House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 010 • 2nd SESSION • 39th PARLIAMENT

EVIDENCE

Tuesday, February 5, 2008

Chair

Mrs. Joy Smith

Standing Committee on Health

Tuesday, February 5, 2008

● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Welcome, everyone, to our committee today. I'm so pleased that we could have a chance to welcome our witnesses today and thank them for coming. Here in the health committee we have looked very much forward to all the people who have come and presented to this committee, so, as I said, welcome.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): I have a point of order, please, Madam Chairperson.

I would like to take a moment to present a motion and give notice as of today, so that it can be considered sometime after the 48-hour period. I have copies in two languages.

I move that the Standing Committee on Health call on the government to strengthen its monitoring and analytical capacity regarding enforcement of the Canada Health Act in order to better identify challenges facing public health care, including excessive wait times for diagnostics and treatment, the high cost of prescription drugs to individuals in the health care system, and the impacts of increased privatization; and that the Minister of Health appear before the health committee within 30 days following the publication of his department's Canada Health Act annual report to indicate what proactive measures his government will be undertaking to ensure that Canadians' rights under the act are fully protected and strongly enforced in light of the current challenges to Canadians' public health care system.

The Chair: Thank you, Ms. Wasylycia-Leis.

Under the 48-hour mandate, we will deal with it this coming Thursday.

Pursuant to Standing Order 108(2), I would like to welcome you to our second meeting of post-market surveillance of pharmaceutical products, prescription and non-prescription.

Committee members, we have with us today witnesses who will be taking part in today's panel on industry. They are representatives of Advancing Canadian Self-Care, Canada's Research-Based Pharmaceutical Companies, BIOTECanada, and the Canadian Generic Pharmaceutical Association.

I would like to remind witnesses that they have 10 minutes per organization, and I will reiterate that because we do keep the time quite succinctly. You have 10 minutes per organization to make your presentations. The committee will hear all presentations first before proceeding to questions from committee members. So I will acknowledge you one by one, and when your time is up, I will go on to the next presenter.

Let us begin with Dr. David Skinner, president of Advancing Canadian Self-Care, NDMAC.

● (1110)

Mr. David Skinner (President, NDMAC): Thank you very much.

Good morning, ladies and gentlemen of the committee. I thank you for this opportunity to appear before you today.

This is Robert White, a colleague of mine and our director of scientific and regulatory affairs.

I am David Skinner. l am president of NDMAC. Our association is dedicated to advancing Canadian self-care. From sunscreens to pain relievers, vitamins to herbals, and toothpastes to acne treatments, self-care health products are vital tools in the personal health management of virtually all Canadians.

Our industry supports the need for risk-based regulatory interventions with respect to safety, efficacy, and quality. We believe that all products with health claims of similar risk should attract the same regulatory requirements, not just for post-market monitoring, but also for pre-market authorization to sell. This means there should be differing regulatory standards for products with differing levels of risk. Sadly, Canadian regulations are confusing, inefficient, and often arbitrary in the way they differentiate between health products of similar risk.

Health products can be divided into two major categories. First there are drugs and devices with risk profiles that require the intervention of a health professional to ensure their safe and proper use. These include prescription drugs, vaccines, medical imaging tools, and controlled substances. The second category of health care products is for self-care, which have risk profiles that permit their safe use on the basis of label directions without requiring the intervention of a licensed professional. The regulation of this latter category is inconsistent, at best.

To illustrate the confusing nature of the current regulations and nomenclature, we need to look no further than the terms of reference for this study. The stated intent is to review the federal government's role in post-market surveillance of prescription and non-prescription drugs. While it is clear that the committee intends that prescription drugs be within the scope of this study, it is less clear regarding non-prescription drugs.

Does this mean the focus is on products such as vaccines, controlled substances, exempt narcotics, and other drugs such as digoxin, insulin, and nitroglycerin, all of which are non-prescription drugs that are regulated under part C of the food and drug regulations but not listed in the prescription drug schedule? Does the committee also wish to include other items that fall under the same set of regulations as prescription drugs, such as toothpastes and sunscreens? If the intent is to include such items as antacids, laxatives, and cold products, then the question arises as to whether natural health products are also included, and if so, why not health products in food form?

The dangers of casting a broad net can be illustrated by the gross error of omission with respect to the establishment of price controls for patented drugs. When these regulations were promulgated, there had never been a single word uttered by Parliament about the rules being applied to sunscreens, chewing gum, anti-dandruff shampoos, nor any other self-care health product for that matter. Yet the patented medicine regulations were, and continue to be, mute on a definition of the scope of these controls.

The consequence of this is that the common definition of drug as found in the Food and Drugs Act has been used, thereby capturing everything from toothpaste and gum to allergy medicines. It has been conclusively demonstrated that self-care products operate in a highly competitive, out-of-pocket consumer pricing environment that negates the need for government price controls. Although the intent of Parliament never was to capture these products, lack of clarity has created a two-tiered market and reduced consumer choice.

This kind of overregulation has encouraged non-compliance and added unnecessary costs to the government and consumers. Our sector needs clarity. We do not wish to repeat the errors of the past by having our members' products lumped into the same basket as new chemical entities.

● (1115)

NDMAC does believe that regulatory efficiency and clarity is one of the greatest tools to ensure public safety and competitiveness. We endorse the need for post-market monitoring of all products under the Food and Drugs Act that carry health claims. The level of complexity needs to be proportionate to the risk of products.

New chemical entities, by definition, have the least market experience and have the least well-characterized safety profile. So these products would most surely be prescription drugs; thus their requirements would be significantly higher than those requirements for self-care health products, such as natural products and non-prescription medicines, as well as cosmetics and foods making health claims.

The regulations for lower-risk products, such as those for self-care, should be consistent, regardless of the form the products take. For example, calcium carbonate, whether it's in a tablet, a syrup, a drink, or a snack bar, is still a biologically active substance being delivered to the body, regardless of the format chosen by the consumer. In fact, it is consumer choice and consumer preference that often determines how this product is placed on the market. If it's promoted for its health benefit, either as a calcium supplement or an antacid, it must be subject to the regulations that reach beyond its fitness for general consumption. From the marketer's standpoint, the business decision to enter the health products market brings with it certain regulatory obligations with respect to ensuring appropriate use and the prevention of health fraud. These obligations should not be something that can be sidestepped through the choice of product format.

As the safety profile of self-care health products must be well known, the adverse events profile is also well documented, which negates the need for extensive post-marketing monitoring and reporting that are required for higher-risk products such as new chemical entities. Manufacturers of self-care health products report all adverse reactions to Health Canada and, on an annual basis, prepare and maintain a summary report with a concise and critical analysis of all adverse reactions for every product on the Canadian market. NDMAC believes that such regulatory oversight is sufficient for self-care health products.

Currently, some self-care health products are captured by part C of the food and drug regulations, where they are regulated alongside higher-risk products such as prescription drugs and vaccines. Other self-care products are handled by part D of the regulations, the natural health product regulations, and still others by part B, the foods regulations.

NDMAC urges the committee to recommend that a simplified, consistent, and comprehensive system of regulation for self-care health products be created outside part C of the food and drug regulations. Within the self-care regulatory framework, post-market monitoring should be established based on well-known safety profiles of lower-risk products and the requirements be made proportionate to the risk.

Thank you for your attention, and I await your questions.

The Chair: Thank you very much.

We will now go on to Dr. Fontana, a consultant with Rx&D.

Dr. Pier-Giorgio Fontana (Consultant, Regulatory Affairs, Canada's Research-Based Pharmaceutical Companies (Rx&D)): Thank you. My name is Pier-Giorgio Fontana and I am a consultant for Canada's Research-Based Pharmaceutical Companies.

I am very pleased to appear before this committee on behalf of Canada's Research-Based Pharmaceutical Companies, Rx&D, to discuss the very important issues of post-market surveillance of pharmaceuticals.

[*Translation*]

Rx&D, as you know, is the national organization representing more than 50 research-based pharmaceutical companies in Canada and the 20,000 men and women who work for them.

Averaging more than $1 billion a year in research and development investments, we are one of the country's most R and D-intensive industries, second only to the telecommunications sector.

[*English*]

Let me begin by stressing that drug safety is of the utmost importance for Rx&D member companies. Evaluation of a drug's safety starts in the laboratory, continues through clinical development, and is pursued with diligence as long as a medicine is on the market. This sustained effort helps ensure that the therapeutic benefits of new medicines outweigh any potential risks to patients.

