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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1110)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Could the committee come to order?

I would like to welcome everybody and ask everyone to please be seated. We're going to have quite a rigorous morning today.

Pursuant to Standing Order 108(2), I'd like to welcome you to the third meeting of post-market surveillance of pharmaceutical products, prescription and non-prescription.

We have with us witnesses who will be taking part in today's panel on federal, provincial, and territorial issues. I'd like to welcome the witnesses who made it today.

Unfortunately, one of our witnesses, Ms. Susan Paetkau, from the Ontario Ministry of Health, will not be with us today due to the bad weather in Toronto. If any of us has ever gone through Toronto on a snowy day, we know we often have the same problem she's had.

We do have witnesses. There are representatives from the Canadian Institute for Health Information and the Patent Medicine Prices Review Board.

I would like to remind witnesses that they have ten minutes per organization to make their presentations. The committee will hear all presentations before proceeding to questions from the members of the committee.

I would like to begin with Ms. Glenda Yeates, president and CEO of the Canadian Institute for Health Information. Welcome to the committee, Ms. Yeates.

Ms. Glenda Yeates (President and Chief Executive Officer, Canadian Institute for Health Information): Thank you very much.

On behalf of the Canadian Institute for Health Information, I want to thank you for inviting us to be part of your study on post-market surveillance.

[*Translation*]

The Canadian Institute for Health Information, or CIHI, gathers data on the health care system , which it then makes available to Canadians. CIHI was set up by the federal, provincial and territorial governments as an independent, not-for-profit organization dedicated to ensuring a common vision of health information in Canada. Our goal is to provide timely, accurate and comparable information.

CIHI's data and reports focus on health policies, support the effective delivery of health care services and inform Canadians about factors that contribute to good health.

● (1115)

[*English*]

CIHI's 16-member board of directors is proportionally constituted to create a balance among health sectors and among regions of Canada. It links federal, provincial, and territorial governments with non-governmental health-related groups, such as regional health authorities.

CIHI produces reports focused on health care services, population health, health spending, and health human resources, thanks to information that's supplied to us from hospitals, regional health authorities, governments, professional associations, and other partners.

Recently CIHI has been developing two new databases in the pharmaceutical area: the National Prescription Drug Utilization Information System, or NPDUIS, and the Canadian Medication Incident Reporting and Prevention System, or CMIRPS.

The National Prescription Drug Utilization Information System was built—and I quote here from a federal-provincial-territorial Ministers of Health press release—“to provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used and on sources of cost increases”.

In 2002 CIHI received funding for the development and implementation of a claims level database, with data and ongoing support from the federal, provincial, and territorial governments. The project is a collaboration with the Patented Medicine Prices Review Board. Each organization will take the lead in areas in which that organization has the expertise, experience, and mandate. Overall, the NPDUIS database provides access to standardized information on prescription drug use and costs from across jurisdictions; information that will facilitate the informed management of drug plans; exploration and analysis of the interplay among plan design, formulary listings, and utilization; analysis of the impact of policy decisions on utilization; analysis of trends in utilization over time and across jurisdictions; and new knowledge through analytic studies.

Due to its complexity, the NPDUIS database has been developed in stages. The first stage was to incorporate drug product information from Health Canada's drug product database as well as formulary and plan information from public drug plans across the country. The majority of federal, provincial, and territorial jurisdictions are currently supplying this information.

The second and much larger phase is the development of the system to hold the claims data. This includes the following information: what drug was dispensed when to which person where, who prescribed the drug, how often the prescription was filled, how much of the drug was dispensed, and how much it cost. Although the patient information is de-identified—for example, there are no names or addresses—this is done in such a way as to enable tracking of drug claim patterns over time. It's important to note that claims data does not include the reason a drug was prescribed, nor does it capture adverse drug reactions.

The current primary data sources for NPDUIS drug claims are provincial drug programs. The data is submitted once policy and technical issues are resolved. these include the legislative ability to provide the data to CIHI, privacy concerns, and the circumstances under which the data can be shared and/or disclosed by CIHI. For example, the data that is accessed by the Patented Medicine Prices Review Board for their analysis is governed by legal agreements between CIHI and each jurisdiction that is submitting the data. As data custodian, CIHI ensures that the data is collected and kept safe and secure for purposes of analysis and research, consistent with our mandate. And on an annual basis, we notify the jurisdictions of how the data has been accessed.

As of February 2008, NPDUIS includes provincial public drug claims data from the plans in Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia, and Prince Edward Island. We are in active discussions with many of the other jurisdictions.

The NPDUIS database is used by CIHI to conduct analysis and to produce reports, is shared with PMPRB for their NPDUIS work, provides an environment in which drug plan managers can conduct analysis, and is a means by which researchers and non-government organizations—such as, for example, the Canadian Agency for Drugs and Technologies in Health, CADTH—can access data according to our privacy policies and principles.

An example of how NPDUIS data can inform the health of Canadians is reflected in the first analysis released by CIHI last September. Here the database was used to identify trends in potentially inappropriate medication use among seniors. The analysis examined claiming patterns for seniors on public drug programs in Alberta, Saskatchewan, Manitoba, and New Brunswick. Specifically, we calculated the proportion of seniors on public drug programs who were using drugs that are either internationally recognized as potentially inappropriate for seniors due to the elevated risk of adverse events or are on a list developed by gerontologist Dr. Mark Beers.

● (1120)

So while I believe this type of study to be a very powerful example of the types of analyses that NPDUIS can support, I should also point out that there are some limitations in the types of analyses that can be performed using the database, in some cases due to privacy concerns or in others because of the lack of availability of the data. For example, our sub-geographical data is limited, in-hospital and private sector drug use data are currently not available in the drugbase, and there are some data-sharing conditions that are stipulated by the submitting jurisdictions.

I will now turn briefly to the other initiative you kindly invited us to speak about, the Canadian Medication Incident Reporting and Prevention System, or CMIRPS. This is a hospital-based reporting system which is in its developmental stages at CIHI and will be pilot tested later this year. We are working closely with Health Canada, the Canadian Patient Safety Institute, and the Institute for Safe Medication Practices Canada to coordinate our country's ability to effectively manage information on medication errors through the development of this database.

I should point out that CMIRPS, as currently designed, does not capture adverse drug reactions. Rather, it is designed to measure system errors caused by inappropriate human actions, such as the patient being given an incorrect medication or the wrong dose of a medication in a hospital setting. Data collected by hospitals and submitted to CMIRPS will be analyzed to inform systems and process redesign, which in turn will make it possible to deliver safer patient care.

That brings me to the conclusion of my presentation. As an organization that is dedicated, and even passionate, about the power of health information to improve health and health services, we want to thank you very much for your interest in our emerging databases.

I will be happy to answer your questions.

The Chair: Thank very much, Ms. Yeates.

Let us now hear from Dr. Brien Benoit, chairperson of the Patented Medicine Prices Review Board. Sir, could you give your presentation?

Dr. Brien Benoit (Chairperson, Patented Medicine Prices Review Board): Thank you, Madam Chair.

Good morning. Bonjour.

On behalf of the Patented Medicine Prices Review Board—and we will call ourselves the PMPRB from here on out, as it is a lot easier—I am pleased to have this opportunity to appear before this committee to discuss the work of the National Prescription Drug Utilization Information System, also called NPDUIS. These acronyms are in our jargon, and if they become part of your jargon, we'll just use those acronyms if it's okay.

[*Translation*]

With me today is Barbara Ouellet, Executive Director of the PMPRB. Following my opening remarks, I will be pleased to respond to any questions you may have.

[*English*]

Permit me to preface my comments today by offering a very brief overview of the PMPRB's role and mandate. We appeared before this committee last year, and many of you have probably heard these next comments, but I see there are new members sitting around.

