MEET THE MANAGER

WAYNE CRITCHLEY

Executive Director

Patented Medicine Prices Review Board

Wayne D. Critchley has been the Executive Director of the Patented Medicine Prices Review Board (PMPRB) since 1990. A career public servant, he has worked extensively in the area of economic regulation.

Prior to joining the PMPRB, Mr. Critchley held a number of senior positions in the Bureau of Competition Policy. Among other things, he was involved in the modernization of the *Competition Act* in the 1980s and the implementation of the Bureau's compliance policy.

Mr. Critchley was born in Winnipeg, Manitoba and educated at the University of Winnipeg.

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PRA: *Could we start by talking about you for a bit? Could you tell us a little about what you've done in government and what you've done at the Board?*

Wayne Critchley: I'm a career public servant at the federal level and have worked in the area of economic regulation. My career started in the competition policy area. I've worked quite extensively in all facets of government activities under the *Competition Act*. I was very fortunate to have opportunities to be involved in the implementation of the major changes to the Act in the late 1980s that increased and expanded the role of the competition tribunal and introduced more effective merger review provisions in Canada.

I've been with the PMPRB for over 12 years now and it was in many ways, I think, a very natural move for me to make. I had the opportunity to deal with some issues in the pharmaceutical sector during my career in the competition Bureau and always found it to be tremendously interesting in terms of the economic and policy issues that it raised. Of course, it is also so important as such a key part of our health care system. When we talk about the evolving role of the Board, I think that one of the things that we have seen over the past 10 to 15 years is the growing understanding and awareness in the system of the importance of pharmaceuticals in health care. We've seen tremendous growth in sales and utilization of drugs. We're all familiar with those figures that drug costs now represent more than 15% of total health care costs, and we have in more recent years, witnessed a growing public awareness of this fact. I hope that our work has helped to create that awareness.

PRA: *Picking up on the theme of evolution, some stakeholders have suggested that the Board is playing an ever more important and integrated role in the policy work of Health Canada. Your partnership with CIHI [Canadian Institute for Health Information] is perhaps an example of this. Do you share that view, or do you see your work differently?*

WC: Well, the PMPRB does have two key functions. We have a very clear mandate and there are two important parts to it. This is not necessarily understood by all stakeholders.

The first is the regulatory mandate to ensure that the prices charged by manufacturers for patented medicines are not excessive, and this is obviously a tremendously important function. The Board operates at arm's-length from Health Canada and from the government, and has significant remedial powers in exercising its quasi-judicial functions where it finds that the price of a patented drug is excessive. As a tribunal, the Board is required by law to apply the rules of natural justice and carry out hearings in an open and public way that provides an opportunity for the drug manufacturer, ministers of health and other interested parties, to be heard, to call evidence and to make their case. Although the provisions of the *Patent Act* have not changed significantly since 1993, there has been considerable evolution through the jurisprudence over the years, in establishing the scope of the Board's jurisdiction and confirming the parliamentary intent behind its work. In

the ICN case, the Federal Court of Appeal said that the purpose of the provisions creating the PMPRB was to ensure that consumers are protected in pricing of drugs in the same way that they were protected under the compulsory licensing system. So I think there has been very clear support in the courts for the Board's mandate and the role that it plays.

The second key function of the Board is reporting. We have a mandate under the Act to report on the prices of drugs in Canada, regardless of patent status. Parliament created this Board to be the federal expert body on issues related to pharmaceutical pricing, and in addition, to report and monitor the performance of industry on research and development expenditures in response to the industry's own commitment to increase R&D spending in this country.

Parliament and the provincial and federal governments are all asking us to do even more on the issues of access and affordability.

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On this point, during the 1997 parliamentary review of the *Patent Act's* provisions governing pharmaceuticals, there was only one recommendation addressed directly to the Board — that we consult on how we could provide more information in this area. When we subsequently consulted more broadly with Canadians, we heard that message time and again — that people wanted more information about the price and cost of drugs, as well as issues related to utilization.