Innovative pharmaceutical companies worldwide invest significant resources in safety departments whose experts, in collaboration with the stakeholders, epidemiologists, and other researchers, focus on post-market surveillance as well as assessing and reducing risk. This work continues throughout the entire life cycle of a drug. The safety experts in each company are part of a system under which manufacturers have an obligation to report adverse events received from any source to national and international health regulatory authorities. These experts follow up individual cases with the health professionals or others involved in the initial report to ensure the accuracy and completeness of the information. This information is subsequently analyzed by the regulatory authorities. Adverse event data is also entered in the manufacturers' global pharmacovigilance database and analyzed for periodic safety update reports, also referred to as PSURs, which are submitted to the regulatory agencies.

Following discussion with health authorities, we communicate to health care professionals in institutions important changes to the safety profile of the product. These changes are reflected in documents approved by the regulator. Occasionally, due to new safety information altering the benefit-risk balance, a product may be withdrawn from the market or its use restricted. Furthermore, pharmaceutical companies have been discussing and reaching agreements with major regulatory authorities, including Health Canada, on approaches to post-market safety planning for individual products before their approval.

● (1120)

[*Translation*]

In addition to informing regulatory authorities of all clinical trial results and ongoing studies as part of submissions to these authorities, the innovative pharmaceutical industry is also committed to increasing the transparency of clinical trials information to healthcare practitioners, patients and others.

[*English*]

In keeping with the work of our industry's global association, the IFPMA, our member companies are committed to posting results of all clinical trials, other than exploratory trials, once a drug has been approved in any country. Moreover, these confirmatory trials are posted at their onset in publicly accessible registries.

This information can be found online at the IFPMA clinical trials portal. This portal and the global industry's guiding joint position statements issued in 2005 can also be accessed through the Rx&D website.

We note that major jurisdictions abroad have developed or are developing clinical trials disclosure requirements. We recommend that the requirements being developed by Health Canada should be consistent with the approaches taken by the regulatory authorities in the United States and the European Union.

We believe that the current health safety system provides a significant level of protection while making available to patients the therapeutic benefits of innovative medicines. However, there is always room for improvement.

Rx&D feels strongly that the post-approval safety efforts in Canada could be maximized by taking an international perspective, harmonized with regulatory authorities like the U.S. and the European Union and consistent with best practices found in other jurisdictions. Health Canada may wish to pursue this more vigorously in order to create greater synergies with these key regulatory agencies. This would allow companies in Canada to better contribute to post-market safety by building more efficiently on the efforts of their global counterparts.

The use of common worldwide definitions and procedures, as well as compatible databases and analysis tools, would maximize the value of all available post-market data. Health Canada would then be in a better position to detect and evaluate potential adverse events as early as possible. In this context, it should be noted that Canada may not have the population size that would allow detection of very rare events.

Similarly, the discussions between the manufacturer and Health Canada on post-market safety planning for individual product should be based on harmonized guidelines and international databases. In this way, the global nature of the plans would increase the value of these post-market safety initiatives. Indeed, Canada has been contributing to the development of international safety standards and guidelines through participation in working groups involving regulatory authorities and industry experts.

Spontaneous reporting of adverse drug events is a valuable means of detecting potential safety signals in the post-approval context; however, it is critically important that the information reported is of sufficient quality to contribute to a scientifically sound decision. Therefore, we suggest that improved means of training and interacting with health care professions be developed to heighten awareness of the need for detailed and accurate reporting.

Detecting and assessing causes of adverse events requires robust methodologies, with the information then disseminated to all stakeholders. By keeping the manufacturer fully informed when evaluating safety signals, Health Canada would allow us to better follow the evolving benefit-risk balance of our products and communicate it in a prompt, accurate, and effective way.

The safety of new medicines can be improved through research aimed at strengthening drug development science already taking place in collaboration among industry, regulatory authorities, and academic centres in the U.S. and Europe.

As an active partner, the global innovative pharmaceutical industry is pursuing research to improve models and predictors for evaluating the safety and efficacy of drugs under development and reliable tests for detecting patients more at risk to certain adverse events.

● (1125)

In conclusion, Rx&D believes it has been a reliable contributor to the current regulatory system, and we are prepared to continue to work with Health Canada on ways to improve it.

We encourage the committee to take a global perspective to harmonizing our definitions, procedures, tools, and requirements with those major regulatory authorities abroad; report quality safety data from the field as a fundamental feature for the capture of adverse incidents in Canada; promote a collaborative approach between industry, regulatory authorities, and academia to create synergies needed to expand our collective knowledge on how medicinal therapies affect patients; and measure the impact on safety of any new initiatives.

[*Translation*]

I would like to thank the committee for this opportunity to talk about our role in post-market safety within a multi-stakeholder regulatory system that is designed to provide—and does provide—a significant level of protection to Canadians.

[*English*]

Let me reiterate that as an industry and a community we are prepared to work with Health Canada in the most efficient manner to maintain favourable risk-benefit balance for our products so that Canadian patients can derive the maximum therapeutic value from the medicine they take.

Thank you very much.

The Chair: Thank you, Mr. Fontana.

We will now continue with the presentation of Dr. Philip Schwab, the vice-president of industry relations at BIOTECanada.

Dr. Philip Schwab (Vice-President of Industry Relations, BIOTECanada): Good morning, Madam Chairman. Good morning, members of the committee. I am pleased to be here today and pleased you invited BIOTECanada to be part of this very important hearing on post-market safety for biologic products and vaccines.

The over 215 members of BIOTECanada are composed of innovative Canadian and world-leading multinational companies that are developing the next generation of life-saving therapeutics and vaccines for Canadian patients. My remarks today will outline some of the advances that biologic products have brought to the Canadian health system and the stringent processes currently followed by manufacturers to monitor safety and effectiveness of new therapies and vaccines, and I will suggest some steps Canada can take to improve post-market surveillance to reflect changing global priorities.

I'd like to start out by describing some of the advances that biologic products have brought to the Canadian health system. Each year, as part of National Biotechnology Week, BIOTECanada asks Canadians what they expect in terms of benefits from biotechnology. Consistently, over 80% of Canadians expect benefits to their health from advances in biotechnology, and today they are receiving those benefits.

The biological therapies and vaccines developed by BIOTECanada members have brought tremendous value to Canadian patients and the health care system. The therapies introduced over the past 20 years have improved the quality of life for patients suffering from crippling diseases such as rheumatoid arthritis, have resulted in better survival rates for cancer patients, and have provided a chance at life for sufferers of rare genetic disorders.

Likewise in the field of immunization, from the development of the polio vaccine to the recent introduction of immunization programs for human papilloma virus, Canada has led the world in the development of vaccines and public immunization programs. Today, Canadian companies are currently developing biotech treatments, such as the company Thallion Pharmaceuticals in Montreal, which is developing a new biological treatment for E. coli O157:H7. Companies like Amorfix in Toronto are developing innovative therapies for Alzheimer's disease, and companies like Biomira and BioMS in Edmonton are developing new vaccines against cancer and better treatments for multiple sclerosis.

While these innovative therapies and vaccines represent hope for Canadians who are suffering from or are threatened by these diseases, patient safety remains the primary concern and commitment of our member companies when they are developing these new products. This dedication is reflected in the actions companies take throughout the life cycle of a therapeutic product to meet, and in many cases exceed, the stringent safety requirements set in place by global regulatory authorities.

Our members comply strictly with Health Canada and global regulations for pre-clinical, clinical efficacy, safety testing, and manufacturing in the pre-market development of novel biological products.

Our members are committed to the registry and disclosure of results from clinical trials through the publicly accessible databases that Dr. Fontana has already mentioned. That is to ensure transparency in the clinical trial process.

Our members comply with global mandatory requirements for post-market pharmacovigilance and they voluntarily maintain global patient registries to continue to monitor safety and efficacy and to update regulatory authorities appropriately when safety issues arise.

Finally, our members are actively engaged in the consultations on the development of the progressive licensing framework.

But one cannot talk about the post-market safety of biological products without also considering the extensive and deliberate processes followed by manufacturers and regulators to assess the risks, benefits, and safety of a new therapy before it ever reaches the market.

A new biological therapeutic must pass multiple hurdles in manufacturing process development and pre-clinical and clinical trials before it ever receives market approval. These studies might take a decade to complete and cost hundreds of millions of dollars.

● (1130)

Add to that fact that over 80% of potential therapies that enter development fail to reach the marketplace and you can see the challenges faced by both innovative companies developing new biological treatments or vaccines and, most importantly, the patients who desperately need those therapies.

Our members work closely with Health Canada regulatory authorities during the pre-market phase of the product's evaluation. As I mentioned, our companies comply with Canadian and global requirements for clinical trial design, and we publish those clinical trial results on public websites.

When a new biological therapy or vaccine receives a market authorization in Canada, Canadians should have confidence that every known measure has been taken to ensure that the product is safe and effective and that the benefits of the new product outweigh any potential risks.

In the post-market area, the safe and effective use of a new therapy represents a complex series of overlapping responsibilities starting with manufacturers and Health Canada, but also involving health care professionals and patients. Doctors have a responsibility to prescribe medications to patients in accordance with the terms of the Health Canada licence and the corresponding product monograph, and patients have the responsibility to adhere to their treatment regimes.

