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Chair

Mr. Bill Casey

Standing Committee on Health

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● (0850)

[*English*]

The Chair (Mr. Bill Casey (Cumberland—Colchester, Lib.)): Welcome to meeting number 121 of the Standing Committee on Health. Today we are discussing the barriers to access to treatment and drugs for Canadians affected by rare diseases and disorders.

I understand there will be an interruption. Apparently, there's going to be a vote sometime this morning. We should be ready for that and we may have to knock off early. I'll try to keep on schedule. I'll try not to be rude but if somebody goes over, I'll have to cut them off because we want to get through as many as we can.

We have two excellent witnesses this morning. From the Patented Medicine Prices Review Board, we have Douglas Clark.

From the Canadian Agency for Drugs and Technologies in Health, we have Heather Logan. They're both anxious to testify. I talked to them earlier and they're anxious to get going.

Welcome.

We're going to start with Mr. Clark.

You have a 10-minute opening statement.

Mr. Douglas Clark (Executive Director, Patented Medicine Prices Review Board): Mr. Chair, members of the committee, good morning. Thank you for the invitation to appear before you today.

[*Translation*]

Before I move on to the questions, I want to take a few minutes to explain where the Patented Medicine Prices Review Board, or the PMPRB, stands in the Canadian health care system, the challenges we currently face as a price regulator, and the ongoing efforts to modernize the way we fulfill our regulatory mandate.

[*English*]

The PMPRB was created in 1987 as the consumer protection pillar of a major set of reforms to the Patent Act, which were designed to encourage greater investment in pharmaceutical R and D in Canada through stronger patent protection for pharmaceuticals. PMPRB is a quasi-judicial body with a regulatory mandate to ensure that patentees do not abuse their patent rights by charging consumers excessive prices during the statutory monopoly period. Its creation arose out of the concern that stronger patent protection for medicines might cause prices to rise unacceptably so as to become unaffordable to consumers.

PMPRB is a creature of the Patent Act, which is the responsibility of the Minister of ISED, but given the nature of the products that we regulate, the provisions in the act that relate to us are the responsibility of the Minister of Health. While the PMPRB is part of the health portfolio, our role as an administrative tribunal with a quasi-judicial function means that we operate at arm's-length from the minister and from other health portfolio members.

Under our current framework, new patented medicines are assessed for the degree of therapeutic benefit they provide relative to existing medicines on the market. Depending on the outcome of that process, patentees are expected to set their prices with regard to a price ceiling that is based on the price of that same medicine in what we call the PMPRB7 countries, the price of medicines in Canada in the same therapeutic class or some combination of the two.

Once a patentee sets a medicine's introductory price in relation to that ceiling and enters the market, it may increase its price but subject to limitations based on changes in the consumer price index. Our only absolute ceiling is that the price of a patented medicine in Canada can never be higher than the highest price in the PMPRB7.

[*Translation*]

The PMPRB's regulatory framework is implemented by the board staff, who are public servants like me and who monitor and investigate patented medicines that seem excessively priced. The staff apply the tests and thresholds specified in the PMPRB's guidelines to identify potential cases of excessive pricing practices. When a price seems excessive, the patentee is asked to submit a voluntary compliance undertaking, which may include a written commitment to lower the price of the patented medicine and to offset any excess revenues.

[*English*]

In the absence of an acceptable VCU, an investigation may proceed to a public hearing before a panel composed of Governor in Council appointed members of the PMPRB's board. During such a hearing, the board panel acts as a neutral arbiter between the parties, i.e., the patentee and staff. If the panel determines that the patented medicine was sold at an excessive price, it may issue an order requiring the patentee to reduce its price to a reasonable level or to repay any excess revenue that resulted from selling the patented medicine at an excessive price.

An order of the board can be enforced in the same manner as an order of the Federal Court.

Since the establishment of the PMPRB over three decades ago, the pharmaceutical industry has changed significantly. R and D is increasingly focused on high-cost medicines such as biologics, genetic therapies targeted to smaller patient populations and medicines for rare diseases. The risk of excessive pricing is often greater for these products since they have few, if any, competitive substitutes and demand for new and better treatments among the more severely afflicted population is very high.

This is especially true for medicines that are the first of their kind or for which alternatives are less effective or have less tolerable side effects.

The current market dynamic has led to affordability challenges for public and private payers that, if left unaddressed, pose a very real threat to the sustainability of the pharmaceutical system in Canada. Between 2006 and 2016, the average annual cost of treatment for the top 10 selling patented medicines in Canada increased by 1,500% and the number of medicines in Canada with an annual per-patient treatment cost of at least $10,000 increased fivefold.

Fully 30% of public and private insurer spending on pharmaceuticals in Canada is allocated to these drugs versus only 5% a few short years ago, yet it covers fewer than 2% of beneficiaries. Drugs designated as orphan by the U.S. FDA or the EMA now account for almost 50% of new patented medicines coming under the PMPRB's jurisdiction every year.

[*Translation*]

The patented medicine prices in Canada are among the highest in the world. When it comes to the 35 member countries of the Organization for Economic Co-operation and Development, or the OECD, only the United States and Mexico have higher prices than Canada. In 2017, median prices of patented medicines in OECD countries were on average 19% lower than the prices in Canada.

[*English*]

Over the past several decades, many developed countries have relied on international price comparisons as a method to contain pharmaceutical costs. As regulators in these countries grapple with a growing influx in very high-cost drugs, they are increasingly looking at other methods for evaluating drug prices that consider the relative cost of the drug in relation to its health benefits and the impact reimbursement would have on total population health and health system expenditure. Although public list prices in other countries are still commonly referenced, they are increasingly a starting point to a more probing and substantive analysis of a medicine's economic value and affordability.

Corresponding changes to the PMPRB's regulatory framework are necessary so that it too can adapt to these changes. As members of the committee may know, the Minister of Health has recently proposed amendments to the PMPRB's regulatory framework that, if passed, would equip us with the regulatory tools and information we need to effectively protect Canadian consumers from excessively priced patented medicines in today's environment. The desired result of these changes is for the ceiling prices of patented medicines in Canada to be more closely aligned with prices in like-minded countries, more reflective of their relative value to the health system and more informed by the affordability constraints of the Canadian economy.

[*Translation*]

The modernization of the PMPRB is just one aspect of the Government of Canada's broader effort to not only make prescription drugs more affordable for Canadians, but also to ensure that Canadians have faster access to new medicines to meet the needs of the health care system.

● (0855)

[*English*]

We are aware of concerns that the proposed changes to the PMPRB's regulatory framework might delay or compromise Canadians' access to the very latest patented drugs. However, there is little evidence to support the argument that lower prices result in less access. The reality is that many countries with similar health care systems and economies to Canada's pay less for drugs yet enjoy the same or better access. The same is true of R and D investment.

Canada is not alone in struggling to reconcile finite budgets with patient access to promising, but costly, new health technologies. While our system can absorb one, two or maybe even dozens of high-cost drugs, it will collapse under the weight of hundreds, no matter how good they are. At the end of the day, the single most important determinant of access is affordability. The best drug in the world won't bring value to society if no one can afford it, or if the effect of paying for it for the fortunate few is to deprive effective health care to multitudes.

Thank you. I look forward to your questions.

The Chair: Thank you very much. There are some interesting numbers there.

Now we will go to Heather Logan, with the Canadian Agency for Drugs and Technologies in Health, for 10 minutes.

Ms. Heather Logan (Acting Vice-President, Pharmaceutical Reviews, Canadian Agency for Drugs and Technologies in Health): Mr. Chair, thank you for the opportunity to present to the committee this morning.

I'd like to start by telling you about the Canadian Agency for Drugs and Technologies in Health, CADTH, and how our work enhances the accessibility, affordability and appropriate use of pharmaceuticals and other health technologies in Canada.