The PMPRB was established by Parliament in 1987—we've just celebrated our 20th anniversary—under the Patent Act as an independent quasi-judicial tribunal. Although part of the health portfolio, the PMPRB carries out its mandate at arm's length from the Minister of Health.

The PMPRB has a dual role. The first part of that role focuses on the PMPRB's regulatory function, which is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to overall Canadian health care. This involves the review of prices of more than 1,100 medications. So every year we have 1,100 or so medications under our jurisdiction, and each year, on average, we have 75 new medicines that come under our umbrella.

[*Translation*]

Pursuant to the Patented Medicines Regulations, 1994, patentees file information on their patented medicines sold in Canada, including on pricing information. In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is indeed excessive, it may issue an order for the reduction of the price to a non-excessive level and for the offset of the excess revenues accrued by the patentee.

● (1125)

[*English*]

Our reporting role constitutes the second part of our mandate, and I believe this is mostly what you're interested in today. Under this role the PMPRB reports on pharmaceutical trends of all medicines and on research and development spending by pharmaceutical patentees, hence contributing to informed decision- and policy-making. The PMPRB reports annually to Parliament through the Minister of Health.

In addition to these reporting responsibilities, under section 90 of the Patent Act the Minister of Health has the authority to direct the PMPRB to inquire into any other matter.

[*Translation*]

In October 2002, following approval by the Federal-Provincial-Territorial Ministers of Health of a Business Case for the implementation of the National Prescription Drug Utilization Information System (NPDUIS), the Minister of Health directed the PMPRB to undertake specific areas of activity related to this new system.

[*English*]

NPDUIS is conducted through a partnership between the PMPRB and the Canadian Institute for Health Information—and you've just heard Ms. Yeates explain her role in all of this. CIHI is responsible for the creation and management of a database of individual public drug plan claims-level data and produces reports of broad interest to stakeholders, while the PMPRB undertakes most analyses of trends in pharmaceutical prices, expenditures, cost drivers, and key policy-relevant questions as described in the business case and endorsed by a steering committee composed of participating federal-provincial-territorial drug plan managers. All jurisdictions are currently participating except Quebec. Ultimately, NPDUIS is a tool to inform and support decisions on drug utilization, cost trends and projections, and overall policies of federal-provincial-territorial drug reimbursement programs.

The work of NPDUIS is not directly linked to Health Canada's responsibility for post-marketing surveillance of pharmaceuticals; however, NPDUIS does involve a number of complementary activities.

[*Translation*]

NPDUIS was originally envisaged to provide a range of important and objective information on: aggregate drug cost and utilization trends as well as factors driving drug utilization, using nationally standardized indices, prescribing patterns, and potential impacts on drug plan budgets from new, or about to be launched, drug products.

[*English*]

Since the inception of the NPDUIS, the PMPRB has released a number of publications under its NPDUIS analytical studies series, the most recent of which include: *Pharmaceutical Trends Overview for selected provinces and First Nations*, published in June 2006, which examined expenditure and price trends among public drug plans; *Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada*, from May of last year, which set out best practices, tools, and methodologies for use by the pharmaceutical industry in predicting the potential financial impact of introducing a new pharmaceutical as part of its submission to a public drug plan for purposes of obtaining the plan's agreement to list the drug on its formulary and provide reimbursement for beneficiaries; and the *New Drug Pipeline Monitor*, June 2007, which, on an ongoing basis, identifies and summarizes information on new drugs that are expected to be launched in Canada within the next two to five years that could potentially have a significant impact on federal, provincial, and territorial drug plan expenditures.

[*Translation*]

A list of additional NPDUIS publications and information can be found on both the CIHI and PMPRB Web sites.

NPDUIS projects currently underway include a new edition of the Pharmaceutical Trends Overview Report and a Methodology and Tool for Forecasting Drug Plan Expenditures.

[*English*]

With respect to the forward agenda for NPDUIS, last week the federal-provincial-territorial NPDUIS steering committee discussed potential research priorities for 2008 and 2009. These include financial implications for public drug plans of long-term demographic shifts, high-cost claimants, methodologies to identify prescribing patterns and track uptake of new drugs, indices to measure trends in drug therapy costs for major health problems, drug utilization relative to expenditure limitation arrangements, pharmacy dispensing fees, and rapid response for ad hoc requests.

The partnership between the PMPRB and CIHI and the collaboration with federal-provincial-territorial drug plans through the steering committee make NPDUIS a valuable resource that provides policy-makers with information and insights regarding Canada's public drug reimbursement programs. For its part, the PMPRB is committed to making this partnership as successful and productive as possible, and to the best of its ability, using objective analytical expertise to analyze questions of public importance.

● (1130)

[*Translation*]

The PMPRB saw its reporting role further evolve in 2005 when it was directed by the Minister of Health, on behalf of himself and his provincial and territorial colleagues, to also begin monitoring and reporting on the prices of non-patented prescription drugs.

[*English*]

Funding for this initiative and for NPDUIS has been provided separately by Health Canada, but both activities will be merged under the umbrella of NPDUIS beginning in 2008-2009. This means that, to the extent possible and appropriate, future NPDUIS studies would analyze issues from the perspective of both patented and non-patented drugs.

[*Translation*]

Thank you. I would now be pleased to address any questions you may have.

[*English*]

That's all, Madam.

The Chair: Thank you so very much.

Members of the committee, the first round is seven minutes, and we'll address the questions to the witnesses.

We'll start with Dr. Bennett, please.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you very much.

I need clarification from the chair. In terms of the federal-provincial-territorial working group or conference, are these witnesses prepared to answer questions on what they're up to, or will Susan Paetkau be re-booked?

The Chair: Yes, we will try to get her back here at another time. Thank you, Dr. Bennett.

Hon. Carolyn Bennett: I thank the witnesses for the presentation. It's very helpful to the committee to hear what you're up to now, but I would love to know what you think should happen.

Dreaming in technicolor, if you had the best possible data in order to do post-market surveillance in a real-world way, what would that system look like? I understand that we haven't yet asked Infoway to come, but I believe that post-market surveillance can be Canada's present to the world, and that we could figure out a way to do things better because of our single-payer system.

At the moment, what I'm hearing is that CIHI is still getting only billing data and provincial drug program data. You're not getting data from long-term care institutions. Is that right? You're not getting hospital data, and you're not getting diagnoses. So you don't know why it was prescribed, and you don't get a notice if someone changes from this medication to that medication. Can you track that or not?

Ms. Glenda Yeates: Yes, we can.

Hon. Carolyn Bennett: But in a real data set, if there were another field there that said why they'd changed, you would have a much better handle on what was going on. Is that right?

Ms. Glenda Yeates: We have a claims system, so it's all of the information that one would typically submit to a provincial government to make a claim: who did the prescribing; who got the prescription; what they prescribed; what they filled in terms of the prescription. But you're absolutely correct; it does not include diagnoses.

Hon. Carolyn Bennett: It sounds as though you're trying to make patterns out of incomplete data sets. In terms of your being able to write a report, as the Canadian Institute of Health Information, you can't really give us a report on what's happening on drugs in Canada.

Ms. Glenda Yeates: Certainly NPDUIS, we believe, is a huge step forward. It will be a massive database, much better and bigger than everything we've ever had. We think it will allow us to track patterns that we've never been able to track before, because in some cases we may be able to link those to hospitalization, for example. We have other data sets. I've been asked to speak about the pharmaceutical ones, but we do have other data sets as well.

But you're absolutely right: there are some limitations to what you can do, even with these very large data sets.

● (1135)

Hon. Carolyn Bennett: So if we're getting only 10% reporting on adverse reactions, and it sounds as though we're getting none from hospitals, the regulations don't seem to be there.

So tell me, in the best possible world, what would CIHI want to have in order to do your job properly, to be able to do an annual report? Would that include e-prescribing, where, with the identifiers off, the data came directly to you?