Manufacturers and Health Canada have an important responsibility to collect adverse event data, to continue to monitor the safety profile of the products post-market, and to take appropriate remedial measures that are reflective of the risks and benefits associated with the continued use of the therapy.

Each of these players in the health care system needs to work collaboratively to continue to improve the post-market safety of these products, including improved communications between all parties regarding adverse events and safety concerns.

In addition to the post-market surveillance required by Health Canada, manufacturers also undertake voluntary activities to ensure the safety and effectiveness of these therapies, including, but not limited to, the creation of extensive patient registries, continued clinical trials, and implementation of risk management plans. These efforts provide valuable information to regulators, physicians, and patients throughout the life cycle of a therapeutic product.

As members of the committee examine this issue, it's important to recognize that efforts are under way in Canada and major jurisdictions right now to continue to strengthen post-market surveillance and safety. Our member companies are engaged with those efforts on the global level.

Both the EMEA in Europe and the U.S. Food and Drug Administration are adopting life-cycle approaches. Our members are pleased that Health Canada is also considering adopting a life-cycle approach to drug regulation. BIOTECanada members have been pleased to be part of the ongoing progressive licensing framework. This framework provides an opportunity for Canada to modernize its therapeutic regulatory system to reflect emerging global standards and emerging science. We are eager to receive more details on the specific legislative changes that are contemplated by the food and consumer safety action plan. We encourage the committee and Health Canada to look to our international counterparts when considering recommendations to enhance Canada's post-market safety.

As I mentioned, key to the success of the post-market initiatives under PLF is the development of stronger communication links between manufacturers and the marketed health products directorate at Health Canada. In many cases, Health Canada has access to adverse events reports from health care professionals, patients, or provincial public health agencies that have not been made available to manufacturers. Manufacturers may also have access to databases and patient registries that track the use and safety of the therapy around the world. Improving this communication will require additional resources at Health Canada.

When potential safety issues do arise in the post-market phase of a product's life cycle, these improved communications between Health Canada and manufacturers about potential risks must be balanced against the known benefits of the product in question. Similar risk-benefit assessments used in the pre-market assessment period should be adopted in the post-market period to put safety signals in context to ensure that a beneficial therapy for the vast majority of patients who use it is not removed from the market due to a very narrow set of safety concerns. Upon consideration of all available safety data, a more balanced and effective range of actions may be taken in considering the risk-benefit profile of the product.

● (1135)

In summary, I again thank the chair and the members of the committee for the opportunity to appear before you today, and I reiterate the commitment of BIOTECanada members to the continued development of safe, effective and innovative breakthrough therapies for some of the most devastating illnesses affecting Canadians.

We look forward to continuing to engage the members of this committee and Health Canada to advance our mutual goal of a healthy, productive Canadian population and a robust Canadian biotechnology industry.

Thank you. Merci.

● (1140)

The Chair: Thank you, Dr. Schwab.

We're now going to hear from representatives of the Canadian Generic Pharmaceutical Association, and Dr. D'Cunha.

Dr. Colin D'Cunha (Director, Pharmacovigilance, Apotex Inc., Canadian Generic Pharmaceutical Association): Good morning, ladies and gentlemen, Madam Chair, and members of the committee.

My name is Colin D'Cunha, and I'm joined today by my colleague, Jacqueline Conant. On behalf of the Canadian Generic Pharmaceutical Association and its member companies, I would like to thank you for this opportunity to participate in the committee's study on post-market surveillance.

CGPA represents manufacturers and distributors of finished generic pharmaceutical products and active pharmaceutical chemicals. Generic drugs fill more than 47% of all prescriptions in Canada, even though they accounted for less than 20% of the approximately $18 billion that Canadians spent on prescription medicines last year. Almost all of the generic drugs sold in Canada are made right here in this country, and Canada's generic pharmaceutical industry employs more than 10,500 Canadians in highly skilled, well-paid jobs. It reinvests about 15% of its sales, that is, about $450 million each year, in research and development.

Addressing my comments to pharmacovigilance in Canada's generic pharmaceutical industry, the monitoring of the use and effect of medicines is an essential focus for any pharmaceutical company. Generic drugs are approved for sale by Health Canada and are identical or bioequivalent to the brand-name version. By the time a generic version is licensed for sale in Canada, the active substances are well documented and their safety profiles are generally well established.

Unexpected adverse events for these well-known substances are rare. Even so, Canada's generic pharmaceutical companies take our post-market surveillance efforts and responsibilities very seriously. All pharmaceutical companies in Canada are required to monitor the use and effect of a given medication and to detect, assess, understand, and prevent any adverse reactions or any other medicine-related problems that may arise. These activities and the science behind them are known as pharmacovigilance in the pharmaceutical industry.

Both Jacqueline and I are members of the CGPA's pharmacovigilance working group. This is a group of scientific experts from Canada's generic pharmaceutical companies who share information about global best practices in pharmacovigilance, changes in international reporting requirements, and various scientific developments.

Our goals in pharmacovigilance are to protect the public's health by monitoring the safety and efficacy of our products; to limit risk, which we achieve by iterative risk management throughout the product's life cycle and by conducting signal detection and safety review of the data available to us; to undertake effective risk management activities, including risk communication, core safety information, registries and post-approval studies where appropriate; and to place a strong focus on any product with an identified safety concern.

Canada's generic pharmaceutical industry operates in a global environment, with about 40% of the generic drugs manufactured in Canada being exported to the United States and to more than 110 countries worldwide. As one can imagine, these countries have a wide range of post-market surveillance requirements. As such, Canada's generic pharmaceutical industry is obligated to ensure our procedures are as robust as possible and comply with the most stringent of international pharmacovigilance regulations.

Generic pharmaceutical companies in Canada have standard operating procedures for the collection, assessment, and reporting of adverse drug reactions, both in clinical and post-marketing experience. These procedures are compliant with national and international regulations and guidelines. Our member companies prepare safety reports to meet regulatory obligations, including the seven-day and 15-day expedited reports for serious adverse drug reactions and the annual and three-year periodic safety reports. We also conduct ongoing monitoring and literature reviews on a global basis to identify any adverse reaction case reports. Our companies also develop customized safety evaluations for any products requiring post-approval risk management. Drugs in this category include isotretinoin, used for acne, and clozapine, used for schizophrenia.

● (1145)

Our risk management process is based either on regulatory guidelines from Health Canada or on established practices in Europe and the United States.

Coming, then, to recommendations, the generic pharmaceutical industry has identified some gaps in Canada's post-market surveillance system. We have made several recommendations to Health Canada. I know that some of these points were included in the presentation by Health Canada officials last week, and we are pleased to share our recommendations with you today.

Canada should align itself with the most stringent reporting requirements of the European Union and the United States, moving toward the use of electronic reporting and harmonization of birthdates for periodic reports. Health Canada should work with other agencies, such as the European Medicines Agency and the FDA in the United States, to undertake a single-source or one-source literature review. This would allow for a concise and highly informative report and avoid duplications in reporting.

Health Canada should provide safety information freely and without charge. Currently, Health Canada requires payment for this information, for adverse drug reactions reported directly to it. This may have the effect of potentially compromising public health, limiting the ability of manufacturers to perform risk benefit analysis and public communication.

Health Canada should take a leadership role in safety, working with all marketing authorization holders and conducting its own safety assessments, which is the current practice for the FDA.

Health Canada should also take a leadership role in coordinating the risk management activities of all relevant manufacturers and marketing authorization holders of a multi-source drug product when a safety concern is identified. This would ensure the best communication and management of the risk to public health.

Post-marketing risk management activities should be identical for both brand-name and generic products. This is the current practice, and it should continue. Generic products have the same risk management profiles as their brand-name equivalents and should not be subject to any additional requirements.

In conclusion, it is essential for all stakeholders, in particular the pharmaceutical ones, to play an active role in drug monitoring programs and to ensure that patients receive only safe and effective medicines.

Canada's generic pharmaceutical industry remains committed to good pharmacovigilance practice and to working collaboratively with both domestic and international health authorities and other stakeholders to minimize public risk and ensure the safe use of generic drugs.

Jacqueline and I both look forward to your questions this morning. Thank you. Merci beaucoup.

The Chair: Thank you, Dr. D'Cunha. I thank all the people who came in to give presentations today. They were very insightful.

We'll now proceed with the questions. The first round will be seven minutes per member.

We will begin with Mr. Temelkovski, please.

Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.): Thank you very much, Madam Chair.

Thank you to all the presenters.

Dr. Fontana, you mentioned in your conclusion that you encourage the reporting of quality safety data from the field, as a fundamental feature for the capture of adverse events. What do you mean by “encourage”? Should it be left to the professionals to decide on that, or should it be mandated, but by their professional associations? What do you have in mind?