CADTH is an independent not-for-profit corporation that was established in 1989. Our primary goal and principal success criterion is impact—by providing better health, better patient experience and better value for Canadians. The members, or the owners, of CADTH are the federal, provincial and territorial deputy ministers of health who fund CADTH. This includes Health Canada and all provinces and territories except Quebec. We are governed by a board of directors that reports to the deputy ministers.

We refer to ourselves as an HTA, a health technology assessment agency, meaning we provide evidence-based assessments of the clinical and cost-effectiveness of drugs, diagnostics, and medical, dental and surgical devices, procedures and programs. In essence, we have two broad areas of work, our drug portfolio and our medical devices portfolio. We have a number of programs and products in place to support the management of medical devices in Canada. However, I will focus my comments today on our drug portfolio.

CADTH provides a range of services to support the effective management of pharmaceuticals in Canada, most notably the CADTH common drug review, CDR, and the CADTH pan-Canadian oncology drug review, pCODR. The CADTH common drug review program is a federal, provincial and territorial process that was established in 2004 to provide a common approach for reviewing the clinical and cost effectiveness of new drugs and existing drugs that may have new uses. We also receive input from patient groups as part of that review.

The common drug review supports coverage decisions for 18 of the 19 publicly funded drug plans in Canada, including the six plans managed by the Government of Canada for such specific populations as the military, veterans and Canada's indigenous peoples. Quebec has its own system for drug reviews through its HTA organization, INESSS, which is very similar to the approach CADTH uses and is increasingly becoming well aligned with CADTH through our excellent relations.

The pan-Canadian oncology drug review program was established by the provinces and territories in 2010, again with the exception of Quebec, and was transferred to CADTH on April 1, 2014. The federal government joined as a funding partner on April 1, 2016. Similar to CDR, the pan-Canadian oncology drug review provides a common process for the assessment of cancer drugs and makes reimbursement recommendations to Canada's federal, provincial and territorial public drug plans and cancer agencies to guide their cancer drug-funding decisions. The CADTH CDR and pCODR programs support funding decisions for individual drugs. We also conduct multi-drug reviews on classes of drugs under the auspices of our optimal use program.

One other service I would like to mention is our rapid response service, where we provide quick evidence reviews on the dauntingly large and complex medical literature. This service is extremely helpful in that it directly addresses the urgent needs for evidence that informs policy and practice. It's a widely used service, with more than 4,000 reports completed in the last decade by federal, provincial and territorial governments.

Early in 2018, CADTH adopted a new three-year strategic plan. The plan articulates a bold new direction for CADTH, and positions us as a key player in enhancing the accessibility, affordability and appropriate use of health technologies in Canada. Under the strategic plan, CADTH is building upon its success as a health technology assessment agency to become a health technology management, HTM, enterprise. We are implementing strategies to enable life-cycle health technology assessment, increased collaboration and engagement, and comprehensive implementation support. We are expanding our reach by embedding CADTH staff in jurisdictions across Canada and by being responsive and agile, catalyzing opportunities to align efforts across the drug review and approval system. It is CADTH's commitment to collaboration and integration that has brought us before the Standing Committee on Health today.

CADTH is pleased to be supporting a national consultation on a proposed supplemental process for highly specialized and complex drugs, including those used in the treatment of rare diseases. As this new initiative will help shape the future of Canada's drug review process, CADTH is planning to initiate an extensive consultation to ensure that Canadians have an opportunity to be able to provide input and to align our own processes with this new supplemental process.

It is estimated that there are more than 7,000 known rare and ultra-rare diseases. Of these, approximately 95% have no effective treatment options. This gap has become the focus of a considerable amount of attention by the pharmaceutical manufacturers for research and development, which can be associated with both high risk and high reward; by clinicians who are searching for effective options to improve quality of life, alleviate pain and suffering, and cure disease; and, more importantly, by patients and families who live with the often significant impact of these diseases.

● (0900)

In our experience, submissions from pharmaceutical manufacturers for drugs that treat these diseases are often associated with several challenging realities.

One, the size of the target population is small, making it difficult to conduct a clinical trial. Regulators such as Health Canada and health technology assessment organizations like CADTH consider randomized clinical trials the gold standard. When less-than-robust trial data are available, there is a correspondingly high degree of uncertainty about the true magnitude of the clinical benefit, or the efficacy, and also the safety and cost-effectiveness of the therapy being reviewed.

Two, clinical trials for rare and other diseases often use surrogate end points rather than real outcomes, which further increases the uncertainty regarding the effects of the treatment on clinical outcomes that are of primary concern to patients, such as mortality and quality of life.

Three, for reasons that are not always fully understood—they perhaps relate, at least in part, to the high cost of research and development, small eligible population and length of time required to recoup the investment to bring the drug to market—the cost of these therapies is invariably extraordinarily high.

In short, drugs used to treat these highly specialized and often complex diseases are often plagued by limited evidence, lower confidence in the magnitude of clinical benefit, extremely high cost and highly uncertain cost-effectiveness. This reality makes it difficult for CADTH's expert review committees to recommend reimbursement and for public payers to offer reimbursement given the finite resources of the public health care system.

In the past several years, CADTH has engaged in numerous initiatives to clarify and enhance our pharmaceutical review processes to address these challenges. These include enhanced training of our review staff to enhance our assessment of treatments with limited evidence; updating the deliberative framework of the CADTH expert review committees to allow for leeway in making funding recommendations for treatments of rare diseases; allowing greater opportunities for manufacturers to submit alternative types of data, so-called real-world evidence; strengthening clinician and patient engagement in the review process; and expanding opportunities for early dialogue and engagement with manufacturers. Most importantly, CADTH recently established a new parallel review process, in collaboration with INESSS and Health Canada, that will allow reviews to be completed within the shortest possible timelines.

Recently CADTH announced an initiative to integrate panels of clinical specialists into our review process to better inform and assist the pan-Canadian pharmaceutical alliance and provincial drug plans to implement drug funding recommendations. These panels enhance CADTH's engagement with the clinical community and further reinforce regional representation for important pan-Canadian funding recommendations. We have partnered with our HTA colleagues at INESSS in Quebec in a pilot initiative to hold joint panels for a truly national approach to these challenging reviews.

Finally but importantly, CADTH is pleased to be able to support the expensive drugs for rare diseases, EDRD, working group in conducting a national consultation about a proposed supplemental process for highly specialized and complex drugs. The EDRD was established by the deputy ministers of health in 2014 to explore the management of rare diseases with evidence-based approaches. The EDRD working group is being co-led by three provinces—British Columbia, Alberta and Ontario. As they were unable to send a representative today to appear before the committee, they gave me approval to share some of the information with you on their behalf.

The proposed supplemental process includes provisions to address several of the challenges I have already spoken about. These include limited data regarding efficacy, safety and cost-effectiveness; high uncertainty in the magnitude of clinical benefit; and the high cost of these drug treatments. While the members of the EDRD working group are best positioned to explain the specifics of the proposed supplemental process, we can confirm that it includes options that may help public drug plans provide time-limited access to these therapies as additional clinical evidence is being gathered.

Consultations have been organized for the EDRD working group to hear directly from clinicians, ethicists, researchers, patient groups and the pharmaceutical industry during web-based sessions on November 5, 6, 8, 13 and 14 respectively. More than 180 individuals have registered to participate in one of these consultations. Following this, there will be an opportunity for interested stakeholders to provide a written submission.

Information from the consultation process will be considered by the EDRD working group to inform discussion at the federal, provincial and territorial level about potential enhancements or changes to the proposed supplemental process. Because CADTH is integrally involved in supporting the provinces in this work, we are able to consider how this new proposed supplemental process might impact CADTH's review process and to modify our own approach accordingly to align efforts.

Ultimately, CADTH exists to serve the needs of its customers by providing evidence-based funding recommendations to support jurisdictional decision-making. We will continue to be responsive to opportunities to enhance our process, and are pleased to continue to support the EDRD working group and our other partners to address access, appropriate use and affordability of drugs, including those for highly specialized and complex diseases.

