was 6.9%.

- Minister de Jong has met with Federal International Trade Minister Ed Fast (in June of 2011) and written him two letters outlining BC's concern with changes to the intellectual property regime for Pharmaceuticals (see Attachments A and B) and Minister Fast has responded (see Attachment C).

- Although other provinces and territories have expressed concern over the potential financial implications, specific positions are not known, and no coordinated effort to inform the federal government has occurred.

**FINANCIAL IMPLICATIONS:**

- BC spent $1.1billion in 2010/11 for Pharmaceuticals.

- Every year of delayed entry of new generics due to patent regime changes would cost BC an estimated* $21M per delayed year (would be cumulative).

**ATTACHMENT:**

Attachment A: Letter to Federal Minister Ed Fast, October 20, 2011
Attachment B: Letter to Federal Minister Ed Fast, March 29, 2012
Attachment C: Response letter from Federal Minister Fast, May 17, 2012

*NOTE - estimate of $21M is an average of annual savings for the years 1995 to 2012.

Attachment A. Letter to Federal Minister Ed Fast, October 20, 2011

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The Honourable Ed Fast
Minister of International Development, and
Minister for the Asia-Pacific Gateway
#205 - 2825 Clearbrook Rd.
Abbotsford, BC V2T 6S3

Dear Minister ~~Fast~~: Ed

It was a pleasure to meet with you in Ottawa in June 2011, and strengthen our long-standing collegiality and discuss our mutual priorities. I know that we both look forward to our jurisdictions continuing to work collaboratively on issues that affect international development and trade, such as the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) negotiations.

As we discussed in June, Canada's acceptance of the changes being proposed by the EC to the intellectual property regime for pharmaceuticals in the CETA negotiations would likely have a significant financial impact on British Columbia (BC). The resulting delay in the introduction of generic products would lead to a requirement to purchase pharmaceuticals still under patent for an extended period. The increased costs would diminish anticipated Pharmacare program savings and would divert resources from the health system overall. The legitimate need to support research and manufacturing in Canada should not be done at the expense of the provincial and territorial public health care systems. If a trade accord were negotiated that added significantly to pharmaceutical drug costs, B.C. would feel compelled to seek financial compensation from the federal government to offset those costs and to maintain health care services to citizens. The challenge in any trade negotiation is to find the appropriate balance and I shall offer all possible assistance as you pursue that objective on this issue.

Thank you again for the meeting and the opportunity to discuss issues of importance to BC and Canada, and I look forward to meeting with you again soon. I hope your schedule has provided you with some personal time with your family in our mutual home of Abbotsford.

Yours truly,

Michael de Jong, QC
Minister

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MAR 2 9 2012

The Honourable Ed Fast
Minister of International Development and
Minister for the Asia-Pacific Gateway
Room 105, East Block
House of Commons
Ottawa ON K1A 0A6

Dear Minister Fast:

I wish to follow-up on a letter I sent to you dated October 20, 2011, regarding the current Canada-European Union Comprehensive Economic and Trade Agreement (CETA) negotiations. In the letter, I raised concerns that Canada's acceptance of the proposed changes to the intellectual property regime for pharmaceuticals in the CETA negotiations would have a significant financial impact on British Columbia (BC), and that BC would feel compelled to seek financial compensation from the federal government if a trade accord added significantly to pharmaceutical drug costs in BC.

I trust that Canada is taking a balanced approach to the CETA negotiations, and is being mindful of the potential financial impacts for provinces and territories. As I expressed in my previous letter, I wish to offer all possible assistance as you pursue the objective of finding an appropriate balance on the intellectual property regime on pharmaceuticals.

I am aware that it is hoped that negotiations will conclude in the fall. Given the quickly approaching deadline, I look forward to a timely response and the opportunity to receive an update and discuss this further.

Yours truly,

ORIGINAL SIGNED BY

Michael de Jong, QC
Minister

Attachment C: Response letter from Federal Minister Fast, May 17, 2012

Minister of International Trade and
Minister for the Asia-Pacific Gateway

Ministre du Commerce international et
ministre de la porte d'entrée de l'Asie-Pacifique

Ottawa, Canada K1A 0G2

MAY 17 2012

MINISTER'S OFFICE
HEALTH
#
DRAFT REPLY
FYI
MAY 23 2012
REPLY DIRECT
FILE
REMARKS
AA MA SA
FA CM

The Honourable Michael de Jong, M.L.A.
Minister of Health
Government of Columbia
P.O. Box 9050, Stn. Prov. Govt.
Victoria BC V8W 9E2

Dear Minister:

Thank you for your letter of March 4, 2012, regarding the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA) negotiations.