Dr. Pier-Giorgio Fontana: We stress the importance of quality reporting, which is done in the field spontaneously by health care professionals. We also encourage them to use the CIOMS V form, which is an internationally accepted standard for reporting. We believe the use of that form, by the very nature of the structure of that template, is going to help them provide the type of information the companies will require in order to make an assessment of the risk of the association between the noted adverse event vis-à-vis the drug.

The fact that an adverse event is reported per se is not as important as all the information that is required to assess the relationship of the causality between the drug and the adverse event.

● (1150)

Mr. Lui Temelkovski: Dr. Fontana, is this format reported to the manufacturers, and is it also reported to Health Canada?

Dr. Pier-Giorgio Fontana: Generally, the way the system works, of course, is that the health care professional has the liberty of filing to both Health Canada and the manufacturer or to either. The regulations for the manufacturer are that whatever we receive, and also whatever we scan in the literature—any source of information with respect to adverse events—should be reported within the specified timelines in the regulations.

Again, the dialogue can be also directly between the health care professional and health care. As has been alluded to by one of my colleagues—I think it was Mr. Schwab—this is an area where we need to be very careful in terms of duplication of information. Obviously, duplication of information can introduce a bias, so we need to be very careful about how this is done.

Mr. Lui Temelkovski: I understand, from all of the presentations we've heard, that there's a lot of dialogue and communication between Health Canada and the manufacturers, whether they're brand name or generic. So there's a lot of communication between the two organizations, but I fail to see the connection between the communication between the joe on the sidewalk who has had an adverse reaction and Health Canada or the manufacturers. As far as I know from speaking with pharmacists, they're not sharing much information with too many people. They're not sharing it with the pharmacist down the street. They're not sharing it with the hospital down the street. They're not sharing it with too many people.

So we're looking at communication not between the manufacturers and Health Canada but between the end user and Health Canada.

Can you help us with that? Do you see the deficiencies that we see, or do you not see a deficiency there?

Dr. Pier-Giorgio Fontana: I think we all—

Mr. Lui Temelkovski: This is to everyone.

Dr. Pier-Giorgio Fontana: Yes. I'll start, if you like.

We invest a lot of resources in educating patients about the appropriate use of medication. As you know, when a product is approved, there is labelling that defines the parameters of use. We need to encourage patients to, first of all, follow the advice of the physician to look at the patient insert, a leaflet that is part of the product monograph and that is inserted with the medication.

We need to ensure that when a patient believes they are experiencing an adverse event, they communicate. Generally this is done with the pharmacist or the physician. Ultimately, though, Health Canada, either from the manufacturer or directly from the field, has access to all this information.

Patients sometimes believe that all drugs are 100% safe. As you know, this is not the case, and they have to be very cognizant about reporting any undue effect. Physicians and pharmacists have a role, when they dispense or prescribe a product, to play in that educational part, especially if it's a new approach.

Mr. Lui Temelkovski: Do they have a role, in your view, to report it?

Dr. Pier-Giorgio Fontana: Absolutely.

Mr. Lui Temelkovski: We understand they have a role to educate the consumer in front of them. If the consumer starts reading the information that is inserted, it doesn't make much sense to them unless they're in the science field. I mean, you can just imagine what it looks like to most people.

Do they have an obligation to report that, or, as I have heard, due to privacy laws they cannot report it here or there? Why wouldn't they report it to Health Canada as opposed to the manufacturer?

Dr. Skinner.

● (1155)

Mr. David Skinner: I think there are two things here. One was earlier said by Dr. Fontana, that nomenclature is very important in terms of trying to understand what we mean by adverse events. Most certainly the serious unexpected adverse events, which are the most important ones that are reported, the quickest and the most detailed, are the ones that don't actually happen as somebody is walking down the street and experiencing some other anticipated adverse event, which is sometimes known as a side effect. But when they are unanticipated and serious, those things do get reported.

The problem then becomes one of educating the patient and the consumer about what to expect from their drug therapy. As you begin to raise their expectations about some of the negative consequences that go along with the benefits, those things tend to not get reported because they're already well characterized and they're expected. So you're not getting that feedback loop as often as possible.

So having good nomenclature around adverse event versus side effect is important to make sure that the robustness of the database is really something you can base decisions on.

The second part is how do we get people to do something that they've not had to do before? How do we get physicians, province by province, to start to report more regularly these kinds of events? As I mentioned, my good old uncle, B.F. Skinner, said that the behaviour that gets rewarded gets done. And I think that's part of the problem. Is it a responsibility? Most certainly it is. Is it part of common everyday practice? No, it's not. It becomes part of common everyday practice when there is a mutual benefit to everybody participating in it.

So I think a lot of the behavioural aspects of doing good reporting relate a lot to some of the rewards that are available—

Mr. Lui Temelkovski: How much would these rewards cost?

The Chair: Mr. Temelkovski, I have to go on to Madame Gagnon.

Thank you, Mr. Skinner.

Madame.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for being with us today and trying to provide us with more insight on your various mandates and on how to interpret your initiatives.

These days, the average citizen feels that he or she may or may not be safe, given the horror stories we read in the paper about deaths, about products that are harmful to the health and about medications that ought not to be on the market. The impression is that we do not have all the information that we would like about the seriousness of the post-market process and about clinical trials.

Mr. Fontana, you say that public posting of information on clinical trials is intended to increase the transparency of the information posted. I understand your objectives. You continue by saying that the International Federation of Pharmaceutical Manufacturers and Associations has to post the results of all clinical trials and that these should be publicly accessible.

But we are not aware of the adverse events. The public has no access to those. That information seems somehow to be shrouded in mystery.

Research protocols are not published. At very least, these protocols are important in assessing the validity of the trials. Do you not think that they should be submitted to an independent body? This point has often been raised by some observers of the pharmaceutical industry.

Could there be a publication on research that leads to adverse events and on all research protocols?

[*English*]

Dr. Pier-Giorgio Fontana: *Merci pour votre question.*

The clinical database is now available through international websites and registries.

We in Canada are in agreement with the recommendation of the International Federation of Pharmaceutical Manufacturers and Associations in publishing in these registries all the clinical trials that are conducted. This is also inclusive of studies that are not started, so that from the outset the protocol or the description of that study is also publicly available.

The fact that some of the studies might not appear in the literature does not mean they escape regulatory scrutiny, because all clinical trials, including the ones that are under way, are part of the new drug submission. So there is scrutiny of all clinical trials, and post-marketing as well—phase 4 trials—will be part of this database.

There can be access, as I mentioned, through portals such as the portal of the IFPMA, and also by Rx&D, but there are other international databases, such as that of NIH or those of the other international organizations. So there is that level of access and transparency.

● (1200)

[*Translation*]

Ms. Christiane Gagnon: From the variety of evidence that we have heard this morning, one gets the impression...You know that pharmaceutical companies must give reasonable information about follow-up both on the trials process and on post-market safety. But healthcare professionals are the ones who have to provide the most information to Health Canada, and they do it voluntarily.

Why is the pharmaceutical industry not proactive? How is it that healthcare professionals have to do it? I will not list all the products that have been re-examined from an ethical standpoint and, at very least, whose negative effects and dangers should be made known. In some cases, even deaths have occurred.

BIOTECanada also comes to mind, and GARDASIL, the human papilloma virus vaccine. It is administered very widely in Canada now, even though we know that there have been five deaths in Europe. You are aware of this, of course. You said you are very proactive in providing information and making sure that products do no harm.

What does a company like BIOTECanada do? I asked Health Canada what its responsibility is and I was told that responsibility lies with the Public Health Agency. The vaccine comes from a company like your own. Now we are told that the Public Health Agency is responsible for it. I was not talking to the right person. I was under the impression that it was Health Canada, because that is the department that you have to report to. Things seem to be at an impasse.

I would like you to answer my questions.

Dr. Philip Schwab: Thank you for your question.

[*English*]

The Chair: Excuse me, Dr. Schwab. You have one more minute, just to let you know.

Dr. Philip Schwab: On your last point, the Public Health Agency of Canada is responsible for the administration of vaccines through the public health offices in the various provinces. So reporting on adverse events from vaccines often comes through the public health system, but then the ultimate responsibility for informing manufacturers rests with Health Canada in the marketed health products directorate. Because the vaccines are distributed through the public health system, they have a role in reporting, but the repository of the reports rests with Health Canada. I don't know what specific product you are speaking about, but I can say that when manufacturers of—

[*Translation*]

Ms. Christiane Gagnon: You mentioned papilloma. You know that there have been five deaths in Europe. Are you going to take it off the market for the time being?