● (0905)

Thank you, Mr. Chair, for allowing me to present today, and I welcome any questions that the committee members may have.

The Chair: Thank you for your presentation.

Dr. Eyolfson.

Mr. Doug Eyolfson (Charleswood—St. James—Assiniboia—Headingley, Lib.): Thank you, Mr. Chair.

Thank you, both, for coming. It was very valuable testimony, and I'll probably by contacting you both off-line regarding some more information on this.

Mr. Clark, thank you for your comment about the claims from industry that, by lowering our prices, we will decrease R and D and decrease access to new medications. I have had to wrestle with that argument from many stakeholders. You've said there is really no evidence to support this. Is that correct? Could you elaborate on that?

Mr. Douglas Clark: The very example of Canada would provide sufficient evidence to conclude that there's not much link. As I mentioned, we pay the third-highest prices for patented medicines in the world, and yet the ratio of our R and D to sales pales in comparison to the countries we compare ourselves to under our regime—the PMPRB7 countries.

The original composition of that group of countries was based on the assumption that if we emulated the types of IP regimes in those countries and priced in line with them, we would come to enjoy a similar level of R and D as in those countries. Obviously, that assumption has not been borne out over time. Currently, we are at an historical low in our ratio of R and D to sales.

When the PMPRB was created, and the patent protection was strengthened for pharmaceuticals, the industry committed to doubling their ratio of R and D to sales from 5% to 10%. It currently stands at about 4.4%, versus over 20% R and D to sales in the countries we compare ourselves to on average under the PMPRB7.

I would say that one need look no further than the Canadian experience to draw that conclusion. There is no empirical evidence, and I'm not aware of any studies that suggest an organic connection between IP and R and D, or price and R and D.

Most of the countries in the PMPRB7 have lower prices and more R and D than us. Also, the same can be said of Austria, Norway and Australia.

Mr. Doug Eyolfson: Thank you.

I just want to make sure I heard you correctly that, despite the fact that we have the third-highest prices in the PMPRB7....

Mr. Douglas Clark: The OECD...

Mr. Doug Eyolfson: I'm sorry. We have the third-highest prices in the OECD. We are at a historical low in our R and D in Canada.

Mr. Douglas Clark: Yes, we're lower than where we started in 1987 when we committed to strengthening patent protection for pharmaceuticals and established the PMPRB to protect consumers from excessively priced patented drugs. We were at about 5% at the time.

The industry did meet its 10% commitment in the mid-nineties, but it's been trending downward since 1999. It's been below 10% since 2003. Apparently, yes, it's at an historical low of about 4.4%.

I don't want to serve as a mouthpiece for the industry, but they would tell you that the way in which they conduct their R and D is no longer effectively or fully captured by our definition. I'll leave it to them to advocate on their behalf.

We feel that we are comparing apples to apples when we look at R and D to sales in Canada versus the ratio of R and D to sales in the PMPRB7 countries that I alluded to.

Mr. Doug Eyolfson: Thank you. That's very useful.

Another statement you said that speaks to some communication I have had from different stakeholders is that the main barrier to access is affordability. Is that correct?

● (0910)

Mr. Douglas Clark: Yes.

Mr. Doug Eyolfson: Thank you. That is something we've always believed. The reason I ask is that there is some literature being put out, particularly through some lobbying by the Canadian Chamber of Commerce, which is making some people believe that if we were to establish national pharmacare, this would lead to a lot of untoward drawbacks for small business. One of the statements they made—and this was from a policy resolution of the Canadian Chamber of Commerce—was that if we make cost the main focus instead of access, we will decrease the development of new drugs. Does that make any sense to you?

Mr. Douglas Clark: To be quite candid, I don't think anything Canada does has an impact on global R and D and innovation on a macro level. I suspect the same conversations probably took place back in the fifties and sixties, when Tommy Douglas was advocating medicare and a publicly funded health care system. I've heard lots of doomsday scenarios. I'm not aware of this particular study from the Chamber of Commerce, but at the end of the day, one would presume that if prices were lower, volume would go up—that's typically how supply and demand works—and more people would have access to the drugs.

Ultimately, it's a matter of finding a juste milieu between access and cost and price. That's where we think we're headed with these changes. That's taking into account value for money, by which I mean pharmacoeconomics or cost-effectiveness, and overall affordability in terms of the market size of the drug and its impact on the budgets of public and private drug plans.

I'm not sure if I answered your question.

Mr. Doug Eyolfson: Thank you. Again, that was very useful.

Now, this is off the topic of rare diseases, but it speaks to the dynamic of our current pharmaceutical environment. We have on one side the developers of the drugs for rare diseases. They say these are very expensive, and I don't doubt that they are.

Mr. Douglas Clark: They're definitely very expensive.

Mr. Doug Eyolfson: They're very expensive to develop. Randomized clinical trials aren't really viable in many of these extremely rare diseases with high mortality. At the same time, we have an essential medicine that we know works: insulin. It was given, basically, to the world by its creator a century ago, and yet we have not seen any decrease in the price of this medication in decades. If anything, some forms of it have actually gone up.

You were mentioning your price review. Is there a mechanism through your agency that can help in terms of influence? You say that you call companies to task if they're charging excessive prices. Would you say that insulin is being charged excessively right now?

Mr. Douglas Clark: To start, I will address the first part of your question.

I think it behooves me to correct a common misunderstanding or misapprehension about R and D costs related to very rare orphan drugs. If you look at the literature, it's pretty clear that R and D costs to bring a drug for a very rare disease to market are only a fraction of the R and D costs of a more common or conventional drug that isn't designated as an orphan. It's somewhere in the order of 25%. The real issue, I guess, is the small patient population and what opportunity that provides to recoup drug costs at the end of the day.

Some people have suggested that the profit margins for companies that are bringing forward orphan drugs are well in excess of the profit margins for companies that are producing more conventional drugs. That might be something that's worth taking a look at over the long term. It's just very difficult to disentangle R and D costs for a lot of these big multinational companies, but I can tell you that in our experience, looking at companies that are single-product and that produce orphan drugs, sometimes we're seeing gross profit margins in the order of 90%. That is—

● (0915)

The Chair: I'm sorry, I have to cut you off there.

Mr. Douglas Clark: Okay. I didn't get to the insulin question, and I apologize.

The Chair: I hate to do it. It's very valuable information.

Mr. Kmiec, you have seven minutes.

Mr. Tom Kmiec (Calgary Shepard, CPC): Thank you, Mr. Chair.

I'll spend most of my time asking questions of CADTH.

Are you subject to any parliamentary oversight? You said the deputy minister of health sits on your board. If I do an access to information request to CADTH, will I get information?

Ms. Heather Logan : No, access to information requests are possible through the provinces, which are members of CADTH. To the best of my knowledge, there's no ability for access to information requests through CADTH.

Mr. Tom Kmiec: So the Auditor General has no jurisdiction over CADTH?

Ms. Heather Logan : I'm not sure that I can answer that question.

Mr. Tom Kmiec: How much of your budget comes from the federal government versus provincial governments?

Ms. Heather Logan : Most of our budget comes from the federal government, but there is a mechanism to access those, to provide those funds by the provinces. The majority of the funding comes through the federal government. It isn't the only source of funding. We also have a small amount of funding through revenues from the pharmaceutical industry as part of the submission process, as well as funding directly from some provinces for programs like pCODR.

Mr. Tom Kmiec: If the federal government is paying most of the way, why aren't you subject to some type of parliamentary review—the Auditor General, the Official Languages Act and things like that?

Ms. Heather Logan : There certainly are opportunities to review CADTH's work and make sure that we're aligning with the needs of our customers. Most recently, as an example, there was a review of all eight federally funded pan-Canadian health organizations and CADTH was part of that.

There were discussions, interviews and assessments of how we conduct our work and what the outcomes of that work are, and opportunities to think about what a future orientation for the drug review and approval system might look like.