Ms. Glenda Yeates: I'll speak to both of those questions.

In terms of the adverse event reporting, first of all, currently no one submits that information to us, and there are no plans for that at the current time. We certainly believe that efficiency in data information is our strength. We think we're very good at standardizing databases. We have good relationships with data providers and in general we think we're a very good place to standardize data. Just as we are able to do that, develop NPDUIS, and then we have agreements with the submitting jurisdictions that we can give access to that data to PMPRB with their regulatory mandate, it's certainly possible that we could, if it were desired by all involved, perform that function as well.

I do think there is some efficiency to be gained by having the data collected as few times as possible, rather than in numerous ways.

Hon. Carolyn Bennett: Would you recommend that on the prescription pad or the BlackBerry prescribing, the diagnosis should be there?

Ms. Glenda Yeates: In terms of the electronic health record, we certainly see the future of what we sometimes call health system use or secondary use like this, drawn from an electronic health record, as being a tremendous efficiency. I think there's a tremendous possibility there.

I understand, for example, that in some jurisdictions diagnosis is not something that is permitted to be shared. I think that's the case in at least one province that I'm aware of. Certainly the limitations of public acceptability and what's available to be shared would need to be worked out. Certainly we think we are a good repositing place for that secondary use of data or the health system use. If we can simplify that and have it come directly from an electronic health record, we think that offers great efficiency in the future.

Hon. Carolyn Bennett: There were two reports. One was the consultant's report on medicines that work for Canadians, the business plan. It was commissioned, I believe, by Health Canada. The other is the blueprint. Can you just tell us how involved you were in both those reports and whether you agreed with the recommendations and whether you see anything changing?

Ms. Glenda Yeates: If I'm understanding the reports you're referring to, we were not involved in those reports.

Hon. Carolyn Bennett: Were you involved, in PMPRB?

Mrs. Barbara Ouellet (Executive Director, Patented Medicine Prices Review Board): No.

Hon. Carolyn Bennett: Maybe we could figure out what consultation means. I'm not sure they can do this without you two. That's a bit shocking, actually.

I think I'll stop there.

The Chair: Thanks, Dr. Bennett.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you, Madam Chair.

Thank you for joining us today. I would like to begin by sharing some general impressions with you. Many players are closely monitoring the whole issue of pharmacovigilance, or the science of assessing the safety and effectiveness of pharmaceutical products, including your organization. What the committee needs is an organization chart showing all of the players, along with their different responsibilities.

Does Health Canada have this kind of organization chart that shows what responsibilities different organizations have and who reports to whom? Today, we are hearing from two of the main players, the Canadian Institute for Health Information and the Patented Medicine Prices Review Board. It is rather difficult for us to see how your respective responsibilities are connected, even though you claim to work with each other. Is an organization chart like this available from Health Canada?

[*English*]

The Chair: We could ask the clerk to get that documentation for you. I believe she has it, if that will help. The clerk will get that information for you, if that is helpful to you, Madame.

● (1140)

[*Translation*]

Ms. Christiane Gagnon: I see.

Mr. Benoit, you stated that your organization, the Patented Medicine Prices Review Board, determines if the prices charged for medicines are fair and justified. Why then do we have the impression that increases in the price of pharmaceuticals are excessive? Moreover, these increases put a strain on the health care system, because substantial sums are invested in pharmaceutical pricing. Many patients find the price of their drugs too costly. Rarely do we hear the PMPRB explain to us that some medicines are too expensive.

How do you go about informing the public of the choices you make with respect to a particular drug?

Dr. Brien Benoit: Thank you, Madam.

I can answer that question. First of all, the role of the PMPRB is to protect Canadian consumers from excessive prices. The meaning of the word “excessive” is poorly understood by the public because drug companies will tell you—as they no doubt did last time they appeared before you—that they spend a considerable amount of money on R&D. Our role, however, is to define the word “excessive” and we do that in several ways.

Firstly, our scientists analyse all of the clinical studies done on a drug. We ask them to identify therapeutic comparators, beginning with comparators in Canada, and if that is not possible, those in seven countries, for example the United States, Great Britain, France and so forth. We compare prices. A price is deemed excessive if it is much higher than the price of these comparators.

The public only looks at the excessive price. It thinks the price is high, but it may not be aware, however, that a particular drug is the only one that can treat a particular illness.

There are different categories of drugs. A drug that is the only available treatment for a particular illness would be a category 2 drug, meaning that its benefits are recognized as being much greater than those of its comparators. This fact justifies charging a much higher price for the drug.

Ms. Christiane Gagnon: The perception exists—and the numbers bear this out—that pharmaceutical companies invest less in research and far too much in marketing. What is your opinion? You claim that they invest heavily in research? Others have observed that...

Dr. Brien Benoit: I would not say they spend “heavily”, Madam.

Ms. Christiane Gagnon: Okay then.

Dr. Brien Benoit: They do invest in research and each year, we do an analysis, since they are required to disclose how much money they have invested in their research efforts.

When Parliament created the PMPRB in 1987, it called on the pharmaceutical industry to invest 10% of its gross revenues in research. The industry may have achieved, or surpassed, the 10% target once or twice over the past twenty years. Last year—Barbara is feeding the information to me—pharmaceutical companies spent 8.5% of their gross revenues on research initiatives.

This figure excludes advertising geared to doctors and the like. It represents money that is invested in primary research and in clinical trials.

Ms. Christiane Gagnon: Ms. Yeates, you stated that your organization plays a supporting role. How do you decide where to target your research efforts? You mentioned some of the areas on which CIHI focuses its research. Who tells you where you should be focusing your attention? After all, a number of organizations are interested in the side effects or effectiveness of drugs. Who provides you with the information and how to you go about getting additional information? For example, do you rely on MedEffect for information on the effectiveness of a particular drug?

Ms. Glenda Yeates: Perhaps I would be better off answering that question in English, given my French language skills. The subject matter is rather technical.

● (1145)

[*English*]

We have a number of advisory groups. We also speak to the drug plan managers across the country if they have concerns or issues in the management of their drug plans. That's one source. We also talk to other experts in the field.

We have a certain expertise, and there are many others, in university research settings, for example, who have different expertise. We try very hard not to duplicate the work they might be doing. We look for gaps in research that our data can answer, which is relevant and deemed important by experts in the field.

[*Translation*]

Ms. Christiane Gagnon: For example, does...

[*English*]

The Chair: Madame Gagnon, I'm sorry, your time is up. It's over seven minutes. Thank you.

Mr. Tilson.

[*Translation*]

Ms. Christiane Gagnon: Do I not have a few more seconds?

[*English*]

Mr. David Tilson (Dufferin—Caledon, CPC): I'm one of the new boys here, so I'm not as informed as some of the other members. But as I understand the process, we're trying to determine how we can lessen the effects from drugs, either through human error or some defect in the drug that wasn't caught in the pre-examination.

As I also understand it, from what has been said by other witnesses and what you're saying, the only people who report to the Ministry of Health are pharmaceutical companies, although it's going to be suggested that hospitals report. Doctors don't and long-term-care people don't—the others who Doctor Bennett referred to.

You, Ms. Yeates, only look at human error. I think that's what you said. So there appears to be a problem.

Monsieur Benoit, your issue is that you have a general mandate and you can get into all kinds of things.

Because of that, I look to both of you, through your experience and what you're doing, for recommendations to the Government of Canada as to how the process could be improved.

We'll start off with you, Monsieur Benoit.

Dr. Brien Benoit: First of all, the PMPRB's role in reporting has primarily a financial impact implication. Our interest in collecting or using a lot of the CIHI data is to analyze it so that we can help the public drug plans better manage their operations. We tell them what's coming in the future—

Mr. David Tilson: Okay. I don't know whether you philosophize as to your recommendations—

Dr. Brien Benoit: I'm just trying to say that our particular mandate at the moment is primarily financial. If we were to take on something like the mandatory reporting of adverse events, we would have to create a different structure.