[*English*]

The Chair: Your time is up now. I hate to interrupt you, but we'll go on to Mrs. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chairperson, and thanks to all of you for your input today. Clearly there are some very divergent views on the question we're tackling as members of the health committee.

It seems to me that when we're talking about post-market surveillance, we're really trying to get from you the best advice for how government, i.e., Health Canada, can ensure that the drugs you put on the market are safe beyond a reasonable doubt and that there are checks and balances in place by government, not by those with vested interests to do that.

I'm very concerned, Dr. Fontana, that you're suggesting, in fact, more collaboration between government and the drug industry on this front, and you have made no recommendations for how you think you need to have proper oversight to ensure that Canadians' health and safety is put ahead of your right to make profits, and that's why you're in the business.

I'm very concerned that you seem to be going along with this risk management model of Health Canada, which of course will aid and abet your bottom line but will do nothing to help Canadians. Why are you not supporting the idea of an independent board to evaluate drug safety, as I understand the representatives from the Generic Pharmaceutical Association are? I'd like to hear from both of you about your views in terms of government's role vis-à-vis safety of drugs and who is in the best position to do that.

● (1205)

Dr. Pier-Giorgio Fontana: Our industry is very clearly regulated as to our responsibility with respect to developing the appropriate labelling that describes the risk-benefit profile of the drug when it goes to market.

As you know, once the drug reaches the market, obviously there could be the occurrence of rare events, which could be serious, so there is an evolution of the labelling based on this post-marketing surveillance. The safety of a product is subject to scientific scrutiny. I believe that good science should be open and there should be checks and balances. I do not believe that safety can be in a repository in isolation, without the manufacturer, the clinical experts, the regulatory agencies, and academia. Science has to be a public forum for challenge and scrutiny. When you refer to the post-marketing diligence program that Health Canada is following now, especially with the last draft guidance that was issued last month, we see that they encourage, or they are favourable to, the use of standards that have been developed through ICH, such as E2E.

Ms. Judy Wasylycia-Leis: Let me stop you there, because in fact I'm not asking about standards. That's part of the problem, as I see it. We've moved to a paper process in which industry regulates itself based on a set of standards.

I'm talking about active oversight pre and post drugs entering the market. I'm talking about preventing things like Vioxx, which clearly was a problem of improper oversight by an independent body, because the drug company didn't do it. I'm talking about things like Evra, the birth control patch that is now on the market, for which the drug company refuses to put out warnings about the risk of blood clots and heart attacks. I'm talking about the fact that we need something to put a check on you. There's nothing wrong with that. Your job is to market and make profits. The job of government is to protect Canadians.

I want to hear from the generic organization on this front.

Dr. Colin D'Cunha: To answer the honourable member's question, our perspective is that the government has the role in regulating. Very clearly, manufacturers that have marketed health products in Canada have a legal obligation to report all adverse reactions known to them. The gap that the previous member got into was what can be done to encourage other people to report. From the perspective of the organization I work for, we receive reports from consumers, health professionals—namely pharmacists, nurses, physicians—other regulatory bodies, and the literature, to name but a few. I think the issue of whether the data should be analyzed within Health Canada or by a third party is something that should be subjected to a policy scrutiny analysis from a perception and reality perspective.

I'd like to close my comment with just one perspective. Even a glass of water is not necessarily safe because drinking too much water for someone who is not in a position to tolerate it may not be a good thing. Forget about the bacterial quality of the water.

● (1210)

Ms. Judy Wasylycia-Leis: I'd like to follow up with all of you on the idea that this whole matter should be out in the public in an open way for dialogue and discussion and transparency. Unfortunately, now it's not. It's very hard for ordinary Canadians to get information about what stages various drugs are at, what's being taken into consideration, what have been the adverse reactions, what's the best advice. The two incidents I mentioned, Vioxx being one, are worthwhile to look at just in terms of the problems with our whole process and the problem with progressive licensing, because in fact what we're seeing is the possibility of a drug on the market for one use, but it has adverse reactions in the case of another usage. It starts to open the door to the use of our drug approval process, without going through all the hoops again, for getting drugs on the market for other purposes. I think that's probably a shoddy way of doing public protection.

I'd like to know if you have an objection to full transparency about the whole drug approval process. Do you have an objection to an independent board scrutinizing both pre- and post-drug market surveillance?

The Chair: Dr. Fontana, the time is just about up, so please give a short answer.

Dr. Pier-Giorgio Fontana: We do not object. The only thing is that, again, we believe in a transparent system, in a way that the manufacturer, the regulatory agency, the prescribing physician, and the patient are part of a partnership of communication. The information is available and is becoming more and more available through the registries I mentioned. The off-label use that you referred to is something that we, the manufacturer, obviously cannot be responsible for. We know that sometimes doctors do that, but that's medical practice. We have a product monograph that clearly defines what indication, what is the target population, what are the risks.

If you look at the product monograph of a drug, you will see that there is a list of adverse events by frequency of event. As I mentioned, though, these are data coming from controlled clinical trials and a controlled environment. Once the drug goes on the market, we have to monitor. If the risk-benefit profile evolves in a negative manner, then there are means for Health Canada to remove the product or restrict the product in terms of usage.

The Chair: Thank you, Dr. Fontana.

Mr. Tilson.

Mr. David Tilson (Dufferin—Caledon, CPC): Good morning.

My question is to all the groups. I'll start with Mr. Schwab.

What is a serious adverse reaction? I know that sounds like a dumb question, but obviously complaints are made and someone has to decide whether it's serious or it's not serious. That decision has to be made, so I assume that somewhere in the bowels of regulation there's a definition as to what that is.

Dr. Philip Schwab: Absolutely, and I believe a physician or a public health professional makes a decision about when an adverse event needs to be reported, and then those—

Mr. David Tilson: I understand that. I want to know what it is. I'm just a simple guy. I don't know what it is.

Dr. Pier-Giorgio Fontana: A serious adverse event is a noxious or toxic side effect of a drug that causes potential injury, or hospitalization, or cancer—there are five or six criteria, which doctors know about, because it's also part of that reporting form I mentioned.

The serious adverse events are reported, again, in the product monograph, and again, they are defined as causing a serious injury, hospitalization, or impairment of some sort. So they are well defined.

Mr. David Tilson: Dr. Skinner, are you okay with that? Is that too loosey-goosey?

Mr. David Skinner: Actually, I was going to define it more broadly. It's any reaction that would require some medical intervention. I'll give you an illustrative example of what would be and would not be—say, a poisoning incident—because this is more commonly part of the entire database of adverse events, as well as a risk profile.

A poison control centre may indeed get a phone call from a mother worried that her child had ingested something from underneath the kitchen counter. That gets logged as a poison statistic. There may never have been an ingestion, just simply that there was a suspicion on the mother's behalf, she made the phone call, and so on. But had there been one that required the child to go to the hospital and have an intervention, that would have been logged as an actual event versus a report. So at a very simple level it requires an intervention, and it also really reinforces the need for good clarity on definition.

● (1215)

Mr. David Tilson: Does Health Canada have a definition?

Mr. David Skinner: Yes, they do.

Mr. David Tilson: This is a question to anyone. Let's move to Mr. D'Cunha.

Health Canada has said that less than 10% of adverse reactions to products are reported to Health Canada. That's not very good, if that fact is true.

Dr. Colin D'Cunha: Underreporting is a known phenomenon, not only in drugs but in other events that are subject to surveillance.

Mr. David Tilson: So what should the pharmaceutical companies do? How can they be more proactive?

That's terrible, quite frankly. Ten percent is not a good statistic.

Dr. Colin D'Cunha: The pharmaceutical companies are already required to report everything. It seems to me the challenge is to have the people of Canada, generally, and the health care professionals practising in Canada be stimulated to report, and then from a public policy standpoint, you can use the classical approach of carrot and stick. You start off with carrots. We encourage you to report, we promote you to report, we legislate you to report, and then finally, we fine you if you don't report. So from a public policy standpoint, go through the four-step progression.

Mr. David Tilson: Last week, we had Ms. Meena Ballantyne, who is the assistant deputy minister, come, and she said:

> It is the responsibility of a manufacturer to report serious adverse reactions. Health Canada also encourages

—I emphasize the word "encourages"—

> reporting from health care professionals and patients.

It seems to me that the load of the reporting is on the manufacturers, and yet only 10% is reported. That's what we're told.

Dr. Colin D'Cunha: If I may respond, I will use a practical example. The load is on the manufacturer to report what the manufacturer is aware of. If the manufacturer is not aware of something, the manufacturer, clearly, can't make up a report and pass it on.

That said, we were looking in my department yesterday at a particular product that I shall choose not to name, and we compared reports in our database to what was in the Health Canada database for reports in Canada. We had 19 in our database, and there were 11 in the Health Canada database, of which two were common, i.e., two were similar. This is why I made a recommendation to Health Canada, and to the committee today, to encourage Health Canada to share their information with manufacturers: because there is increased granularity of nine reports that I was not able to see respecting privacy law. I could see only what's up on the website, something that all of you in the committee can also see, which was not a lot of detailed information.