This came up again when we did our survey last year of key stakeholders as part of our environmental scan. The major concerns people have are the rising cost of drugs, but they also recognize that there is a need to ensure adequate research and development of new drugs. For example, people are very concerned about this issue of emerging technologies. They see the promise of wonderful new technologies to treat disease in the future, but wonder at what cost? People are very concerned about the issues of access to these drugs and their affordability. These are very legitimate concerns and I think Parliament and the provincial and federal governments are all asking us to do even more on this and we want to respond to that as best we can.

PRA: *You mentioned briefly the "Road Map" work you did and the environmental scan. Could we also talk about last year's symposium?*[1] *How did it contribute to the evolution you're seeing?*

WC: The symposium was the first time that we've put on a conference like that. It was a direct response to the kind of request I mentioned we've received, especially from non-industry stakeholders, for more information and a better understanding of what some of the issues are in this whole area of drug price control.

We were very pleased with the response. First of all, we had a lot of success in lining up a top-notch group of speakers. As you know, we had some leading people from other countries and certainly from Canada. In some ways we exceeded our objectives in that we had a much larger contingent of people who do not work for industry who attended. We have had positive feedback from many of those groups about the event and the opportunity to take part. It was a one-time special event and I think it was very useful and we learned a lot. But more importantly, our objective was to allow stakeholders to learn about some of these issues and I think they were able to do that.

PRA: *How about some of the specific technical challenges you've been working on through the Working Group on Price Review Issues? For example, where are you now on category 3 issues?*

WC: Let me answer your question by creating a context. First of all, the Working Group on Price Review Issues is a consultative group that we established a couple of years ago to look at some specific issues that had been raised by the public and others in our Road Map exercise. We thought it would be appropriate to consult and involve stakeholders in this policy development work.

There were 12 members on the Working Group representing a broad range of stakeholders, including consumer groups, provincial ministries of health, and of course, the pharmaceutical industry. I must tell you that we have been really pleased with the way this process unfolded. The Working Group was given three issues to look at. On the first two issues they achieved consensus and made concrete recommendations to the Board on how to proceed.

The first question was how to calculate the US price for price comparison purposes. This may sound very technical, and it is, but it is also a question that affects the bottom line. I thought it was a very significant achievement for this group to reach a consensus on how best we should address the issue of incorporating the US government prices into our price calculations. And we have, of course, implemented that recommendation and

[1] Current Issues in Pharmaceutical Price Regulation in Canada, Ottawa, October 7-8, 2002.

that's been in place now for two years. That was the first real success of the Working Group.

The second one was on the issue of transparency. And here they clearly came at this from different perspectives, different agendas, and they all probably would have liked different outcomes. Nevertheless, they reached consensus on how best we should open up our price review process to be more transparent and more open. I was very pleased with this as well. I think they deserve a lot of credit for the way that they developed a better understanding of the different points of view and were able to reach some consensus themselves. The Board agreed with their recommendations and we've since put them in place.

I think the transparency question is so very important. I mentioned earlier that the process envisaged by the Act for hearings by the Board is an open, public process. However, although our compliance policy has been successful, and clearly is a much better alternative to the cost and length of a public hearing, it has meant that most of the price reviews have been done by Board staff and have not, in the past, been made public or reported.

Now we are providing summary reports of the reviews of all the new active substances. These reports are quite comprehensive. They explain how the guidelines were applied, what comparative drugs were used, what appropriate dosages were used, what evidence was relied on by our panel of experts, what prices are in other countries, how the cost of treatment of the new drug compares to the cost of treatment of other drugs, why they were used, and so on.

We are now providing summary reports of the reviews of all new active substances, but we have to do more to communicate that this information is available.

— Wayne Critchley

This is a new initiative we've only recently introduced, and I think we have to do more to communicate the fact that this information is available. We're certainly asking for feedback on these reports because we believe they can be expanded and improved and we're eager to do that with useful feedback. I think this has been an important change.