Mr. Tom Kmiec: May I ask you about your board? You mentioned that it's the deputy ministers of the different provincial health departments who are on the board. Do any of them have a relationship with pCPA? Do they sit on the same board? Do they work with pCPA? Are they the same members?

Ms. Heather Logan : Our customers are the deputy ministers of health, but our board includes some deputy ministers, some assistant deputy ministers and some researchers, ethicists and clinicians, so it isn't just deputy ministers of health. Some of the assistant deputy ministers who are on our board are also affiliated with the pCPA governing council, which provides oversight to the pCPA office.

Mr. Tom Kmiec: For some them, then, there's an overlay. This means that the body that is designed to approve and recommend then sends it to pCPA, which then undertakes negotiations on behalf of the different provincial drug programs or health programs. Some of them are the same people.

Ms. Heather Logan : That is correct.

I would just clarify that the recommendations that come through either CDEC, which is the CDR expert review committee, or pERC, which is the pCODR expert review committee, are entirely independent of the board of directors. They're entirely independent of the clinicians and the patients who provide input. They are developed independently.

Mr. Tom Kmiec: For any of the reviews, are there legislated timelines in the review process?

Ms. Heather Logan : Not to the best of my knowledge. They are our own established timelines and we adhere to those in almost every instance.

Mr. Tom Kmiec: In your presentation, you talked about moving from an assessment to management. Who gave you that authority to undertake that? Was it the provincial government? Was it the federal government? Or was it just a decision internally?

Ms. Heather Logan : The transition to a health technology management strategy or enterprise reorganization came from several different things that happened simultaneously. In the federal government budget in 2017 there was additional money provided to CADTH to support that transition to an HTM strategy. That was probably the biggest impetus to allow us to put people and processes in place.

Mr. Tom Kmiec: That begs the question: did the federal government initiate that, then, or was it something that CADTH requested from the federal government in that budget?

Ms. Heather Logan : It was both. It is both. We knew that this was something we needed to do. As a health technology assessment organization, the process has typically been to review each drug as it comes forward and to make—

Mr. Tom Kmiec: Forgive me, but I'm going to have to interrupt you. I have a very limited amount of time and I have a lot of questions written down.

Can you tell me why in your decision-making in the recommendations....? I'll give you a specific example. In the case of Spinraza, you gave criteria for the recommendation that fall within the kind of jurisdiction you've laid out. Why is it that you look at price instead of just efficacy? It seems to me that price is a question for the PMPRB when it's a patented medicine, and then for the pCPA during drug negotiations, not for the people who do an assessment or the management and a review of whether this is efficacious for patients or not.

Why is price being considered? In the case of Spinraza, the recommendation was “substantial reduction in price”. That doesn't seem to have anything to do with whether this works for patients or not.

● (0920)

Ms. Heather Logan : Each of our expert panels has a deliberative framework that tells the committee how to consider its review process in making funding recommendations. Cost-effectiveness and clinical impact are central to that discussion. In fact, cost-effectiveness is an assessment that equalizes how we assess those drugs and technologies across the system to ensure value for Canadians.

When the cost-effectiveness ratio is exceedingly different from what would normally be funded, the expert review committee provides guidance that would help pCPA understand what would make that therapy come in line with other therapies that are being approved in the Canadian system. It's guidance to pCPA—

Mr. Tom Kmiec: I'm sorry to interrupt you again. My point is that there already are two bodies that look at price: the trademark, patented-medicine side, which is represented by the gentleman to your right, and then the pCPA, which negotiates on behalf of the public drug program.

What I see too often is that CADTH says yes, but with substantial price reduction and for a limited patient population, as in the case of Spinraza. I have constituents who do not get access to it because the provincial government says, “You can't have access to it because you fall outside of it. Oh, and negotiations are ongoing.” They still can't get access to it.

It just seems to me that there is a disconnect, which is why I asked you the question in the beginning: How closely are you tied to pCPA? Shouldn't there be either a dual process, where negotiations are started earlier, or early on, along with the review; or should there be more parliamentary oversight, so that parliamentarians—if we're footing the bill, the taxpayer is paying for this—have more oversight over what you are doing in order to streamline the system?

Ms. Heather Logan: I would respond in two ways. There is more alignment across the drug review and approval system now than perhaps at any point in history. We do work very closely with pCPA, with PMPRB, with the provinces, with Health Canada and INESSS. I would say it's better than it's ever been.

I would also say that this new proposed supplemental process will begin to address many of the issues you've talked about, so having an opportunity for conditional listing, for example, having an opportunity to negotiate price and to conduct both the regulatory and the HTA assessment almost in parallel, has never been done in this country. We're moving in that direction, so I think you're going to start to see some of those things happen.

The Chair: You're over time, but I'm going to let you go because we were a little over time on this side. We'll just have one last question and one quick answer.

Mr. Tom Kmiec: Trevor Richter is the current director of CADTH common drug review, and he wrote an article in 2018, “Characteristics of drugs for ultra-rare diseases versus drugs for other rare diseases in HTA submissions made to the CADTH CDR”. It's available on Orphanet.

In it, he acknowledged the higher rate of negative HTA recommendations for ultra-rare disorders, and suggested it may be warranted to apply different standards when evaluating these therapies. Do you agree with Mr. Richter's assessment? If so, what is CADTH doing?

Ms. Heather Logan: In my presentation, I specifically articulated some of those challenges. Drugs for highly complex, specialized, ultra-rare and rare diseases are often plagued by a number of problems. They have insufficient evidence, so we have limited confidence in the ability of that drug to have the kind of clinical impact being proposed, among other factors.

We are working with the EDRD working group to not only address it at a systems level, but to start to recognize that there may be a very small group of drugs that have to be put through a supplemental process so that we can provide access while the system is still generating new knowledge.

These drugs are expensive and there are risks associated with every drug, so there is a balance between speed and confidence in our ability to list those drugs. We are working with the provinces. We've also implemented a number of things already to start to address some of those, like these clinical panels that I mentioned in my presentation. In the review process we can convene clinical panels for small targeted diseases where we need to hear directly from clinicians, and that information can then be fed directly into the expert review committee, so it would—

The Chair: I have to end it there, but thanks very much. We are quite far over.

Mr. Davies.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair.

Thank you to both witnesses for being here.

Mr. Clark, you stated that the mission, or the raison d'être of the Patented Medicine Prices Review Board is to protect Canadians from excessive pricing. You've also pointed out that we have the third-highest prices among the OECD countries. In fact, I've actually heard they are the highest prices in the world.

Would it be fair to say that we are not meeting the goal of protecting Canadians from excessive pricing?

● (0925)

Mr. Douglas Clark: That's a great question. We are doing the best we can with the tools currently at our disposal, but it's for that very reason that we are trying to move forward with these quite ambitious reforms that I alluded to.

I would say today, no, we are not doing a very good job, but it's because the landscape has changed so dramatically, as I also alluded to in my presentation. When the PMPRB was established, arguably those drugs we were regulating were within reach of the everyday consumer. They treated common ailments. They cost $100 to $1,000 a year. Eight of the 10 top-selling patented medicines are biologics, they're complicated, and so a whole different framework is necessary to—

Mr. Don Davies: I'm just going to stop you there. I don't want to get into that.

Every other country in the world is dealing with exactly the same situation.

Mr. Douglas Clark: That's absolutely correct, yes.

Mr. Don Davies: The fact that we're still third highest strikes me as indicating that what we are doing is not meeting our goal. By the way, I'm not shooting the regulator—

Mr. Douglas Clark: No, no that's fine.

Mr. Don Davies: I think it would get into policy reasons.

You also said that when the Patented Medicine Prices Review Board was set up back in the late 1980s—

Mr. Douglas Clark: It was in 1987.

Mr. Don Davies: —in 1987, so 30 years ago—at that time I remember distinctly it was the Mulroney government that stated that their policy was that they were going to extend the patent protection to drug companies, and two things would happen. One was that we would attract research and development to Canada. Two, with the set-up of this board we would protect Canadians from excessive pricing. Yet here we are 30 years later and by all accounts R and D is actually less today than it was. We're actually below that original 10% goal and, of course, we're paying the third-highest prices in the world.