Mr. David Tilson: Does anybody else have any comment on this? I'm troubled by this 10%.

Dr. Pier-Giorgio Fontana: I certainly agree with my colleague that we are regulated in a very stringent manner with respect to our reporting obligations under the Food and Drugs Act. We report what is known, either through the literature or from reports of physicians, patients, or pharmacists.

Now, Health Canada regulates the manufacturers but does not regulate the medical or pharmaceutical profession, so the equality of the data or the 100% reporting is something we cannot enforce.

I certainly indicated earlier that we spend a considerable amount of resources and effort to educate physicians on their obligation to report, but it's an effort of education and of partnership.

Mr. David Tilson: If I take a drug, if I'm prescribed a drug, and there's a problem—I'm ill or there's something wrong with me—I'm not going to call up the manufacturers. I don't even know who the manufacturer is. I'm just a guy. I'm going to call up my doc.

Dr. Pier-Giorgio Fontana: Exactly.

Mr. David Tilson: But he or she doesn't have to do anything. They can say, "Oh, well, we better get you off that and get you onto something else". Meanwhile, the drug's being prescribed to other people. There's a problem there.

● (1220)

The Chair: Could you just wrap that up? We're out of time.

Mr. Skinner, would you like to make a comment on that?

Mr. David Skinner: I will just add something very quickly.

I'm always intrigued by the 10% number, because if you know that 10 in 100 are reported, you must have known that there were 100 to begin with. So the number itself is not that meaningful to me, other than the fact that it is underreported.

For self-care health products, all of ours come in original packaging. Having a 1-800 number and manufacturer contact information...we have an awful lot of consumers actually calling directly to manufacturers. But I think one of the biggest tools is an education so that patients have an appreciation for the idea that when they do get a side effect, an adverse event, and they have a concern about it, they talk to their doctors and ask their doctors to report it. If the patient isn't getting to the doctor, the doctor's not getting it. Then if they go and they don't ask their doctor to report, it may not get reported.

The Chair: Thank you so much, Mr. Skinner.

We're now going to go into our second round. I would just remind committee members that we have now five minutes per question and answer.

Mr. Thibault, would you start the questioning, please?

Hon. Robert Thibault (West Nova, Lib.): Thank you all for appearing and informing the committee.

I understand that with 10% being reported, the other 90% would be an estimate, because of the fact that people aren't required to report, either pharmacists or MDs.

I'm also a little concerned about the definition—if you're looking at serious adverse effects as opposed to adverse effects. You could have adverse effects that, if repeated over time, can become quite serious for the individual patient. At one moment, it might not require hospitalization, but it could weaken the patient and he could require hospitalization or suffer serious health effects because of other matters.

That could happen because of the improper use of a drug or the mixed use of different drugs, including self-help drugs.

I just want you to consider those things and how we capture that. I know it's not easy because we're always caught in the dilemma—where I'm sure everybody is caught—which is to make drugs available. If I have the illness, and especially if it's critical, then I'll try anything. If I'm going to die otherwise, I'll try anything. I'd like to have the drug available.

I applaud the use of off-label, but I worry that because the use of off-label isn't regulated too well, the critical events or the adverse events aren't being reported. There is no real way to report them or to share it with other professionals in the industry who may be using them off-label.

But I want to come back to the current definition. If you require hospitalization, is the hospital required to report it to Health Canada or the manufacturer at the current time?

Dr. Pier-Giorgio Fontana: The treating physician should be reporting that event.

Hon. Robert Thibault: He should be. Is he required to?

Dr. Pier-Giorgio Fontana: At the present time, it's not obligatory.

Hon. Robert Thibault: I'd like to see us find a way that you can do that, but I understand the shortage of physicians out there and I understand the burden of paperwork on them. They have to file for unemployment, for Canada Pension Plan, for insurance, and they are becoming more bureaucratic than clinical. In certain instances, you wouldn't want to raise that level too much.

But you'd think, with the electronic databases of the hospitals and all those things, that you'd be able to have a very efficient way of reporting these incidents to Health Canada and to the manufacturer.

Is any work being done on that?

Dr. Pier-Giorgio Fontana: Yes. The reporting can also be done electronically, and again, I think we have to encourage patients to report any event.

We, the manufacturer, through the source, have to report both serious and non-serious adverse events, especially the ones that are called “unexpected”, which are not in the labelling.

But I believe that at the present time the system is more efficient. I think we've also seen an improvement in the quality of reporting, as per some audits that were conducted by Health Canada over the last four or five years. So there is a certain level of compliance overall.

Underreporting is not only a Canadian problem; it's a problem in the United States, and even the FDA is wrestling with that aspect of reporting.

However, I must say that numbers are not really the only important aspect; it's the quality of these reports. As I mentioned, to make a scientific assessment of the relationship between the drug and the effect, you have to have quality data.

Your colleague mentioned earlier that some people may be reluctant to communicate this information because they do not want to lose their privacy. However, quality reporting doesn't involve the identification of the patient. You can just put initials. But you certainly need the age, you need to know the background, the terms of co-morbidity, you need to know the—

● (1225)

Hon. Robert Thibault: Do I have time for one more quick question?

The Chair: You have 50 seconds, Mr. Thibault.

Hon. Robert Thibault: Okay.

You were giving the example of 19 cases of adverse effects. I remember what I think were called beta blockers that were used to treat people with severe arthritic pain, and then there were some adverse reactions—some people had heart problems—and all of a sudden these drugs were removed from the market. I might have the term wrong. It might not have been beta blockers; it might be another drug.

The counter to all of this information being out there is that you can send out a false fear to people. If you have 19 adverse reactions out of 300,000 users, it might not warrant the other people worrying and not benefiting from the good use of these drugs. Before you send the message out to all pharmacists and all doctors and put the thing in the magazine, how do you keep that gate...not scaring people but giving them proper information?

Dr. Colin D'Cunha: First and foremost, the assumption is that one receives quality data. Typically when a case is received by a drug safety associate who is a health care professional by background, the quality of the data received is peer-reviewed, medically reviewed, and management reviewed, and then submitted as per the regulatory timelines, either 7 or 15 days for the serious expeditable or in the periodic report format that my colleague, Dr. Fontana, alluded to.

Before we can make any public communication, we invariably end up in a discussion with the regulator, no matter what jurisdiction we're in, to agree on the format of the communication and the quality of the signal or the issue we have seen. As recently as December 2007, Health Canada signed a data exchange agreement with the EMEA. They do sit in on monthly calls, so it's their forum to share information with the other regulators. This is where we don't want to clutter the system, as Dr. Fontana alluded to, with duplicate reports going in, because you falsely attribute things, which is the very point I think you were trying to make.

The Chair: Thank you, Dr. D'Cunha.

Patrick Brown.

Mr. Patrick Brown (Barrie, CPC): I want to touch upon progressive licensing. Perhaps I could get some comments in terms of your association's position on it. Also, perhaps you could discuss the phase 4 clinical trials and the more stringent safety and monitoring it may have on the marketplace and the cost that would be involved for your association.

Dr. Pier-Giorgio Fontana: The progressive licensing framework is an attempt by Health Canada to address the issue of updating the regulations and to be in line with the way new pharmaceutical products now are being developed. There is an awareness, obviously, that there are some limitations, as I mentioned, as to what controlled, double-blind, randomized clinical trials can do. They have come to grips, really, with the realization that approval cannot be a point-in-time approach but needs to be based on the life cycle of the product. That's what progressive licensing means, that you monitor the safety of the product. You study very well during the clinical program, but then obviously when the drug reaches the population at large you may see some new events that may alter the safety benefit. Progressive licensing will provide the regulatory framework to address this life cycle concept.

This is not only in Canada but also in the U.S, which is the critical path. Through the critical path there are some consortia in terms of the science that will help make that risk assessment more predictable. Now we're working on biomarkers, on solid science, and again, through progressive licensing we will have a framework to accommodate these evolving thoughts as to the most effective way of managing the drug throughout the life cycle.

● (1230)

Mr. Patrick Brown: Do you think the proposed life cycle approach would increase or decrease the number of warnings and advisories that Health Canada would make? Additionally, do you think Health Canada should have the power for a recall?

Dr. Pier-Giorgio Fontana: Yes. I believe that progressive licensing will also help the manufacturer to know exactly what the requirements or the standards are that TPD expects. We certainly encourage, as I mentioned, the harmonization of the standards, recognizing that the Canadian population is a small one so there is a need to have access to international databases, and this is where we need to have consistency of the nomenclature, consistency of standards in phase 4.