Now to your question about the category 3 guidelines. The third issue that the Working Group was asked to look at was the guidelines for non-breakthrough drugs. This is an area that has always been full of controversy, and obviously it's a very complex question. Our guidelines are pretty straightforward in concept, by limiting the prices of non-breakthrough drugs to the most expensive drug to treat the disease. However, industry members have argued that that is too restrictive a test, that drugs that offer moderate improvement should be allowed a higher price than an existing drug. Non-industry stakeholders push the opposite point of view, that drugs that don't offer a moderate benefit over an existing drug should not be allowed a price as high as the most expensive drug that's already on the market.

Our Working Group spent a fair amount of time on this and identified a whole host of issues — I think 38 in total. Again, they were able to reach consensus on a lot of those specific issues such as how you select comparators, or how you determine the dosage forms, or what's the appropriate indication to use if there's multiple indications. Interestingly, their consensus ended up validating a lot of the current provisions of the guidelines and current practice.

Where they did not ultimately reach any agreement was on whether there should be a change to the price test, and if so, what that should be. Instead they made the general recommendation that the Board should look at whether the guidelines can better reflect the differences in the incremental value that may be offered by new drugs.

I think it's important to keep in mind that this cuts both ways. You could say that it brings us back to where we started. For example, industry wants a higher price for any improvement and non-industry wants lower prices for those new drug products that offer no improvement. But they have suggested a different way of looking at it. They suggested looking at it from the concept of the incremental value of these new drugs.

The Board has just had its first opportunity to really consider that report and its recommendations. As you might expect, we have a number of questions. For example, what does "value" mean? How can the guidelines be used to help give us greater confidence that new drugs are priced at a level that provides value for money? How can the guidelines be structured to recognize real incremental value and not just a promise of it, while at the same time not encouraging drugs that are not valuable in improving outcomes? So this is a very complex issue. I think it's obvious that if anyone anywhere in the world had the perfect answer, I hope we might have found it by now.

The Working Group has made some important suggestions, and the Board is taking them very seriously.

They have asked us to do some more work in assessing the recommendations. The Board meets in February and then again in May and they have asked us to come back with some ideas as to how to proceed in terms of further policy development work, and of course, further consultation. We will not be putting out proposed changes to the guidelines in the immediate future, but we will be looking at what further policy work might be done in this area and how we should consult in that policy development work.

PRA: *On a similar note, where are you in your work on breakthrough drugs?*

WC: Breakthrough drugs are next on our research agenda, after completing the piece on the guidelines for non-breakthrough drugs. The Working Group recommended that we take their "value" recommendation and use that to inform the review of the guidelines for breakthrough drugs, and obviously we will be looking at that very carefully because that's an equally tough issue.

Drawing from the symposium for a moment, one of our speakers from Europe made the comment that the pricing of breakthrough drugs internationally is a black box. This again links back to a point raised by some of our stakeholders in our environmental scan — the issue of the cost of emerging technologies. We can spend a lot of time talking about the non-breakthrough drugs, but in terms of cost implications, in terms of health implications, emerging technologies may be more important, and here our tools in some ways are cruder. So I think if we can find a way to do more work on how best to assess the value of new drugs, then that's going to be very exciting and important work and that's probably where we should be putting our effort.

The Working Group recommended that the guidelines better reflect differences in incremental value that may be offered by new drugs.

— Wayne Critchley

We currently limit the prices of breakthrough drugs to the median of foreign prices, which is a pretty rough kind of measure, but at the same time, it still is an important measure, and it has had an important impact. Over the years, we have seen a change in the relationship of drug prices in Canada to prices in other countries. At least for the prices for patented drugs, our prices used to be at the high end, in some cases the highest or second highest to the US, and now prices are at the median level. I think that this has been part of the evolution in the 15-year history of the Board where we have seen price stability in Canada today as contrasted to 15 years ago.