I'm also a practising physician, so I know many—or most, I would say—adverse reactions don't ever get reported. Most of them, fortunately, are relatively minor, and the only ones that will eventually come to—

Mr. David Tilson: As I understand it, Dr. Benoit, from previous witnesses, the only things that are reported are serious adverse reactions.

Dr. Brien Benoit: That's exactly what I've just said. Most of the minor adverse reactions are not reported. If this committee is to make a recommendation—I'm going to speak for our particular organization—we would like to know what your objective is, and then we could say how we would fit into that objective, because at the moment, adverse reaction is not part of our business.

Mr. David Tilson: Ms. Yeates.

Ms. Glenda Yeates: Thank you for the question.

I should maybe be clear: we are not a federal body, we are not a regulatory body, and we are non-profit—

Mr. David Tilson: I understand that. It's just that both of you are aware of the problem—

Ms. Glenda Yeates: Yes.

Mr. David Tilson: —and it's in that capacity that I'm asking you to offer your suggestions.

Ms. Glenda Yeates: Our expertise is in collecting and building databases. If it was desired that we build a database that would collect this and there were mechanisms put in place to have people submit that data to us, I think we would be very happy and able to do that. If it were thought that a body with regulatory power, such as Health Canada, would be the appropriate place to actually do the regulation and the data were to be submitted directly to them, I could certainly understand that model as well.

I was previously a deputy minister of health in a province, and I do certainly appreciate that this is a very real challenge for the country. To have a place where people can submit this data and have it clear that there is the capacity to both build a system to manage that but also to build the expectation in the system is no small undertaking, but I think it is one that is laudable, and certainly there are different potential avenues to do that. Clearly the regulatory framework would have to be such that the agency had the power and the ability to do that and they would be of some interest in the country.

● (1150)

Mr. David Tilson: With respect to reporting—I lost some notes here, so I'll have to wing it—the witnesses we had last session talked about harmonization with the United States and the European Union because of the number of drugs that go there, or indeed come here. What are your thoughts on that, and could you comment as to how that would take place?

Ms. Glenda Yeates: I certainly think the problem is not unique to Canada. I think cooperating internationally, wherever we can, makes a lot of sense for us. In many of the databases we hold, for example, we work with international standards.

Ultimately we hope to be able to compare Canada to some other countries. If we work on the same standards, I think that makes it much more possible in the future to do so.

Mr. David Tilson: Are we there now? Do we have the same standards as the European Union and the United States?

Ms. Glenda Yeates: I can't speak for our standards on adverse drug reporting; I'm not familiar with those. The example I'm most familiar with is hospital data collection. There are international classifications of hospital data that we at CIHI are the representatives of for Canada. We work very hard to make sure that data is collected in the same way across the country, and according to international standards.

Mr. David Tilson: How do you determine that there has been human error?

Ms. Glenda Yeates: The system we're building now looks to submission on the basis of individual practitioners, and there are thresholds that people have. I could ask my colleague Michael Hunt to speak to some of the specifics of that threshold.

Mr. Michael Hunt (Manager, Pharmaceuticals, Canadian Institute for Health Information): As a statistical organization we actually don't make that determination or judgment as to when an error occurred, or if an error occurred. We rely on the institutions who supply us with data to make that determination prior to giving us the data.

Certainly we want to look at contributing factors. The goal with those is to look at things within the system that we can modify to make the system safer. We don't make the determination of when an error occurred; we collect the data around that error to be able to inform on preventative strategies.

Mr. David Tilson: Someone has to do that, though, to determine whether the problem is with the drug or whether there has been an over- or under-prescription.

The Chair: Your time has run out.

Mr. Hunt, if you could summarize very quickly, I'd appreciate that.

Mr. Michael Hunt: Within the data we collect we look at whether it is a product-related issue. Was it a naming, packaging, or labelling issue? Was it a systems issue? For example, is there a way to deliver drugs within institutions in a safer way? Was it a patient identification issue that contributed to the error?

There's a fairly large piece of data that needs to be collected around contributing factors to the error. Then you can apply that information to put forward better quality standards, so we deliver safer heath care.

The Chair: Thank you, Mr. Hunt.

We're now going to to our second round. I'll remind members that our second round is five minutes for question and answer.

We'll start with Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): Thank you very much.

It's regrettable that Susan Paetkau, if I'm pronouncing her name right, was unable to come.

I notice that she's co-chair, and I understand she co-chairs that with the representative of the federal government. I think we probably could have sent a dog team to Tunney's Pasture to get the federal representatives to come. I certainly hope they will accompany Madam Paetkau when she can come.

The Chair: Mr. Thibault, we certainly will try to get her here.

● (1155)

Hon. Robert Thibault: Thank you.

Hon. Carolyn Bennett: We want them both here. We want the federal co-chair as well, because it seems—

The Chair: Madam Bennett, you can submit your suggestions to the clerk. We'll certainly be—

Hon. Carolyn Bennett: No, no. They were part of the original ones. We need the federal co-chair.

The Chair: Great.

Mr. Thibault.

Hon. Robert Thibault: Thank you.

When I look at the documentation provided in your presentation and past presentations, I see that on this question of data collection we have the MedEffect of Health Canada, we have NPDUIS that is shared between both your organizations, CMIRPS with CIHI, and COMPUS with the Canadian Agency for Drugs and Technologies in Health.

We have these four parallel organizations. Then we also have everything happening under Infoway, which hopefully is within these, but there might be some other silos or some other organizations. Yet at the end of the day, we hear from our witnesses, and I think it was confirmed, not statistically but in principle, by Dr. Benoit, that we know about only 10% of serious adverse effects or events, and we know very little about what we wouldn't consider serious—serious being something that requires hospitalization or further treatment that you can't necessarily solve by just discontinuing treatment—but what could be relevant.

It would seem to me that we should have 100% of those. Hopefully we'll be able to resolve that and get hospitals and clinicians to report on those.

In the case of those that are not life-threatening or that we don't consider serious—and I put this to Dr. Benoit as a practitioner—how do you know about them through your system? I know it would apply, especially in the case of off-label use of drugs, but even with regular use of pharmaceutical products for which there can be some adverse events that are not life-threatening, how do you know about events in the past or elevated risks involving them, under other practitioners?

Is there a good way out there? Is there a good exchange of information?

Dr. Brien Benoit: Mr. Thibault, I work primarily in a hospital. I'm in a tertiary care hospital, so we have a quality assurance program that is quite intrusive. Even a minor medication error creates what we call an incident report. The incident report is then reviewed by the unit manager, and, if it is minor, dealt with. For example, the nurse gave—

Hon. Robert Thibault: Seeing that I only have five minutes, perhaps I'd like to ask the question this way. I take it that you have a good system within your hospital. Do we have a good system of sharing that with other hospitals and with sole practitioners working in a clinical situation?

Dr. Brien Benoit: The answer, regrettably, is not as far as I know.

Hon. Robert Thibault: Perhaps I'll go to Madame Yeates on this one. You indicated that your organization is very good at standardizing the data we're receiving. In the coming years, with the systems that we are now working on or that we have in place, do you see this matter being resolved, given the way we are going? Are we heading to the point at which that information will be available?

Ms. Glenda Yeates: I think there's tremendous potential with things like the development of electronic health records and electronic medical records, but I also think that we, as a country, need to take specific steps and be clear about what we want. Standardization of data fields and definitions is not the stuff of headlines, but in fact it is very important for the data to be useful.

Unless we focus and are clear about what data we want to be collected in the same way and reported centrally, my sense is that there will be local solutions built, and we simply won't necessarily build in the capacity to share it centrally.

My own view is there's much opportunity in the future, but I think we will have to take specific steps and actions to ensure that we're clear about what data we think is useful.