The structure of phase 4 studies can be very expensive because they involve large cohorts, so we need to make sure we address the right questions. A study that is done without proper scientific questions being addressed would not be a useful study and it would waste a lot of effort. So we have to ensure that we do the right study and that this study will comply with the evolving regulations we have been seeing.

Mr. Patrick Brown: Could you touch briefly on what the costs are of these phase 4 trials so as to maybe get an understanding of it? What percentage of the drugs produced by your companies would go through phase 4 trials?

Dr. Pier-Giorgio Fontana: I don't know. Every study is different, depending on the number of patients. But they are expensive in terms of the resources. Also, at the sides you have to have expert people within the company. You have epidemiologists. You have groups of people looking at the signals that might be emerging.

This is an expensive effort. That's why we need to ensure that there is international cooperation, so that eventually the study could be manageable at the national level.

Mr. David Skinner: Regarding your earlier question about the impact of the progressive licensing framework, one of the core messages we'd like to deliver is that we don't want to lump all products together in one framework. The progressive licensing framework, if you look at the life cycle that they've described, starts with pre-clinical trial, clinical trial, new drug submission, new chemical entity, and all that.

When it comes to self-care products, none of that applies. They've been on the market for 20, 50, sometimes 100 years. They've been through all of that. If a product has been switched from prescription to non-prescription status, they've already had 20 years of experience with all of that.

So to have the same kinds of requirements that are anticipated for new chemical entities apply to everything under part C of the regulations would be a tremendous cost barrier to things like anti-dandruff shampoos, sunscreens, and other things that you can use every day for yourself. So that's a big thing.

With respect to the authority to recall, yes, I believe they should have the authority to recall. Health Canada has the ability to cancel your licence to market, so it's a very sharp tool with a big consequence. They can't say they want you to recall a product and keep it off the market while its under study. All they can do is say your product can no longer be marketed.

So they can take a product off, but it may be killing a mouse with a shotgun.

The Chair: Thank you, Mr. Skinner, Mr. Brown.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair.

Thank you, ladies and gentlemen.

Dr. Fontana, when my colleague asked about the accessibility of studies earlier, your answer was that the studies are available through the association's portal. Since these studies come from the industry, what do you do to make sure that even the greatest sceptics can feel comfortable that the studies are balanced and objective?

[*English*]

Dr. Pier-Giorgio Fontana: All studies, as I mentioned, will be registered through public databases. The quality of those studies is discussed with the regulatory agencies and is reviewed by ethics advisory boards. So there are at least two levels of scrutiny with respect to the scientific methodology and whether the right questions are answered. This is not done exclusively by the manufacturer, so there is peer review. The information will become available, but at the outset there is a level of scrutiny that we encourage.

● (1235)

[*Translation*]

Mr. Luc Malo: You all more or less said that the rules should be brought into line with international standards. I was wondering if those included ICH standards. It has shortened evaluation periods in its criteria. I ask the question because I wonder whether shortening the evaluation period for a drug would not have major repercussions on public health.

[*English*]

Dr. Pier-Giorgio Fontana: The length of a study varies depending on the disease. I think there are obviously international standards with respect to the length of a study. To demonstrate the efficacy of a product you don't necessarily have to test the product for a year. However, certainly for safety, studies are required to be longer.

There is a sense now that standards have been lower in recent years, but I do not agree, personally, with that view. As a matter of fact, if you look at the number of studies in the average new drug submission in the last 10 years, it has doubled. The number of studies that are required for a new drug submission has doubled. The number of patients has doubled.

I do not believe we are lowering the standards. I do not believe the time to review a drug is necessarily correlated with the outcome of that review. In other words, you could have an excellent review done in six months and a terrible review done in three years. So we have to be very careful about associating this concept of time with the quality of the data, the quality of the review.

The other thing I would add is that in Canada we see drugs actually available on the market significantly later than in some other jurisdictions, so there is time as well to observe the experience on the market.

I believe we have a system here in Canada, in some cases, where the international standard actually might not be followed. Health Canada was an observer of the International Conference on Harmonization. They endorse the standards that they feel are adequate, but the don't necessarily endorse others.

I hope this will address your question.

The Chair: You just have 50 seconds left, Monsieur.

[*Translation*]

Mr. Luc Malo: I want to come back to the very first answer you gave me. I have quite a significant figure here. The figure is that 89% of studies show adverse or contentious effects which are not published in the scientific literature.

Can you comment on that figure?

[*English*]

Dr. Pier-Giorgio Fontana: The only thing I can say, again, is that virtually all studies are subject to regulatory scrutiny.

There's the editorial policy of a journal. You could submit a study to a journal and be refused publication. So I do not believe there is an intentional attempt not to disclose negative studies.

The other thing, too, is that the regulatory authorities do not discriminate in terms of saying, this study is positive, this study is negative. It's the bulk of the evidence, it's that risk-benefit balance that we look at. It doesn't necessarily come from one trial.

[*Translation*]

Mr. Luc Malo: Are you saying that it is a question of methodology and that, in some studies, it is more...

[*English*]

The Chair: I'm sorry to have to interrupt you, Monsieur Malo.

Thank you, Dr. Fontana.

Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thank you, Madam Chair.

I want to go back to some comments that have been made already. One was made by my friend in the NDP, where she stated that it's your guys' job to make money and it's the government's job to ensure safety. There was no reaction from any of you. Do you accept that, or do manufacturers have some responsibility for safety?

● (1240)

Mr. David Skinner: Manufacturers ultimately bear the burden of safety and efficacy and quality. The regulations that are in play are there to protect the public from fraud and danger. Actually, it goes to the heart of a lot of issues we talked about, such as cost recovery.

Are the activity levels that go on within Health Canada to protect the public from fraud and danger a public benefit or is that a benefit to manufacturers? If it was a benefit to the manufacturers, certainly we wouldn't have criminal law outlining fraud and danger consequences.

So we do ultimately bear the responsibility. If there's an incident, regardless of what the regulations may say, the manufacturers are going to have to be accountable for that, in a commercial way, in a safety way, in every sense of the word.

Mr. Steven Fletcher: Out of fairness, I wanted you to have an opportunity to clarify that.

Dr. Colin D'Cunha: From my perspective, if I may draw your attention to the bottom of page 2 from my presentation, it says, “To protect public health by monitoring for the safety and efficacy of our products.”

Enough said.

Mr. Steven Fletcher: I love the different uses of words. In one of your comments you said that in an effort to get doctors to report, we need to “stimulate” them to do so. I wonder if—because I don't have enough time here to hear how you would stimulate doctors to do so—you could table to the committee a list of stimuli that would encourage that.

Dr. Colin D'Cunha: Being aware that the Canadian Medical Association is presenting to you on February 26, and as a member of the CMA, I'll defer to what the association tables before I decide to make further comment.

Mr. Steven Fletcher: Okay.

We don't have time to hear it all now, but I would also encourage you to table to the committee any key gaps in current legislation or regulations in Canada for ensuring post-market safety of products. I think we would all be very interested in hearing what you have to say.

My last question is, does your industry support Health Canada's proposal to move to a life-cycle approach to regulating health products, which could include attaching conditions to the licences of products, which companies would need to fulfill to keep their products on the market?

Dr. Pier-Giorgio Fontana: Yes. We encourage the approach, as I mentioned earlier, through progressive licensing.

One area where again we should be cognizant, because the resources are limited and the data necessarily has to be large, is that we need to ensure that whatever we do will be Canadian regulation, structured in a different way but so that ultimately the standards that will be required for post-marketing are somehow homogeneous, so that the questions that are being raised through post-marketing trials are valid scientific questions with a very clear outcome.

There are epidemiological methodologies now that require scientific discussion. As I mentioned earlier, good science is not the prerogative for any group, and that's why we encourage the spirit of transparency and collaboration. ICH is a forum; CIOMS is a forum. There are all kinds of international fora to ensure that we are all aligned.

The Chair: Mr. Fletcher, you only have about 50 seconds.

Mr. Steven Fletcher: I'll just let the members respond. I'm done with my questioning.

Dr. Philip Schwab: I'd like to respond to that briefly. Our members have been very actively involved in discussions with Health Canada around the progressive licensing framework and the life-cycle approach.

Regarding your specific question around marketing approvals with conditions, we are examining that quite closely as well. We would just add the caveat that discussions around that type of framework need to also occur with the provinces, because our members who manufacture biologic products are somewhat concerned that anything less than a full market approval by Health Canada will inhibit the ability of provinces to make positive decisions regarding reimbursement of those products. We encourage very careful collaboration, so that provinces definitely understand what those notices of compliance with conditions actually mean.

● (1245)

The Chair: Thank you so much, Mr. Schwab.

Mr. Skinner, did you have a couple of comments?

Mr. David Skinner: I'll add very quickly, because it goes to something I raised earlier, that the life cycle changes, and having attachments to that.... I'll give you a good example.