As you know, CETA represents a huge opportunity for Canadians in British Columbia and in the rest of the country. The EU is already Canada's second-most important partner for trade and investment, and the relationship holds great potential for growth. Through CETA, Canada would gain preferential access to the EU, the wealthiest single market in the world.

s.13,s.16,s.17

As you know, the Government of Canada continues to closely engage British Columbia and other provinces and territories to ensure their perspectives are taken into consideration in the CETA negotiations, including through regular debriefs on the ongoing negotiations related to intellectual property issues.

British Columbia's continued support and commitment remains essential to the successful negotiation of a high-quality, ambitious agreement with the EU, and we remain committed to working with your government in this regard.

.../2

Canada

## Appendix 12 – Drug Shortages

**PREPARED FOR:** Honourable Michael de Jong, QC, Minister of Health

**DATE AND TIME OF MEETING:** TBD

**ATTENDEES:** TBD

**BACKGROUND:**

- There have always been periodic shortages of both brand name and generic prescription drugs. However, there appears to be an increase in the frequency and duration of various drug shortages.
- Drug shortages are a national and international issue that have raised concerns about overall patient safety and continuity of patient care.
- A number of factors contribute to drug shortages, including shortages of raw materials; process problems at specific manufacturing plants; and quality control issues resulting in the recall of substantial lots or manufacturing plant shut downs.
- Changes to reimbursement of generic prescription drugs is not considered to be a contributing factor to drug shortages.
- In February 2012, an extensive national shortage of certain injectable drugs produced by Sandoz Canada emerged. For some of these drugs, Sandoz is the sole supplier.
- Sandoz Canada is part of the Novartis Group of companies in Canada (see Appendix 2).
- The shortage is due to reduced operation at the Sandoz manufacturing site in Boucherville, Quebec to remediate facility manufacturing quality-control issues identified by the U.S. FDA, as well as other related logistical supply chain issues.
- Production at the plant is ongoing but at reduced capacity for medically necessary drugs. This situation is expected to continue through December 2012.
- Clinical alternatives have been found for some Sandoz drugs, but there are few or no alternatives for other drugs, necessitating careful allocation of existing stock.

**BC AND CANADA MITIGATION STRATEGIES:**

- Major concerns with regard to drug shortages are continuity of care and patient safety. The Ministry of Health (the Ministry) will continue to monitor drug shortages closely to identify issues with continuity of care and patient safety issues.
- The Ministry is actively working with Sandoz, Health Canada, other provinces and BC's health authorities, Health Shared Services BC, health professional associations and the Colleges, to manage the situation.
- BC is also a participant in a Provincial/Territorial task group (P/T Drug Shortage Task Team) to identify and develop new strategies and reporting tools to better monitor and manage drug shortages in the future.
- In BC, a province-wide process has been developed for specific shortages and issues in order to minimize any patient impact, both in acute care facilities and in the community. Emergency Operations Committees were also activated to deal with the situation.

- A provincial working group with representatives from the Ministry, each health authority and health professional associations and Colleges has developed a framework for substitutions, alternate treatments, priority setting and rationalization. Clinical specialists have also been engaged.
- The Ministry is also providing communication updates to pharmacists, physicians, dentists, and other health professionals working in the community. The Ministry has established a webpage on the PharmaCare website to provide updated information sent through partner organizations. The Ministry has also established a network of specialty community pharmacies servicing hospices to help collaboration.
- Community pharmacies have been instructed to place orders through their usual supplier, and allocations are based on historical utilization over the last calendar year.
- BC hospital pharmacies are working through their group purchasing organization (HealthPRO Procurement Services) and Health Shared Services BC to place orders.
- Health Canada has also approved new drug products that have been affected by the reduced production by Sandoz and more new drug products are expected.
- The Ministry continues to collaborate with all stakeholders including drug manufacturers, wholesalers, the College of Pharmacists of BC, the BC Pharmacy Association and the College of Physicians and Surgeons of BC to ensure drug shortages are managed and communicated in a timely and efficient manner.
- FPT partners are working together to develop risk mitigation strategies to manage drug shortages, including developing a more comprehensive reporting system. To be successful, full cooperation with industry, distributors and pharmacies will be needed.

**BC PATIENT IMPACT:**

- Due to the significant efforts by health administrators and health professionals across the province, patient impact directly resulting from the shortage in BC has been minimized.
- There are no known significant adverse patient impacts attributable solely to drug shortages in BC.