Hon. Robert Thibault: Do you currently, in your systems, collect any data on adverse events related to off-label use? Do you have that as a separate category in your data?

Ms. Glenda Yeates: No, we don't.

Hon. Robert Thibault: Thank you.

The Chair: Thank you very much.

We will now go to Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): I have a few questions for the panellists today. I first wanted to ask what you think of the life cycle approach, in terms of regulating the health products. It was suggested in the blueprint for renewal in 2006 that this might be a way to have better surveillance. Also, do you expect that progressive licences will be subject to phase four clinical trials? And do you have any idea, on a broader level, of what types of costs would be involved with that?

● (1200)

Ms. Glenda Yeates: As an agency responsible for collecting national statistics from the provinces and territories, essentially from not a voluntary but from a consensus point of view, this is not a question we've looked at, in a sense. We very much view ourselves as a body that provides information for others to have those kinds of policy debates, as opposed to entering into them ourselves, so I'm afraid it's not a matter we've considered nor have a view on.

Dr. Brien Benoit: I can honestly say that our mandate is to regulate prices, but we currently have a discussion paper out there for all our stakeholders, which goes to re-benching, re-looking at the price of a medication once it's been on the market for a number of years.

As you alluded, Mr. Brown, after the drug's been out there for several years, obviously, some of the things that have not been picked up in the clinical trials come to the surface: either the drug becomes less effective or it becomes more effective for perhaps another indication. Would that be an occasion when the pharmaceutical manufacturer might ask for an increase in his price? Conversely, we might determine that the drug is not as effective as projected and lower the price.

One of the things we're currently discussing is post-market surveillance. We're in the process of looking at our guidelines, which are almost 15 years old, and if necessary, changing them to adapt to the modern environment.

Mr. Patrick Brown: I think Mr. Tilson alluded to my next point. One figure we've heard mentioned is 10%, in terms of adverse reactions that are reported. How could we get a better picture of that? Would hospitals have the ability to do mandatory reporting? How much would that assist in making the picture less murky?

Additionally, in terms of manufacturers, if there were a requirement for them to report as well, would they even have the ability to track that? What mechanisms would you suggest would give your organization a better ability to have the full picture of what the accurate percentage is?

Ms. Glenda Yeates: We tend to have very complete data sets at the moment, so we are blessed, in a sense, in this country with very complete data sets from hospitals. In the discharge abstract database, for example, we have information on virtually every hospital encounter; it's a very high percentage. We have very high percentages for some of our other databases as well.

I think it's clear one can have less complete, less comprehensive databases that can be used to pinpoint issues. From a data and statistical point of view, I think you usually start these things in stepwise motions. You want to start collecting data in a certain sector. That would give you information you could then use to improve safety and reach conclusions.

If the question is if we started in hospitals, if we started in a certain place, would that be helpful, I think the answer would be yes. Certainly we have data collection systems for hospitals, for example. The technical means of doing that, certainly, is—

Mr. Patrick Brown: So you have data assistance collections from hospitals. Do you have a fair degree of data from hospitals?

Ms. Glenda Yeates: We have data from hospitals. I should be clear, it's not about adverse drugs events, that's not one of the things reported to them, but there is a very comprehensive and clear data submission process. If there were a consensus or a regulation or something that required additional reporting, there is a vehicle currently in existence for hospitals to report data.

Mr. Patrick Brown: Would that be helpful?

Ms. Glenda Yeates: Would a regulator find that helpful? My assumption is you would find out certain things from in-hospital use. They would be different from the things you would find out from community use, but they would nonetheless, I presume, be quite useful.

The Chair: Thank you, Ms. Yeates.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you for joining us today.

Over the course of the last three meetings, we have met with organizations and departmental officials all of whom are connected in some way with the study under way on post-marketing surveillance of pharmaceutical products.

First of all, I wonder what proportion of their budget and how much time each organization spends on post-marketing surveillance of pharmaceutical products?

Secondly, I am curious as to how all of the organizations responsible for post-marketing surveillance of pharmaceutical products work together and how information is shared? What happens when an agency receives information that could require more in-depth studies on its pharmaceutical products and their effects?

● (1205)

[*English*]

Ms. Glenda Yeates: Thank you for the question.

Currently we do not have a mandate, essentially, or a request to be in the field of post-marketing surveillance. So when you ask about how much of our budget...that's not an area we have been asked by our governors to pursue.

There are many possibilities in health information. They've given us their priorities, but thus far this has not been a priority.

[*Translation*]

Mr. Luc Malo: Why were you invited here this morning?

[*English*]

Ms. Glenda Yeates: I think it's the fact that we have databases under development in the pharmaceutical area that give us the potential tool, if there is a desire to use them.

There is some potential from the databases that we have, and it's useful for people to know.... We don't want to duplicate databases; they're expensive to build. From our point of view, it's useful for people to understand what now exists, and if that is something that can be built on, added to, or in fact could be useful in some way to others, I think that would be helpful.

[*Translation*]

Mr. Luc Malo: Therefore, at present, none of the data that you collect is used for post-marketing surveillance.

Dr. Brien Benoit: Mr. Malo, I would have to give you the same answer. None of our budget is tied to post-marketing surveillance. All I can say—and Ms. Ouellette has just supplied the figures to me — is that our participation in the National Prescription Drug Utilization Information System will cost $805,000 over the next year. As you know, the NPDUIS has many other participants, including the Canadian Institute for Health Information. We have no funding for post-marketing surveillance. We are not involved in this field at the moment.

Mr. Luc Malo: Would you like to see your mandate expanded to include post-marketing surveillance?

Dr. Brien Benoit: Our mandate is set out in the Patent Act and pursuant to section 90 of this legislation, Health Canada can ask us to participate in certain inquiries. A request to get involved in this area would need to come from the Minister of Health.

Mr. Luc Malo: Earlier, you were telling us that pharmaceutical companies are not spending the portion of their budget that they should be spending on R&D.

How can you get pharmaceutical companies to spend the money in order to reach these targets?

Dr. Brien Benoit: There is nothing we can do to force them to meet these targets. They simply tell us how much they invest in R&D, and we draw up a report. You claim it would be ideal if they spent a minimum of about 10% of their budget on R&D. I believe this is in line with a voluntary agreement concluded between the government and the industry 20 years ago.

Mr. Luc Malo: Would the marketing of pharmaceutical products that present some problems post-marketing be avoided if companies met the 10% target?

Dr. Brien Benoit: As I see it, there is no easy answer to that question.

Mr. Luc Malo: You seem to be smiling, Ms. Yeates.

Ms. Glenda Yeates: I really do not have an opinion on the subject.

Mr. Luc Malo: Thank you very much.

Thank you, Madam Chair.

[*English*]

The Chair: Thank you, Monsieur Malo.

Mr. Fletcher.

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

I'm interested in the integrity of the data. People will receive drugs either in an institution or in the community. Does CIHI have any data for people in the community?

● (1210)

Ms. Glenda Yeates: Yes, the NPDUIS database is in fact based on community claims from provincial drug plans. We don't actually have drug data for in-hospitals, but we would have drug data from public drug plans, which typically are drugs that are prescribed in the community.

Mr. Steven Fletcher: How are you tracking adverse events?

In the community—I'm just trying to figure this out on the ground —the doctor fills out a prescription on a little piece of paper. Generally, you can barely read it. I don't know what your handwriting is like, Dr. Benoit, but the handwriting I've seen from your profession is not something to write home about. That prescription goes to the pharmacist and they somehow decipher it. Right at that point, there seems to be lots of room for error. The pharmacist, then, fills the prescription. Who knows if the person is taking the medication as prescribed? If something bad happens, it's blamed, perhaps, on the medication, or perhaps it's due to something completely different. How can you tell? And how do you mine for accurate information?