Vitamin K, until recently, was a prescription drug. There's a lot of history behind that. Some of the attachments to how it's sold depend on its final use. As a prescription drug, it has certain aspects with respect to post-market surveillance. If you expose that to a larger audience without the intervention of a health professional, then you can attach other kinds of post-market requirements to give you feedback. Then, as you discover that there's no increased ADR as a result of it, you can remove some of those encumbrances. So it does have a good, positive life-cycle approach when applied appropriately for the kind of product you're thinking of.

The Chair: Thank you, Mr. Skinner.

Mrs. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chairperson.

Well, as usual, my good friend Steven Fletcher has distorted and taken out of context my remarks. Let me try to get back to what I think is the issue of the day, which is recognizing that drug companies, both brand name and generic, have a responsibility for their products.

It's also recognized that you can't have the fox in charge of the henhouse, so our job today is to try to find a way to make sure that there is good oversight from the government of those companies producing the products in which you obviously have an interest in terms of your profit margins.

My question is, given an issue such as the one involving Vioxx, where drugs on the market doubled the risk of heart attacks and stroke and three million prescriptions a year were being written when it was taken off the market, have we learned anything from it? And what changes do you think government should put in place to protect Canadians from that kind of situation?

Does anybody want to answer that?

Dr. Pier-Giorgio Fontana: I can certainly comment on the fact that some of these instances have shown that adverse events can occur after a number of years. And the post-marketing effort that Health Canada is trying to regulate in a more structured manner takes care of the recognition that side effects sometimes can happen after so many thousands of patients have been exposed.

Ms. Judy Wasylycia-Leis: But I don't think we're seeing that from Health Canada. Whichever incident we're looking at, there's usually a history of all kinds of evidence and all kinds of reports of problems. Canada is very slow to react before getting involved in trying to get more stringent warnings, and it never gets involved in withdrawals. There is no process. It doesn't engineer a process afterwards to see whether the drug was withdrawn soon enough. There's never any analysis.

We have a situation.... I'll go back to Ortho Evra, the patch for birth control. It's on the market. The drug company is basically saying that it's safe but might not be safe for a certain high-risk group of women. But there's no withdrawal. There are all kinds of lawsuits in the States. There are settlements by the drug company. We're sitting in Canada. We're going to wait. We have 93 incidents already in the one year, of which 17 were serious. There were two deaths. So when does something kick in when we have enough information to protect Canadians and tell them that there is a serious risk if they take that drug? We don't have that now. So what do you suggest ?

Dr. Pier-Giorgio Fontana: There have been recent cases of market withdrawal when the information, for example, originated in Australia, and that information was communicated by the manufacturer to Health Canada, and there was an agreement between the manufacturer and Health Canada to withdraw the product.

We have to realize that sometimes, as in these cases, some patients benefit from the drug. Also, when you withdraw that product from the market, you have to address issues. What are you going to do with people who really benefit from that drug because—

Ms. Judy Wasylycia-Leis: Okay, fine. Then put on a label that says clearly, “This product could cause blood clots or heart attacks”.

Dr. Pier-Giorgio Fontana: We are doing that.

● (1250)

Ms. Judy Wasylycia-Leis: Well, it's still not clearly on the label with respect to Evra.

Dr. Pier-Giorgio Fontana: I cannot comment.

The only thing is that "Dear health care professional" letters are accompanied as well by public advisories on the Health Canada website. So again, in terms of transparency, we are not just communicating this information through Health Canada. Health Canada will then decide whether there is a benefit to changing or altering to the point where substantial steps have to be taken to restrict the product. But the patient is also advised, so there is a way of communicating now.

Ms. Judy Wasylycia-Leis: Well, in the case of, say, Evra, the patients weren't advised. So lawsuits were entered into, because serious harm and death happened, because there wasn't that information.

So why wouldn't we then, if we're going to enter into this risk management model, err on the side of telling all? Say there are problems with this drug in certain circumstances. Be up front about it from your end, from Health Canada's end, and from the doctor's end, as opposed to waiting and seeing what the science is. Why don't we accept the science and practise the "do no harm" principle?

Dr. Pier-Giorgio Fontana: When those risks are well established and there is consensus about those risks, the labelling goes on to the extent that you even have what is called a framed warning. So it's very clear in the labelling what the major risks are.

If you look at the labelling of some drugs, especially drugs for critical care medicine, you will see that these drugs are very frequently accompanied by very clear, bold.... The problem is that sometimes people do not take these warnings seriously. The manufacturer is really doing everything possible to communicate that information. Doctors have, of course, the responsibility to prescribe appropriately, and the patients have to have a dialogue with the physicians to report how they feel, and they have to read the patient leaflet.

Ms. Judy Wasylycia-Leis: Sometimes doctors don't know, as in the case of Vanessa Young, who died because she had a drug for the wrong—

Dr. Pier-Giorgio Fontana: But the labelling was correct. The labelling was correct.

The Chair: Thank you, Dr. Fontana. Our time has run out now. Thank you, Ms. Wasylycia-Leis.

I just want to say that Mr. Tilson is next for questioning. But we are running out of time. There is a new committee coming in at one o'clock, and this committee does have two pieces of business that have to be completed before one o'clock. So there is no time for further questions.

Go ahead, Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): On a point of order, I have a suggestion.

I've never done this before, but I think the questions the Library of Parliament prepared for this hearing are so exceptional. Because this is so complex, I wonder if we could agree as a committee to put those questions into a letter to these witnesses and have them answer in writing. I don't think we're going to be able to figure out exactly what the concerns have been in a complete way without getting answers to questions such as their participation in the blueprint and a number of other things.

I suggest that might give more information to the researchers and to us, as parliamentarians, with which to write the report.

The Chair: Thank you, Dr. Bennett.

Mr. Fletcher.

Mr. Steven Fletcher: My concern is that we had the opportunity to ask those questions. Also, I don't know how much time or how many resources that would take for the witnesses. We may be asking them to do an excessive amount of work. Do they know what they're getting into?

The Chair: Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I think Carolyn's suggestion is an excellent one. It's a matter of sending all the questions to the witnesses and asking them to answer to the best of their ability. If there are problems, they'll let us know. I think it would be very helpful.

The Chair: Could we have a consensus? Who agrees that we should send the questions in? Can I have a show of hands, please?

[*Translation*]

Ms. Christiane Gagnon: Does that mean questions that we are asking here today, or questions that we ask in writing?

[*English*]

The Chair: It's in the briefing notes.

We will do that then and submit those questions.

There was a consensus, Mr. Fletcher.

An hon. member: It's tied, Madam Chair.

The Chair: It is tied. Let's try it again.

Who would like the questions sent to the clerk? Raise your hand.

There are five.

Who is against doing that?

There are two.

Well, we haven't got a consensus. Having said that, I would excuse the presenters.

Excuse me, presenters, could I ask you to do something for me, please, as chair? If you could, and with our thanks for your presentation, I would like you to quickly exit outside the door, and if anyone wants to speak with you, they can speak with you outside the door. We have two pieces of business, and I do have another committee that needs to be in right away.

I sincerely thank you for your presentation today. It was very insightful.

If I could get the committee together as our presenters are making their way out, I would like to ask two things of the committee.

We will be asked to adopt a budget at next Thursday's meeting. This is to cover the expenses of witnesses, who will be travelling to Ottawa, as well as to cover part of our study on post-market surveillance.

We also have another issue. There has been a request for some fruit and cookies to be brought in because we have a meeting between eleven and one. The cost is not very much; it's around $50 a meeting. The sandwiches are very expensive, but cookies and fruit will tide us over and are not too much. Can we agree that it is okay to bring those in?

Some hon. members: Agreed.

The Chair: Yes, it is agreed. Thank you. We will do that.

I would also like to remind members to please send in their suggestions for witnesses for future meetings on toy regulations. That meeting is on April 1. We need witnesses and we don't have them. We also need witnesses on natural health products. That meeting is on April 15. The clerk emailed your offices last Wednesday concerning this matter. We're bringing this up because the witnesses have not come forward.

Ms. Kadis.

● (1255)

Mrs. Susan Kadis (Thornhill, Lib.): Along those lines of committee business, I thought it was very important today to mention that this committee should seriously examine these baby products. There has been a suggestion that they may be dangerous, and this was just very recently out into the public. I think it behooves the committee to, in some way, find an opportunity, perhaps by having an extra meeting. I know I'm willing to do it because this involves children and babies.

The Chair: It's two minutes before one o'clock. Perhaps what we can do is put that on the agenda for Thursday's meeting for discussion. We could put it in the toy products one.

This meeting is adjourned.

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

Also available on the Parliament of Canada Web Site at the following address:
Aussi disponible sur le site Web du Parlement du Canada à l'adresse suivante :
http://www.parl.gc.ca