I also think that we have a wide acceptance that the median is not an unreasonable standard. The question though is, is that enough? Does that provide enough confidence that our health care system is getting value for money with these new drugs? I'm not trying to prejudge and say we're not getting value for money — maybe we are. Maybe it would be appropriate for prices in some cases to be higher, I don't know. I guess the question is whether we can develop better tools to evaluate that.

It's quite by coincidence that we happen to have a case going in front of the Board. The Board just issued a Notice of Hearing into the price of Remicade. This means that we will have an opportunity to do the policy work in a broad way while at the same time the Board is also looking at a particular drug. The Remicade case I think is a very important one. We obviously have an important drug, a drug that I think most people recognize as being a breakthrough, and the real question is going to be whether or not this particular breakthrough drug warrants a price in Canada that is higher than the median price. I think this could turn out to be a pivotal case.

PRA: *How about novel delivery forms? It sounds like you are thinking more broadly around health technologies and value for money, and that the Board is inviting you to do some policy work on these questions. Will you be addressing new delivery systems too?*

WC: On the specific issue of novel delivery forms, the guidelines currently do not recognize novelty in delivery as a specific criterion itself. So a drug whose only incremental value is a new delivery system doesn't get any kind of favourable consideration under the guidelines today. The issue is, does it also include a therapeutic advantage? I think that's where our focus will be.

PRA: *Could we return to some ideas you touched on earlier? You talked a little bit about your reporting mandate and how it's evolved. Would it be fair to suggest that you expect that evolution to continue, especially in view of some of the recommendations from Kirby and Romanow, as well as the FPT [Federal/Provincial/Territorial] progress towards the Common Drug Review [CDR]?*

WC: First of all, the Common Drug Review, as your question suggests, is an FPT initiative of participating drug plans, but I do think it has wider implications.

We're an observer in the Common Drug Review and that is a role that falls naturally within our mandate but also our historical role as an observer on FPT pharmaceutical activities. We are the federal expert tribunal on pharmaceutical pricing matters and it's absolutely essential that there be as much collaboration and coordination of the various activities as possible. Romanow went so far as to recommend creating a new National Drug Agency that would bring all of these things, even the review for safety and efficacy, under one agency.

Obviously there is room for debate as to whether you need one agency or whether you can accomplish the same goals with a group of many organizations that have different roles. But the key thing, whether it's one agency or many, is that these activities be coordinated. The last thing we need in the health care system is overlap and duplication, and to the extent that we can work to minimize that, then so much the better. As I understand the Common Drug Review process, it is evolving as an attempt to reduce overlap and duplication and this is something that I expect industry to support as it will reduce the need to make submissions to all these various jurisdictions.

I think we have a wide acceptance that the median international price is not an unreasonable standard.

— Wayne Critchley

The CDR process will permit a submission and a review, but jurisdictions will still retain their appropriate autonomy to make decisions as to what drugs they list. How do we fit in? We're not part of the CDR as we're not a drug plan, but I can't imagine that any drug plan in Canada (and I don't mean in the future under CDR but I mean even in the past) relishes having to make a decision on whether or not to list a drug if they don't know whether or not it may be excessively priced.

PRA: *So you don't see the CDR as providing an opportunity for an expanded role for the Board in any way?*

WC: No. Not immediately, but the question can also be linked to the issue of transparency we've already talked about.

Many of our non-industry stakeholders argued that there should be greater opportunity for public involvement in the price reviews conducted by Board staff for purposes of applying the guidelines. Historically manufacturers have always had access — they make submissions, they're in communication with the staff — but the non-industry stakeholders have not. They've not been denied that access, but the system hasn't worked in a way that actively invites it. There are some non-governmental stakeholders who think the provincial governments should be making submissions to us. They don't currently, but some stakeholders have argued that they should and that there should be greater work on our part to encourage and invite submissions from provincial governments and from others.