# ADVICE TO MINISTER

| CONFIDENTIAL<br>ISSUES NOTE<br><br>Ministry: Health<br>Date: May 10, 2012<br>Minister Responsible: Michael de Jong | **Studies looking at heart health risks, psychiatric risks of anti-smoking drug Champix** |
|---|---|

ADVICE AND RECOMMENDED RESPONSE:

- Champix is an effective drug that has helped many people quit smoking and go on to a healthier, smoke-free life.
- We made this decision based on a thorough review of solid clinical research and evidence, which found that the benefits of covering this drug in our smoking cessation program outweighed the risks.
- The ministry, the national Common Drug Review, and Health Canada reviewed all the available research on Champix before B.C. decided to cover this drug.
- All three continue to monitor research and data on the drug.
- In fact, research released just this month in the British Medical Journal shows no elevated risks of cardiovascular issues from taking Champix.
- With any prescription drugs, there are benefits and there may be side effects.
- That's why people need to talk to their doctors about whether this drug is right for them, and to ensure they're monitored while taking the drug.
- If Champix is not right for them, smokers have two other drug options: nicotine replacement therapies, such as the patch, and Zyban.
- We do know tobacco use kills more than 6,000 British Columbians every year.
- And the risks of smoking are well-documented in hundreds of studies...
- ...and in many families in British Columbia, missing a loved one who was a smoker and died from lung cancer or other cancers, emphysema, COPD, heart disease or stroke.

Secondary messaging (more technical):

- The latest study in the British Medical Journal analyses data from 22 other studies, and concludes there is no elevated risk in cardiovascular issues from using Champix versus a placebo (sugar pill).
- That means no statistically significant increase in heart attacks, strokes, mini-strokes, angina, etc.
- A 2011 study drew a link between suicide, self-harm and depression and the smoking cessation drugs Champix and Zyban. However, that study had limitations, as admitted by the researchers.
- It relied on people self-reporting, which can cause "reporting bias" in a study, skewing the results. We need further study of this issue.
- As the authors of the BMJ study on Champix and heart health say, studies with

**flaws or limitations can cause public alarm and real harm, since patients and doctors may avoid a drug treatment that could help a person finally quit smoking.**

- **The ministry's drug coverage decisions are made through its rigorous drug review process, which considers clinical evidence, research, patient input, and information from other jurisdictions.**
- **Champix and Zyban are covered in other provinces and territories, such as Alberta, Saskatchewan, Ontario, Quebec, the Yukon and the Northwest Territories.**
- **Both drugs have been reviewed and recommended for funding by B.C.'s independent Drug Benefit Council.**
- **The ministry will continue to monitor any new clinical information.**

## BACKGROUND REGARDING THE ISSUE:

- The drug safety concerns raised for Champix (varenicline) primarily revolve around possible increased risk of psychiatric problems (e.g., depression and suicidal behaviour) and cardiovascular problems (e.g., heart attack and strokes).
- On May 4, the British Medical Journal published a study on the smoking cessation drug Champix (varenicline) and its effect on cardiovascular health.
- The study, by American researchers from the University of California San Francisco (UCSF), took data from 22 randomized trials of Champix (double-blind scientific studies using a group receiving the drug and a group receiving a placebo).
- The researchers analysed the data from these 22 trials, and found the rates of treatment for serious cardiovascular events in the Champix group (heart attacks, strokes, TIA, angina, etc.) was neither clinically nor statistically significant compared to the placebo group.
- A previous study in November 2011 in the online journal Public Library of Science (PloS) One, looked at the risks of suicide, suicide ideation, self-harm and depression in patients taking Champix or Zyban, another smoking cessation drug.
- The authors, researchers at Wake Forest University (North Carolina), Harvard, and John Hopkins, analysed the Federal Drug Administration's database on adverse events from 1998-Sept 2010 (note: Champix has only been on the market for the last 4 years).
- The study found 3,249 cases of suicidal behaviour, self-injury or depression, with 90 per cent of these cases associated with Champix and seven per cent with Zyban.
- The authors concluded Champix and Zyban have an increased risk of reported depression and suicidal/self-injurious behaviour. The authors recommended Champix not be used as a first-line treatment for smoking cessation.
- However, the study was NOT a randomized, double-blind trial with a placebo group. It instead relied on self-reporting of symptoms by the patients. This type of study often suffers from a research flaw or limitation called "reporting bias."
- Reporting to the database is voluntary and the database consists of case reports.
- Case reports do not prove that the drug caused the event, nor is it possible to evaluate each event to see what really happened.
- Since researchers only knew about the reported adverse events, and not about the whole group taking the drug, it was not possible to determine an incidence rate of adverse effects for each drug.

# ADVICE TO MINISTER

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Program Area Contact: Eric Lun
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