Dr. Brien Benoit: Mr. Fletcher, the questions you're posing are the obvious ones in the current context of what we're discussing here today.

It would be extremely difficult, because compliance with the prescription is one of the big problems the medical profession faces. In the context of a clinical trial, where everybody is being surveyed and you come to the clinic and the nurse checks you and they look in the pill bottles to see how many are left and so on, it's very easy to come to a conclusion that this dose or this medication is effective. But when you get out in the real world, where the patient says, "My headache was worse today, so I took four pills instead of the prescribed one pill", I don't know how you'd ever be able to control that. Perhaps you'd have to ask the health professional, the nurse or the doctor, to code some kind of reaction to that. If we go to electronic medical records and so on, it may be easier, but right now it's very difficult.

Mr. Steven Fletcher: Is it even possible? You could code it and everything else, but even at that initial step, from the recommendation to the pharmacist, it could be garbage in, garbage out.

What do other jurisdictions do? Are there any examples of this working?

Dr. Brien Benoit: I'm not sure I totally understand your question. Could you rephrase it?

Mr. Steven Fletcher: Okay. Is there any jurisdiction in the world where post-market surveillance of pharmaceutical products is conducted, in the institution or in the community, in a manner that has credible findings?

Dr. Brien Benoit: I don't know the answer to that. Your point is why reinvent the wheel if some other country or organization has come to some kind of arrangement in terms of what we're thinking of doing.

Mr. Steven Fletcher: That's one of the points, yes.

Dr. Brien Benoit: I don't know the answer to that, Mr. Fletcher.

Mr. Steven Fletcher: Does CIHI?

Ms. Glenda Yeates: No, it's not a question we've looked at, I'm sorry.

Dr. Brien Benoit: The issue of post-marketing surveillance and the reporting or evaluation of adverse reaction is something relatively new, at least to our organization. We're invited here today presumably to give our opinion from the point of view that we come from, but we've never been approached in any direct way to get involved with this.

Mr. Steven Fletcher: Well, if we're going to do something about it, it would seem to be a wise move to investigate what happens in other countries and what other countries are doing. I don't know who the committee could ask about that.

At CIHI do you guys meet your counterparts internationally, or do you have contacts internationally?

Dr. Brien Benoit: Mr. Fletcher, as a matter of fact, our particular prices are compared with...I think somebody mentioned the European Union. We have seven countries that have similar health care systems to our own, with whom we compare the prices. It may be—

● (1215)

Mr. Steven Fletcher: Yes, I know that, but we're talking about surveillance—

Dr. Brien Benoit: Somebody would have to ask them.

The Chair: Mr. Benoit, our time is up for this particular question. Do you have anything else you would like to add to that?

Dr. Brien Benoit: I don't think so.

The Chair: Thank you so much.

The next in line would be the member from the NDP, but she's not available today. She's on another assignment.

I will go to Mr. Brown, please.

Mr. Patrick Brown: Thank you, Ms. Smith.

There's one part of the question that I didn't get to in my last round. Hospital reporting has been mentioned, and I wanted to touch on the manufacturing, on how a manufacturer would be made aware of adverse reactions as well. You mentioned that hospitals would have a vehicle through which they'd be able to report.

Can you think of a similar vehicle through which manufacturers would be able to report? And because they don't have the same direct monitoring of a patient that a hospital would, is it even possible, from your perspective, to keep accurate statistics on that?

Ms. Glenda Yeates: Well, we in a sense have prided ourselves on being able to work with people across the health sector in ways that make sense for the task. We have submissions directly from hospitals. In some cases, we have submissions from provinces. We'll have an entire province hand over data to us. In other cases, we work with individual medical practitioners. Orthopedic surgeons submit joint replacement data to us for that particular registry. Again, if there is the mandate, if there is the desire, if there is funding....

We work well with others in the health sector to support the health sector's data and information needs. Certainly that has involved working with the private sector in others of our databases. Again, if there is a will, if there is a desire, we can certainly accommodate submissions from others.

Mr. Patrick Brown: So you also work with individual practitioners. You mentioned orthopedic surgeons, but what about family physicians? When you think of the physicians outside of hospital settings, are there vehicles similar to the one you mentioned for hospitals that would enable those physicians to report on an active level?

Ms. Glenda Yeates: At the current time I think the reporting mechanisms are better for institutions than for individual practitioners. But there are two initiatives there that I will speak to.

We are all hopeful that electronic medical record development in the country will enable data flow and feed back information that primary care practitioners will find useful. We are also working with the College of Family Physicians of Canada on certain things right now to understand whether we can have a partnership with them that would meet the needs of some of their members for data, and comparable and standardized information.

So where there is a will to collect data in a standardized way, we certainly work well with a variety of health stakeholders across the country.

Mr. Patrick Brown: Are there any comments on that?

Dr. Brien Benoit: Not really. At the family doctor level there are probably many adverse reactions. At the moment, if a serious adverse reaction occurs the physician is obliged to inform the Ministry of Health or the medical officer of health of his municipality. That's an ethical obligation, but it's not mandated by law.

Mr. Patrick Brown: Because we've heard that 10% figure, it makes you ponder what ways there are to find out if there's a much greater percentage of adverse reactions. I'm curious about what potential vehicles exist to enhance that reporting so we can have a greater effective knowledge of the reactions out there.

This may not fall within your ability to comment, but I've asked folks previously at this committee about Health Canada and whether they should have the authority to recall pharmaceutical products, either prescription or non-prescription. Do you think it would help this overall issue if Health Canada could recall products?

Dr. Brien Benoit: I really have no comment on that.

The Chair: Thank you, Mr. Brown.

Mr. Dhaliwal.

Mr. Sukh Dhaliwal (Newton—North Delta, , Lib.): Thank you very much, Chair.

I welcome the panel. I'm probably the newest person on this committee today.

I will pick up where Mr. Brown left off. I was at the Surrey Memorial Hospital and ran into one patient who was the victim of adverse effects as a result of a physician prescribing that medicine. Instead of it being simply professionally ethical to report these to the Ministry of Health, should we make it mandatory for health professionals and institutions to report these adverse effects?

● (1220)

Dr. Brien Benoit: That's the only way you're going to get a high level of compliance.

Mr. Sukh Dhaliwal: Ms. Yeates, do you have something to add?

Ms. Glenda Yeates: We have a number of databases that are voluntary, and it really depends on whether the practitioners are interested in reporting. For example, in our orthopedic joint replacement registry database, upwards of 70% of the orthopods across the country are submitting data.

Mr. Sukh Dhaliwal: Do you agree with Dr. Benoit that it should be made compulsory, to improve on this 10%?

Ms. Glenda Yeates: Given our history and what I've heard people say, voluntary reporting has not led to very high percentages. It may well be that a different approach is appropriate. On whether that needs to be mandatory or whether there should be some other series of possible options, I haven't studied that matter and don't have a view.

Dr. Brien Benoit: It is mandated in Ontario that a physician must report to the Ministry of Transport if a certain individual is not able to drive a motor vehicle. Then the ministry asks the patient what their problem is. If we have somebody with unstable diabetes, angina, seizures, or whatever, we are obliged to tell the Ministry of Health that person has a condition that would preclude their driving a motor vehicle. That is mandated by law, and every physician automatically does it if that circumstance arises.

Mr. Sukh Dhaliwal: My question is to Glenda Yeates.

Because I am pretty new to this, what is your relationship with the health care providers and the professionals? How do you fit with those fellows?

Ms. Glenda Yeates: We are essentially a vehicle for the collection of data, so we don't have a mandate to make recommendations, to make policy prescriptions, to regulate anything. But we know that many people who do have those mandates to regulate, to make major decisions, whether that's within a regional health authority or a hospital, or at a provincial or a federal government level, need data to make those decisions, and they need it standardized and collected. So that essentially is where we fit in.