Would you agree with me that the policy of granting drug manufacturers extended patent protection has clearly, after 30 years of data, not resulted in more R and D in this country and lower prices for Canadians?

Mr. Douglas Clark: We've been quite transparent in acknowledging that fact. There is no natural connection between the degree of patent protection a country offers and the level of R and D. You can do your research and development in China and still benefit from the same term of protection in Canada as a domestic company that did all of its R and D here. So, maybe it's a quid pro quo arrangement. Back in the day, I think that's how it was seen, that it would increase our IP regime for pharmaceuticals. You bring in more R and D but there is no organic nexus between those two things. They have been quite vocal in saying so in recent years.

Mr. Don Davies: We just signed the United States-Mexico-Canada Agreement. That agreement will extend the minimum data protection period for biologics from eight years to 10 years. So, we've just replicated that policy of extending patent protection to drug manufacturers. That means, of course, that U.S. drug companies will be able to protect their biologics from competition in Canada for a full decade.

As you just pointed out, Mr. Clark, given that according to the PMPRB seven of the 10 medicines—and I think you said eight—

Mr. Douglas Clark: It's eight.

Mr. Don Davies: —contributing to drug sales in Canada last year were biologics, would you agree with me that the impact of extending data protection on biologics by two years will have a deleterious effect on the amount we spend on drugs in Canada?

Mr. Douglas Clark: It could. I think the important thing to understand about data protection is that it typically operates in parallel to patent protection and runs now for 10 years. It did run for eight, and patent protection is 20 years from filing, so typically data protection is almost redundant in a way. It's subsumed within the patent term, so it will really depend on how many drugs are coming onto the market in the future, biologics, for which there is less exclusive time left under patent than there is under data protection. That's a very difficult thing to forecast. I think a bigger picture of what that supports in terms of a policy adjustment is a more robust PMPRB to equip us with the tools that we need to more closely scrutinize these types of drugs.

Mr. Don Davies: You sort of anticipated where I was going with that, so thanks for that.

I want to pierce the veil of secrecy that seems to be such a part of this whole pricing of prescription drugs in this country. We had Dr. Joel Lexchin who said that:

> drug companies will not open up their books to reveal their R and D costs for new medications. There's a figure of $2.6 billion that's bandied around as being the cost of getting a new drug to market. That kind of figure is based on confidential data that won't be released. If drug companies want to prove that they need to charge these significant amounts of money that they do for new drugs, then they should prove to Canadians and to insurers that those prices are actually justified. However, so far, they haven't.

To what degree, Mr. Clark, are drug companies' research and development costs for a particular drug revealed or considered in PMPRB reviews on excessive pricing?

● (0930)

Mr. Douglas Clark: I would say not at all. It's not unique to Canada the fact that both prices and R and D are not disclosed publicly.

Mr. Don Davies: Not even to your...?

Mr. Douglas Clark: There is a mechanism in our act that would enable a hearing panel of the board to compel that type of information from the company if it felt it was germane, and if it required that information to make a ruling on whether the price of the drug was, in fact, excessive. But there have been all manner of drug transparency bills proposed before various state legislatures in the U.S., whereby they are trying to compel companies to open up the books and actually reveal how much they are spending on these drugs and whether there is some proportionate relationship between R and D and prices. To date, that has really failed. I think a lot of people in the know are not big supporters of that, because they are concerned that if you just regulate prices on the basis of profit, you turn pharmaceuticals into a utility. That's the argument.

Mr. Don Davies: You said there's a statutory power to compel that information. How often is that used by the PMPRB?

Mr. Douglas Clark: I couldn't give you numbers off the top of my head.

Mr. Don Davies: It sounds like it's quite infrequent.

Mr. Douglas Clark: Yes, it certainly is.

Mr. Don Davies: I wanted to get—

The Chair: You're over, but I'm going to let you go a little further because everybody else has.

Mr. Don Davies: Mr. Clark, at the last meeting, we heard an example of a drug, for a rare disease, called Cystagon. People were paying $15,000 a year and it was under that special access program. The company didn't apply to be licensed for that. They applied to be licensed for Procysbi, which cost $350,000 per year. It's the same drug and the same molecule, except that there's a coding that's different, so the release is different.

Is it time for us to consider some form of compulsory licensing or at least address that? When we have a company that is foisting on to the public the same drug that costs many times more than another drug that we know is available, that tells me that something is wrong with the system.

What's your fix to that?

Mr. Douglas Clark: How much time do I have?

The Chair: None.

Mr. Douglas Clark: There are a couple of corrections.

It's not the same company. It's a different company. The actual ratio between the price of Cystagon and the price of Procysbi is even more outrageous, I would say. It was closer to $5,000 a year for Cystagon and about $300,000 for Procysbi.

I can't really speak too much to that particular example because that drug is currently under investigation and could potentially go to a hearing. Typically, when you see an original version of a drug that has conventional release characteristics—you just swallow it and it gets absorbed by the stomach—it gets genericized with a brand name company to retain some market share. It comes out with an extended release version of that same product, which is analogous to the situation—

The Chair: I'm sorry.

I have to end it now.

Mr. Douglas Clark: There's about a 15%, or 30%, or maybe double price markup, but a 60-fold markup is unheard of. I think it speaks for itself.

The Chair: Thanks very much.

We're going to go back to seven minutes with Mr. McKinnon.

Mr. Ron McKinnon (Coquitlam—Port Coquitlam, Lib.): Thanks, Mr. Chair.

Thank you all for coming here.

Mr. Clark, you mentioned that you're recommending changes to the regulatory framework.

Can you go into more depth into what specific changes you need there?

Mr. Douglas Clark: Sure.

I should specify that there are three legal instruments that make up the legal framework of the PMPRB: the Patent Act, the regulations and our guidelines. The act is obviously the responsibility of Parliament, the MPs. The regulations are the responsibility of the Minister of Health, subject to being ratified by the Treasury Board. The guidelines are our own responsibility.

So, it's not that we're recommending these regulations or sponsoring them. They originate from the Minister of Health, from Health Canada.

That being said, I can describe in very broad strokes the nature of the changes that are proposed. For people who are interested in the details, the actual proposed regulations were gazetted on December 2.

There are basically three types of changes. It's proposed that the basket of countries that we compare ourselves to for pricing purposes be changed so that it's no longer such a premium set of countries because we realized, as I mentioned, that this aspirational policy didn't bear fruit over time in terms of an R and D footprint in Canada. We're looking at a group of countries that are a bit more similar to Canada in terms of health systems and economy, and more reflective of OECD median prices.

The second thing that Health Canada is doing is introducing new factors that the PMPRB can consider in trying to make a determination as to whether a price is excessive. Currently, there are only four or five factors in the act that we can look at, and they don't provide us with much insight, especially in the current context with the types of drugs that are posing sustainability challenges to payers. These new factors are pharmacoeconomics, market size and GDP. They'll enable us to leverage the work of CADTH, for example, in trying to set a cost-effective threshold for a lot of these new drugs and take a look at overall affordability in terms of the expected market size of the drug relative to GDP or GDP per capita.

Then the third type of change is enabling us to have visibility into what prices are actually being charged in Canada. The whole pricing issue has gone underground in recent years. I'm sure you're familiar with this. Most public payers negotiate confidential rebates with patentees, so list prices really don't reflect what's truly being paid in the market. Unfortunately, the PMPRB is doubly handicapped in the sense that it doesn't know what prices are truly being paid in the countries that we're comparing ourselves to, and in addition, it doesn't even know the current prices being paid by public payers in Canada. This is because of a very unfortunate court decision dating back to 2009.

It's proposed that we actually can compel that type of information. The main rationale for enabling us to do this is so that companies will be able to comply with these new, much lower price ceilings that will result from our application of these new factors of pharmacoeconomics, market size and GDP. So, it's in the companies' interests to provide us with that information.