Our expertise is to work with the stakeholders across the country. We are not a federal nor a provincial body, so we can work well with most stakeholders in the health system to understand what data they would need, what would be feasible to collect, and we operate in that way and then provide the data to our stakeholders for their use. Those uses sometimes are regulatory, sometimes they're decision-making needs, sometimes they're just an individual hospital wanting to know how they're doing.

We then also make reports to Canadians. For example, we put out indicators that would give the Canadian public some sense of comparability in terms of indicators.

Mr. Sukh Dhaliwal: My understanding is that you don't get involved in the post-market surveillance, then. Is that true?

Ms. Glenda Yeates: That's right, at the current moment we are not involved.

Mr. Sukh Dhaliwal: And how would you, if you need to?

Ms. Glenda Yeates: Well, we are a data provider. I think the relationship with PMPRB is probably a good example of where we have data. Again, all of the legal arrangements, all of the arrangements allow us to pass that data on in a very appropriate way, under appropriate conditions, to someone else to do another function in the health system. I think we would have the ability to do that. In fact, the drug database that we are currently building, that's been spoken of this morning, wouldn't be able to do everything, but, again, I think it would have some power to assist in that process.

Given how expensive it is to collect data and given it's expensive to standardize it, it does make sense to understand what exists now and how that might feed into or support post-market surveillance or any other number of health activities.

● (1225)

Mr. Sukh Dhaliwal: Thank you.

The Chair: Thank you very much, Mrs. Yeates, and thank you, Mr. Dhaliwal.

We are now going into a third round, which is quite unusual, but because of the lack of our third witness group we're allowed to do that.

We also have, committee members, two issues on business that we need to discuss after we have questioned all the witnesses.

We have Mr. Fletcher, Ms. Gagnon, Mr. Brown, Mr. Fletcher again, and Mr. Temelkovski.

I would ask that we start now. It's still a five-minute round, but you don't need to use all that five minutes if you don't choose to.

Mr. Fletcher.

Mr. Steven Fletcher: Going back to the real world and data integrity, a doctor in an institution or in the community prescribes a drug, an adverse reaction occurs, he or she is obligated to report it. What incentive is there for the doctor to report it? I can think of a lot of disincentives, not the least of which could be possibly legal issues or paperwork or just not accepting that there was an adverse reaction. How do you deal with those types of situations or how do you account for those types of situations when you're examining data?

I guess that goes to CIHI.

Ms. Glenda Yeates: I think your point is very well taken. There are many times when we will receive data because someone has mandated it, so either the hospital says it must happen or.... In the case of the hospital databases that we have, for example, it's usually the province that requires that their hospitals all submit data to us so that they can have an overall standardized picture of what's happening.

In some instances there is an incentive that drives enough data submission, but in general, I would say, there has to be someone who decides it's important to collect it. Because, as you say, it takes time, it takes money, it may be inconvenient, people may perceive risk to collecting it, often they need to have that mandated in some cases. For the databases for which we have the most complete coverage, those have been, generally speaking, mandated, often in our case at a provincial level.

Mr. Steven Fletcher: To go back to my previous line of questioning, which you didn't have an opportunity to respond to, have you been in discussions with other jurisdictions in regard to post-market surveillance, or even looking at post-market surveillance?

Dr. Brien Benoit: Not that I know of.

Mr. Steven Fletcher: So what advice would you give this committee to ensure that we provide the best advice to the minister and the Canadian public? That's an open-ended question.

Those will be my questions, Madam Chair.

Dr. Brien Benoit: I'll take the question in my role as a physician rather than as chair of the PMPRB, because I think your objective is a very valid one and good one, and it's very current.

There are all kinds of difficulties in implementing a very good mandatory reporting system for adverse reactions. I think at the moment, in terms of physician input, you'd need to have discussions with the medical establishment, because any type of reporting is burdensome. If you have a busy family practitioner and a person comes in and says “I have a rash from taking this particular pill”, your natural instinct is just to say, well, stop taking the pill and I'll give you something else, when in fact that particular rash may be part of bigger picture. So there's no incentive really to report adverse reactions, unless they are catastrophic, surprising, or unexpected according to what the product information brochure says. If you look at any product information brochure, you're going to see every possible adverse reaction listed there. Most physicians just skim over them; you only look at the most important ones.

You'd have to have some kind of mandatory regime to oblige the reporting of adverse reactions, in my opinion. In hospitals it would easier to acquire, but out in the community it would be difficult.

● (1230)

Ms. Glenda Yeates: My sense is that it would be very important to have a clear sense of role. As we all know, there are very complex linkages in the sense of who does what. So I think we would need to have an agency or someone responsible with a very clear role to do this in order to understand what works, but data also will be huge part in doing this effectively. Speaking perhaps from our data provider perspective, it would important not to duplicate unnecessarily, but to build on and look at how we could use the data that currently exists to further this very important objective.

The Chair: Thank you both, Dr. Benoit and Ms. Yeates.

Now we'll go to Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: Good day. I have two questions for the witnesses.

Ms. Yeates, there are two types of analyses. I would like to focus on the Canadian Medication Incident Reporting and Prevention System pursuant to which data on medical accidents and incidents is collected, analysed, exchanged and reported.

Earlier, I asked you to describe for me the role you play in monitoring the safety of pharmaceutical products. You responded that this was neither the role, nor the mandate of your organization. However, the mandate of CMIRPS includes collecting data. I am trying to understand the responsibilities the various players have when it comes to pharmacovigilance. MedEffect also gathers data, just as CMIRPS does.

Are you involved in this process? Where do you draw the line? Do you rely on information from these two databases? Would it be preferable to have only one database? Can you explain the difference to us? Do you all work together, or do you work alone?

[*English*]

Ms. Glenda Yeates: I will ask my colleague to speak to some of the other databases and the linkages, but initially I would just make the distinction.

I am not a pharmacist, so this is a distinction that was not initially obvious to me. But in regard to the language, we were asked and funded specifically to develop a database to gather information on “medication incidents”, which are distinct from, as I've learned, “adverse events”. Medication incidents are really about the processes of care.

Certainly I think we've seen a number of hospitals in this country that have had tragedies in emergency rooms, for example, where medications that looked very similar or that were stored in an emergency room were inappropriately given and they had tragic results. The concern was that one of these situations occurred in eastern Canada—I think it was in Halifax, or within Nova Scotia—one occurred in Saskatchewan when I was there, and they've occurred in Alberta, yet it seemed we had no place to actually collect those kinds of problems. So we were funded specifically and asked to develop a database to collect in-hospital medication incidents.

I think it will be a very important database. Currently we've developed the structure to find the definitions. The system is ready for piloting in September. I should be clear that at this time I can't answer what proportion or what kinds of inputs we will get to that.

We have been working with others, such as the Canadian Patient Safety Institute, because we realize it will take on-the-ground support for individual physicians and hospitals to be encouraged to actually submit data to the database. We have partnerships there to try to encourage that kind of submission so that we can build the database so we don't have to make the same mistakes in one part of the country as we've made in the other, but rather, we can learn from them.

The distinction that I've had to appreciate, since learning of this, is "medication incidents" versus "adverse events". When we do get data, at the current time it's designed to do the one and not the other.

I'll ask my colleague to speak to some of the linkages you mentioned.

● (1235)

Mr. Michael Hunt: From the outset with the CMIRPS project, the vision was that it wasn't to be built in silos. So if you look at the organizations that have been involved in the product from the beginning, Health Canada is certainly up front, as is the Canadian Patient Safety Institute, within their mandate of safety within the country, and the Institute for Safe Medication Practices Canada, or ISMP, has also been involved in the field.

If you look at the components of the data we're managing to collect, there will certainly be incidents or errors that will occur that are essentially associated with the product. So we have naming, packaging, labelling, look-alikes, and sound-alikes. Certainly that's data that Health Canada is very interested in, in their legislative role, so we would look at making sure that data is available.