I should emphasize, however, that this information will not be made public. It will be kept confidential by the PMPRB. Unfortunately, if we were to reveal the true prices in Canada, it would have a domino effect, a cascading effect. Internationally, it would be a race to the bottom, and we would no longer be able to secure those kinds of deals.

I hope that answers your question.

● (0935)

Mr. Ron McKinnon: Thank you.

You mentioned that you're doing the best that you can with the tools that you have available. Is that what you mean—that you need those kinds of regulatory changes—or are there other tools that you have in mind that you'd like to see?

Mr. Douglas Clark: I think that's the ideal. If we had to pick our top three, that's where we would land.

I think it would be helpful if we had a more enhanced ability to compel information from companies, and if we had something in the nature of administrative monetary penalties in the cases of non-compliance. Currently, if a company prices above our ceiling, it's required to lower its price eventually and to pay back excess revenues. The only real stick that we have is if it's a wilful policy of pricing above our ceiling. If the company does it knowingly, we can order that twice the amount of revenue be paid back to the consolidated revenue fund, but I don't think that's much of a deterrent, really. Many other regulatory bodies that have an enforcement function to them have some kind of means at their disposal to incent compliance, and I would say that that's a gap in our regime.

Mr. Ron McKinnon: Thank you.

I'd like to extend that question to you, Ms. Logan. What tools do you need to help us end up with better pricing for drugs, better affordability?

Ms. Heather Logan: We need to continue to advance the collaborative nature of the partnerships between Health Canada, INESSS, PMPRB and pCPA. We need to be willing to be innovative and try new things. This aligned review...I think you heard from the people who presented from Health Canada. It really started from a conversation between two people that we could accelerate this process. Rather than having sequential processes, we now run them in parallel at the request of the manufacturer. It's a voluntary initiative.

We need to be willing to try to do those things, and to be able to learn when they don't work, and to build on them when they do, first and foremost.

Secondly, we also need to be able to work with the provinces to understand, from their perspective, the kind of data and information that they need in order to publicly reimburse medications. Some of those conversations are already taking place.

Thirdly, we need to be able to continue to advance in this health technology management approach. What that means is a full life-cycle approach for drugs; that not only do we review them, and then provinces, if they have the ability to fund, fund them, but we then keep an eye on how they function in the real world. We need to collect evidence and bring that back into the HTA process to reassess the clinical and economic value of that drug, and make a different choice, if that's the best decision for Canadians.

If we're not seeing the clinical outcomes that we expected to see, that we negotiate again, either working with PMPRB or pCPA, and potentially, for a very small number of drugs where they truly don't perform, if they don't perform, to have the ability to reinvest funding from those drugs into drugs that we know are doing a better job for Canadians. We need to continue doing a lot of the things that we're already starting to do.

● (0940)

The Chair: We will now go to our five-minute round, starting with Ms. Gladu.

Ms. Marilyn Gladu (Sarnia—Lambton, CPC): Thank you, Chair, and thank you to the witnesses for being here.

What's the average time for CADTH to approve a drug?

Ms. Heather Logan: Both pCODR and CDR have targets. In general, it takes between six and nine months. It depends on the complexity of the file, and whether there are specific requirements to go back to the manufacturer for clarification.

Ms. Marilyn Gladu: I have the same question for PMPRB. How long does it take to process the drug and get that price?

Mr. Douglas Clark: It really does depend on the drug. We do have service standards. Typically three months, but it will also turn on whether the patentee is inclined to comply voluntarily or whether we end up in a hearing. If it's a hearing, then there are no service standards that apply to hearings. It really depends on how long it takes for the board panel to dispose of the issue.

Ms. Marilyn Gladu: The reason I'm asking that is because I have heard concerns about the changes that are being proposed to the PMPRB. Dr. Eyolfson made a great point when he said it's not price that's keeping us from getting more R and D. It may have to do with the amount of time and the number of hurdles that people have to go through before they have price certainty in Canada. If I look at some of the suggestions that I heard, Ms. Logan, the streamlined process sounds like a really great idea for cutting the amount of time it's going to take to get there.

Is there anything we can do to improve the price certainty at an earlier time for people who are trying to bring drugs to Canada, so we can keep those clinical trials and that research happening?

Mr. Douglas Clark: Before I came to the PMPRB, I worked at the Competition Bureau and dealt with many different industries and sectors of the economy. Everybody wants price certainty. No one gets it. What you want is the most predictability and visibility in the regime, but there is no country that I'm aware of where a company can go back to its headquarters, and say this is the price we're going to get before it goes through the various processes, the HTA process, the negotiation process.

It would be nice if we could provide perfect certainty. We're certainly aspiring to bright-line tests in the new framework that is being contemplated, but at the end of the day, this is the one concern that is recurrent from industry that has some legitimacy in Canada.

It really is like a relay race at times. We are working more collaboratively. We are working to collapse processes and have them run concurrently, instead of consecutively, but at the end of the day, we have a federal health and safety regulator. We have a pan-Canadian HTA regulator. We have a federal price ceiling regulator, and we have the pCPA. We have a patchwork of coverage in the market, public payers by the pCPA and private insurers.

There's no question that by not having a single national buying authority, reimbursement authority, to harness the collective buying power of the populace, we are leaving money on the table. That's why, at the end of the day, PMPRB exists. It's to compensate for the fact, by having a regulator, we don't have a national reimbursement authority or negotiating authority. Drugs are not part of our publicly funded health care system.

● (0945)

Ms. Marilyn Gladu: Can you tell me why we picked South Korea as a country we want to put in the bucket of similar countries?

Mr. Douglas Clark: What's wrong with South Korea?

Ms. Marilyn Gladu: I don't know anything about their health standards, but I would be surprised if they had the same access to drugs and health outcomes. I just don't know. That's why I'm asking.

Mr. Douglas Clark: As I mentioned before, PMPRB is supportive of the changes to the regulations, but they don't originate with us. We don't have policy authority over them. I think you'd be better served by directing that question to Health Canada.

There are criteria they've identified in the RIAS that they considered in selecting those 12 countries. Part of it is GDP per capita. Another part is a similar health system, similar access. I can only assume that's true of South Korea.

The Chair: Mr. Grewal.

Mr. Raj Grewal (Brampton East, Lib.): Thank you very much.

We've had a lot of testimony on rare diseases. I'd like to know what jurisdiction, if any, gets it right, and if there any best practices that Canada can follow and learn from when it comes to developing a policy on combatting rare diseases in this country.

Ms. Heather Logan: There are pockets of excellence around the world. There are components of the process that work exceedingly well in some jurisdictions. If any jurisdiction had this mapped out perfectly, I think we would be one of the first organizations to try to copy that jurisdiction as much as we could. What's being proposed, in particular by the expensive drugs for rare diseases working group, is truly innovative. Based on consultation and further discussion with assistant deputy ministers and deputy ministers at the jurisdictional level, if some of these provisions move forward it will alter the way drugs for rare diseases—highly specialized and complex drugs—move through the system and how patients and clinicians get access.

Mr. Douglas Clark: It's hard to improve on that answer, but some of the reforms we're looking at do, in fact, borrow from best practices abroad. Canadians try to incorporate these reforms into our regime and adapt them to the Canadian system. At the end of the day, everybody is struggling with this issue; everybody's grappling with it.

I've heard good things said about the U.K. system, which is one model we're relying on quite heavily in moving forward with these reforms. Anecdotally speaking, I was there last year meeting with a friend of mine who is responsible for rare diseases access for a particular company I won't name, headquartered out of the U.K. I told her it sounded like the U.K. really had it all figured out. Her answer was that the U.K. was the worst country she'd ever worked in. She said her counterparts in other countries would tell her that industry thinks the U.K. is the worst country but that it is somehow getting the best price. We're figuring it out as we go along, but I think we're on the right track.

Mr. Raj Grewal: In terms of the patent process, do you think there are areas we can improve on in this country that would make it more beneficial for pharmaceutical companies to develop their drugs in Canada?

Mr. Douglas Clark: Well, I think you might have missed a line of questioning on that very issue. I don't think there's anything we can do under our patent regime that will serve as a policy instrument to attract R and D to Canada. The literature would suggest that other policy instruments are much stronger determinants of where pharmaceutical R and D investment is located, and they typically are things like head office location—companies usually focus their R and D efforts in proximity to their head offices—scientific clusters, access to good patient data, genomic data.

At the end of the day, all the IP regimes pretty much resemble one another in their approach to pharmaceuticals because we all have to comply with our WTO minimal norms and standards in that area under the TRIPS agreement. I would discourage that whole line of thinking, that something you can do by adjusting patent protection in Canada is going to have a material impact on R and D, either positive or negative.

● (0950)

Mr. Raj Grewal: We had patients and parents of patients come in to testify, and we heard a lot of testimony on the frustration of getting access to drugs and reimbursements, together with worries about provincial governments changing the rules halfway through. Is there anything we can do, from a federal pan-Canadian strategy perspective, to make this easier, to ensure that people or families who have to deal with rare diseases can have easier access or opportunities to get these drugs?

Ms. Heather Logan: I'll offer a comment to start.

One of the key elements that I think will be absolutely necessary to have in place, and that currently needs some infrastructure support and coordination, is around real-world evidence. If you imagine a future state where we can conditionally approve a drug, or where the payers conditionally approve a drug, their level of confidence about the clinical impact may be muted, so we have concerns about implementing the drug. However, because of patient need, there is a desire to do so.

You'd want to be sure, given the cost of these drugs, that at some point over the course of time you can evaluate whether the clinical outcomes you think you're paying for are actually the clinical outcomes you are paying for. The ability to collect, to analyze and to use real-world evidence is an area that I think we could excel at in this country. We have exceptional researchers and exceptional analysts. We have done an insufficient amount to coordinate that system.

Having said that, on October 21, CADTH, the Institute of Health Economics, Health Canada and one other organization, whose name I'm forgetting at the moment, organized a summit. An action plan is coming out of that. If there's a way to support that action plan, if it's supported by partners, it would be a positive step.

The Chair: Thanks very much.

Now we go to Ms. Gladu.

Ms. Marilyn Gladu: I have a couple of questions. The first one is a very difficult question. We know that part of what the PMPRB does is determine if the price of a drug is excessive. We saw the costs of some of these drugs that were presented by the individuals who have come, so what is the maximum amount we would want to pay for a drug for a lifetime use?

Mr. Douglas Clark: The answer is that it depends on the drug and how effective it is and how much value it brings for the cost you're paying for it, right? Now unfortunately, all we can do in setting price ceilings with respect to these types of drugs that are first to market, first in class, have no competitors, is to look at the prices the company that has the patent for that drug is charging in other countries. Those prices do not reflect, as I mentioned, the true price in the market.

Increasingly, what we're seeing is that, because many countries try to control or at least contain costs in the pharmaceutical realm on the basis of what we call external reference pricing, comparing with other countries, there's been a convergence in the pricing of these new drugs that are coming onto the market. There's very little daylight between countries today, so it's not a very valuable reference point. I think that's why we're trying to look at, if those factors are approved, things like value for money, market size, GDP.

It will be a drug-by-drug assessment, so there's no one single answer. There may be instances where a drug that costs a million dollars a year is really good value. It all depends on the clinical effectiveness of that drug and how it compares to other drugs.

Ms. Marilyn Gladu: Okay. We have this list of countries that we're going to put in the bucket. One way of shortening the time to approve access for drugs for Canadians would be to say, you know, that because these people who are in the bucket are in countries that we very much respect—the U.K., France, etc.—if it was approved in their country, it would be automatically approved in Canada without our having to do anything else. What do you think about that idea?

Mr. Douglas Clark: Well again, that's not within the purview of the PMPRB. It's a Health Canada question, but it is actually moving in that direction to some degree, especially for the SAP drugs that they're trying to get onto the market and formalize their presence in Canada. They are contemplating working with the EMA, to a lesser extent the FDA, and I'm not sure about Australia, and accepting at face value the market authorization that's been granted in that country as a basis to grant it in Canada. It will still be on a case-by-case exceptional basis. I think it's mainly for those rare disease drugs that are on SAP currently, but it's a very good idea and it's one that's being adopted by Health Canada.

● (0955)

Ms. Heather Logan: I would add that the regulatory review of drugs and devices, R2D2, is actually including the use of foreign reviews as one of the projects. Again, Health Canada is the best organization to speak to that, but from what we hear from the regulators, they're already beginning to determine how that might happen and under what conditions. That kind of discussion is already under way.

Ms. Marilyn Gladu: What about if we try to incentivize doing more clinical trials in Canada? We're punching above our weight, but we want people to not just do clinical trials but somehow incentivize them to build their facilities and get their drugs produced here.

Is there a way that you could incentivize people to do clinical trials by saying, if there's no negative outcome of the clinical trial that you do in Canada, you have automatic approval, or something like that?

Mr. Douglas Clark: That could work, I suppose, but again it's sort of outside our wheelhouse.

I think I said that Innovation, Science and Economic Development would be better suited to answer those types of questions

However, I think if we had the answer, the policy would be in place and we'd have a lot more clinical trials taking place in Canada.

Ms. Marilyn Gladu: This is just one last question, from the private sector viewpoint.

Normally, if we knew the price we wanted to negotiate was the median price of an OECD bucket, we would just make that a contract term in every negotiation we had, and would demand that the manufacturers provide us with evidence that we're receiving that price.

Why don't we do that?

Mr. Douglas Clark: We do get that evidence, and if it turns out that they're not complying with their price ceiling, then we'll take appropriate action. An investigation will be commenced, and enforcement action will be taken; it could go to a hearing.

The reality is, as I mentioned, ceiling prices based on list prices bear less and less resemblance to the outcomes of those negotiations between the pCPA and the companies. The rebates are quite significant, but they're unknown to us.

List prices are a bit more relevant to private payers or out-of-pocket payers, because that's typically the starting point to negotiation. They have a lot less group buying power. They can't come together as a collective and negotiate, and avail themselves of that countervailing power.

However, I don't think there's a need to do that. I think we exist as a mechanism to ensure that takes place.

The Chair: Okay. Thanks very much.

My little note says that Ms. Sidhu is next, but Dr. Eyolfson is going to ask the questions on her behalf.

Dr. Eyolfson.

Mr. Doug Eyolfson: Thank you, Mr. Chair. That's a pleasant bonus.

I'm going to expand on Ms. Gladu's line of questioning. I was hoping she'd have more time to do this, so I'll just simply continue it.

We talked about how you identify prices that are quite above the median of the OECD countries, yet you said we are paying among the third-highest prices in the OECD.

How has this not been addressed in these places and corrective action taken, both with the rare disease ones, and again going back to insulin, and many other common drugs that we're paying much, much more for—sometimes orders of magnitude more—than other OECD countries?

Mr. Douglas Clark: The problem is that we're conflating what the PMPRB does currently with what's proposed.

Currently we compare our prices to PMPRB7, which is a fairly premium-priced set of countries.

What we're proposing is to compare ourselves to this basket of 12 countries where, on average, prices are more aligned or in tune with the OECD median. In the future, if these amendments come to pass, our list prices should converge toward the OECD median.

However, today, if you're a breakthrough drug or substantial improvement drug, you start off at the median of the PMPRB7, and then you're allowed to increase price in keeping with CPI until you hit that absolute ceiling of the highest international price. Typically, that's the U.S., where prices are two times to two and a half times higher than everybody else.

We start off at a ceiling that's not that stringent, and then it creeps up, it drifts up, toward the U.S., as opposed to going down towards the European countries that we compare ourselves to.