We talk of the entire environment of reporting. This is not a mandated reporting area, so this is a cultural change. This is a change from a reporting culture of naming and blaming to one of learning and sharing. The system design is really there to share the data. We want to be able to share the incidents or errors that occur back with the institutions where they occurred, do that in an aggregate way so that they can look at other institution incidents, and then use that data to put in place safety strategies.

CMIRPS, from the beginning, is a cooperative venture. We have most of the players at play. Certainly in our initial consultations we include health care practitioners—nurses, physicians, pharmacists—those involved with the delivery of medications within the institutions.

So from our perspective, it's well linked right from the outset. It's a good concept of sharing that data. We're the data gatherer and we're to make sure that the data we gather is valuable, that the data set is useful, and that we find mechanisms to share that in a privacy-sensitive way.

The Chair: Thank you, Mr. Hunt.

Mr. Brown.

Mr. Patrick Brown: I don't have any further questions. I'm not sure if Mr. Fletcher does.

Mr. Steven Fletcher: I have no further questions.

The Chair: We'll now go to Mr. Temelkovski.

Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.): Thank you very much, Madam Smith, and thank you to the presenters.

Madam Yeates, do you feel that you have the network and contacts to undertake post-market surveillance data management?

Ms. Glenda Yeates: We have a very good relationship with government: the federal government, provinces, and territories. We have good relationships with practitioners, although that is a very large group, so I would characterize it as good relationships with leadership.

In many ways, what's often critical for us is that there is agreement among those parties about what is a priority to collect. I think we can facilitate the collection and the standardization, and based on our good relationships, work that out, if there's an agreement about what people want to achieve. If, fundamentally, there's a disagreement about whether we should be collecting this, we have no mechanism, and even with good relationships, it won't produce actual data if people don't have some consensus around what's to be collected.

Mr. Lui Temelkovski: How would you enhance what Health Canada already does in this field, and why would you do so if it is outside the Patent Act?

Ms. Glenda Yeates: Again—maybe I'll speak a little bit with my previous hat, as a provincial deputy minister—I think post-marketing surveillance is of great interest to a great many health stakeholders across the country. Health Canada certainly is interested, the provinces and territories are interested, and in my experience, practitioners are as well. I think there is a lot of interest, potentially, in doing this.

Often it is a matter that the devil's in the details. It depends on who is going to pay, what it's going to look like. Those would be things that would need a fair bit of working out.

My sense is there could well be interest. There seems to be some common interest among the parties.

Mr. Lui Temelkovski: Dr. Benoit, did you have a comment on that?

Dr. Brien Benoit: I think this whole initiative is great. In my opinion, it's long overdue. But you have a lot of work to do in terms of how you're going to implement it.

You have different organizations; you have CIHI that can collect the data, if it's obligatory that it be reported to them. I'm not sure what our role in this would be exactly. We do have a regulatory component to our organization, but it's driven by the Patent Act. And this is not part of the Patent Act, as far as I know.

● (1240)

Mr. Lui Temelkovski: Right.

In terms of competitive groups that are collecting data, such as IMS, what's your take on that? Can this go to a private company, or should we keep it close to our chest?

Ms. Glenda Yeates: Well, it depends on what one wants to achieve. We certainly have the kinds of governance structures.... We are governed, essentially, by the health sector as a cross-section, so governments are represented, hospitals, practitioners. Often that builds a degree of trust with the sector because of the governance model, and certainly we are very strictly regulated in a privacy sense.

In the past that has worked well. It has given people the confidence that we handle their data well. I think we have a very strong track record that we've built up in terms of being very strict and able custodians of data and being appropriate. We certainly wouldn't be the only possibility, and it would really depend on what the goals were, but we think we have a strong track record and strong basis in terms of what we do.

Mr. Lui Temelkovski: I have two short questions.

The Chair: How about one short question? You're just about out of time.

Mr. Lui Temelkovski: In terms of aboriginal data collection, Dr. Benoit, could you answer this question?

If there is an issue regarding the safety and efficacy of a particular product, does such a situation affect the pricing? Would you examine how its non-excessive price was calculated?

Dr. Brien Benoit: I'll give you a short answer. Right at the moment our price regulations apply at introduction. We are currently asking for discussions and proposals regarding a real-world efficacy after the drug has been on the market for a few years. But at the moment, we don't look at the price after introduction—

Mr. Lui Temelkovski: So it would be helpful.

Dr. Brien Benoit: —except for the consumer price index every year. They're allowed a small percentage.

Mr. Lui Temelkovski: Okay, and what about the aboriginal issue?

The Chair: Your time is up now. I'm sorry to interrupt you.

Are there any closing comments the witnesses would like to make quickly, just to sum up what Mr. Temelkovski has asked? Is that fine?

Mr. Lui Temelkovski: Maybe you can answer the aboriginal question.

A voice: You get the FNIHB data.

Ms. Glenda Yeates: Yes, when we talk about jurisdictions that can submit data, one of those jurisdictions is the federal government's first nations and Inuit health branch, so again, that is a group we are working with. We don't currently have their data in NPDUIS, but discussions are ongoing, as they are with a number of other jurisdictions.

That's certainly something we would see in the future.

The Chair: Thank you.

I want to especially thank you for coming out on such a snowy day. We're so glad that you were here in Ottawa and not caught in some airport today. Your insightful wisdom has been very helpful to every member of this committee.

As you know, we do have two more items of business. To committee members, if you want to talk with the witnesses—I would ask the witnesses to leave the room very quickly so we can complete our business—any conversations can be held outside that doorway over there.

Thank you again.

Committee members, we're now going on to a couple of other items. As I mentioned at our meeting on Tuesday, we'll be asking the committee today to adopt a budget to pay witness expenses for our study on post-market surveillance. The request at this time is for $39,950.

I would like the clerk, if she would, to speak to this. A couple of comments might answer some questions before they've been asked.

The Clerk of the Committee (Mrs. Carmen DePape): It's a pretty standard budget for a study like this one. We have calculated for about 20 witnesses from outside the area. There's also money for some working lunches, three of them, if we need them. And there's also money for video conferences, if we need some.

The Chair: Is it the will of the committee to pass this budget?

(Motion agreed to) [See *Minutes of Proceedings*]

● (1245)

The Chair: On a second issue, Ms. Kadis brought us the issue of the safety of certain baby products at our meeting on Tuesday. So as mentioned at the meeting, we are going to incorporate this as part of our meeting on toy regulations scheduled for April 1. That was also discussed at the last meeting.

I also wanted to mention that the motion that Ms. Judy Wasylycia-Leis gave notice on, on Tuesday, will be on the agenda for the meeting of February 14, Valentine's Day, because she will not be here until then and she made that request. So I think that's a prudent thing to do out of respect.

The committee will meet next on Tuesday, February 12, at 11 a.m., on the subject of the supply of radioisotopes. Witnesses that have been invited are MDS Nordion and the Canadian Society of Nuclear Medicine. The Canadian Coalition for Nuclear Responsibility was also invited, but they were unable to attend, so we'll try to get Mr. Roger Collier, author of the article on isotope surplus that recently appeared in the *Canadian Medical Association Jounal*. We're working on that right now, and hopefully we'll be able to get him.

Dr. Bennett.

Hon. Carolyn Bennett: Is the nuclear responsibility gang going to send us a report? I certainly have a couple of very lengthy e-mails from them.

The Chair: We certainly could make that request.

Hon. Carolyn Bennett: Yes, okay.

The Chair: Okay, we'll do that and get back to you on that, Dr. Bennett. That's a good question.

Also, to let you know, the Minister of Health has confirmed that he will be attending the meeting from 12:15 p.m. to 1 p.m. on Tuesday. So he's made himself very well available for all of us.

Ladies and gentlemen, the meeting is adjourned.

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