● (1000)

Mr. Doug Eyolfson: Thank you.

This is something that's come up before, and I need a refresher.

We had talked about the patent protections that were given back in the 1980s. There was an agreement from industry. Was it 10% of their profit would be to R and D, or—?

Mr. Douglas Clark: No, it was 10% of sales.

Mr. Doug Eyolfson: Yet the figure we have now is that they're spending about 4% of their sales.

Are they not in breach of this agreement?

Mr. Douglas Clark: Well, it was a handshake agreement. It's not a contract, so they're in breach of a handshake undertaking, I suppose, which—

Mr. Doug Eyolfson: You mean this wasn't actually written. It was more of an agreement.

Mr. Douglas Clark: It was memorialized in a letter from the then head of what was called something different at the time, but is now called IMC, and the minister of consumer and corporate affairs at the time.

The industry really takes issue with the way we are defining the scope of R and D today. They've done a number of studies that they say support the fact that they're actually doing more R and D in Canada than we are accounting for.

I think the studies speak for themselves. To me, they reflect more the industry's footprint in Canada, as opposed to just their R and D, strictly speaking, but I know that this question.... The R and D definition hasn't changed over time, and the R and D on those cases is gone—

Mr. Doug Eyolfson: Yes. That actually answered my question.

I'll end with this last question. As we've said, a reference was made to Dr. Lexchin's earlier testimony that they bandy about these figures of $2.5 billon for every drug but it's confidential data. Is there not some body that has the power to legally obtain this, to actually tell them that we are legally requiring them to disclose this to us?

Mr. Douglas Clark: That number, as far as I know, originates with a Tufts University study. I started off years ago in patent policy for the federal government. I was eventually transferred to—

Mr. Doug Eyolfson: I understand that. As I say, we're not sure how accurate the figure is.

Is there not a mechanism? As we've said, it goes back to the confidentiality. The industry says that it needs to charge these high prices because their R and D is so expensive, but they're not going to tell us what their R and D is.

Mr. Douglas Clark: Right.

Mr. Doug Eyolfson: Is there not some legal mechanism in the regulations so that we can say, no, we need you to tell us what this is costing you to make to justify the prices...?

Mr. Douglas Clark: No, not really. As I said, it could be compelled in a hearing context, but it's really difficult for most companies that are large multinationals with a huge inventory of products to disentangle the actual R and D that was spent, including the failures that got your product to market. Even if you could compel it—and I'm not aware of a jurisdiction that does—it would be very difficult to figure out.

You can look at SEC filings in the States, the 10-K filings, and get some insight into how much is being spent on R and D. Most companies spend about twice as much on marketing as R and D these days, but like I said, every once in a while you'll see a company that's a single-product company. Then there's pretty transparent visibility into what their R and D was, what their cost of making and manufacturing was, the cost of production—the cost of sales, I should say—and what their gross and net profit margin is. Sometimes it can be quite exorbitant.

Mr. Doug Eyolfson: Thank you.

The Chair: Your time is up, Dr. Eyolfson.

We tried to get that information here, too, and we were unable to get anywhere near it.

Mr. Douglas Clark: You're in good company.

The Chair: The next questioner is Mr. Davies.

Mr. Don Davies: So the way we price drugs in Canada is that we take seven comparator countries, three of which—the U.S., Switzerland.... Is Mexico part of that seven?

Mr. Douglas Clark: No.

Mr. Don Davies: Switzerland and the U.S., I think, are the top two.

Mr. Douglas Clark: Yes.

Mr. Don Davies: We take the most expensive prices in the world and we get a very high average. We take that as the median and then we allow the drug prices to go up to the highest price in the world. Do I understand that?

Mr. Douglas Clark: Well, it depends on the circumstances. Oftentimes companies don't increase their price—

● (1005)

Mr. Don Davies: But they're allowed to?

Mr. Douglas Clark: There's a formula that's based on CPI. Provided they're compliant with that calculation, then yes, they can increase their price in keeping with CPI on an annual basis until they hit that wall, that absolute ceiling that is the highest international price. That doesn't happen in every case. It does in some cases. It doesn't in others, but—

Mr. Don Davies: I'm talking about the system.

Mr. Douglas Clark: Yes. That's the system.

Mr. Don Davies: If it's our system that permits that, it's no surprise to me that we're paying world prices.

Mr. Douglas Clark: I agree with that.

Mr. Don Davies: I'm not a health policy expert, but it would strike me as quite logical, as you pointed out, that if we just get a more representative larger basket with lower prices and take that as the median price, the prices will come down. That's a matter of logic. What's the barrier to doing this? Why is this government not doing that now?

Mr. Douglas Clark: Well, as I mentioned, list prices are only half the battle, right? The real price is the price net of rebates, which—

Mr. Don Davies: That's where I'm going to go next, but just in terms of isolating this factor, why don't we change the comparator countries to the 12 more representative ones and get the U.S. out of there now?

Mr. Douglas Clark: Well, that's been proposed, so that train has left the station. There is a regulatory process, and it takes time. I think it's complicated in this particular instance by the fact that we have other components to that regulatory proposal—namely, the new factors for the PMPRB to consider in determining what constitutes an excessive price. Those are very controversial, so we're facing a lot of—

Mr. Don Davies: Can I ask you, Mr. Clark, who makes that decision, ultimately, about the comparator countries?

Mr. Douglas Clark: Ultimately, the Minister of Health makes it, but it is subject to ratification by cabinet, by Treasury Board, like any regulation.

Mr. Don Davies: So cabinet could make this change, if they wanted to, when they want to?

Mr. Douglas Clark: Subject to the strictures of the regulatory process and the duty to consult, etc., yes.

Mr. Don Davies: How long have they been consulting on this?

Mr. Douglas Clark: We've been consulting on reforms to our own pricing guidelines since June of 2016. Health Canada put out a proposal in May of 2017 to sort of entrench the types of changes that were being contemplated in our guidelines discussion paper in a white paper. That was in May of 2017, and that eventually morphed into an actual set of proposed regulations that was pre-published in the Canada Gazette, part I, in December of last year, followed by a 75-day consultation period.

Mr. Don Davies: I have limited time, so I'll stop you there.

I will leave my last question with each of you. It goes back to the secrecy.

Mr. Clark, we talked about how “the PMPRB bases its cost comparisons on public list prices, even though it’s well known that drug companies secretly negotiate substantial discounts and rebates, cutting the true cost of medicines by as much as 50% for some countries.” I would ask you to comment on that.

Ms. Logan, I haven't had an opportunity to really ask you any questions. CADTH is sort of based on the Therapeutics Initiative in British Columbia. We had testimony from Dr. Tom Perry, who said that “it repeated one of the mistakes of the B.C. government, and that is to guarantee secrecy to the pharmaceutical industry's sponsors on the grounds of protecting commercial or trade interests.”

So there's all the research that goes in, secretly paid for; researchers pledged to confidentiality; and all that research of comparing efficacy, not in the public realm. I'd like to hear comments from each of you on that, if I could.

The Chair: I'd like to point out that the bells are ringing for a vote. If you could give concise answers to that rather long question, that would be great.

Mr. Douglas Clark: I agree with you that it's problematic. That's why, in the three elements of the regulations I outlined earlier, one of the proposals is to enable us to get access to that information and regulate on the basis of the real prices that are being paid in the market. We would really like to do that.

Ms. Heather Logan: One of the values in our new strategic plan is transparency. That's driving a lot of change within the organization. One of the things we're working hard to implement is to reduce the number of redactions in the reports that are made public. The public will see more and more of what we get from manufacturers rather than less and less. That's because we're committed to transparency.

Mr. Don Davies: Thank you both.

The Chair: Thanks very much.

You've been extremely helpful in painting a very difficult situation. It will be a big challenge for us as a committee to come up with recommendations, and we really appreciate your contribution here. It's been very helpful.

I'm sorry we're having to end early, but we have to go and vote.

The meeting is adjourned.