Now that was something where the Working Group did not reach consensus, and so was not part of the recommendations and therefore has not been implemented to date. However, it certainly is an area for follow-up. For example, we have an updated list on our Web site of the new drugs that are under review. I know that some patient organizations check it to see what's going on or to raise concerns with us. What we're really talking about is that in the future there will be increasing demand for even more openness and more opportunity for people to have input into the processes. So from this perspective, in time, we can expect pressure for closer coordination of the CDR's work and our own.

PRA: *Could we return to Kirby and Romanow for a minute? Are you responding to their recommendations in any way?*

WC: No. The Board will not be responding directly because the recommendations in both cases were made to the government. But certainly we are looking at those reports (and others of course) very carefully, and looking at issues that are of importance to us. One of the things I thought was very important in both reports was the fact that they identified the need to address catastrophic drug coverage. This is an important issue, speaking personally anyway, and one hopes that governments will be giving this issue a good deal of consideration.

The other key thing, and more so with Romanow, were the recommendations that were directed towards the need to do even more work in terms of developing evidence-based approaches, more information, more openness, more sharing of information and greater coordination among the various players. It's very complex in any country, but particularly here because we have a unique mix of public/private coverage for drugs, and because the public side is largely provincial as opposed to federal. So we've got that whole issue of the different levels of government. It's very complex, but just shows the importance of working on it.

There's been a lot of improvement, I think, in recent

years in the collaboration between governments. We've been fortunate to be part of the NPDUIS [National Prescription Drug Utilization Information System] initiative, which is a wonderful example of increased collaboration among the two levels of government. For pharmaceuticals it recognizes the need to have a good database, a good information system that allows you to study and analyze what the major cost drivers are, the expenditure trends, the impact of different programs, and so on. By having a national database, it's going to be easier to do cross-jurisdictional comparisons to find out which programs are most effective, and hopefully over time to expand it to include the private sector and to include a link to outcomes.

I think that this is very encouraging. As I said earlier, the question of whether all this has to be done through a single agency, as Romanow has recommended, or whether there's a way of doing this with more players, those are questions that governments can work out. I think the main point is that there is a growing consensus on the need to expand the work in developing good data and ways to analyze that data to improve evidence-based decision making and help to ensure the most cost-effective utilization of drugs possible.

PRA: *We haven't talked in detail yet about the work you do in evaluating the innovative industry's R&D spending, which of course is a Board hallmark. Can you comment at all on the recent proportional declines in basic research, as well as the absolute declines in applied R&D?*

WC: As we've noted, the role of the Board here is one of monitoring and reporting, as opposed to evaluating, developing policy or setting standards. In fact, the question of the R&D performance of a manufacturer is not even identified in the Act as one of the specific factors that should be taken into account in reviewing the price of a drug. There was some discussion in the Working Group as to whether the Board should read it in, or whether the regulations should provide specifically that we should be required to look at the R&D performance in reviewing price. However, there was no agreement on this point.

I really think the key role here is for the Board to inform, to do the reporting and to help inform whatever public debate takes place over the appropriate targets. Do the current targets continue to be appropriate after 15 years? We try to help that out by doing comparisons internationally, and some of the results from our recent study were reported at our symposium. The final study will be released early in 2003. It essentially shows, that while we saw over the past 15 years a tremendous increase in R&D spending in Canada in line with the commitments made by industry — especially in the early years when there was a faster rate of increase than other countries — our overall performance is still at the bottom end of the group of countries that we use for price comparison purposes, and that basic relationship has not changed. Is that appropriate or not appropriate? Is the money spent in the right areas or not? These really are not questions that the Board can properly take a view on, but I hope and believe that we at least help to inform the discussion of it. We keep coming back to the question of evidence-based decision making. It's got to be the same thing in policy making, even more broadly in terms of industrial policy. These are very tough questions that you've raised about where Canada wants to position itself.

PRA: *I also wanted to ask you about any work you do in quantifying export flows from Canada to other markets, particularly the US.*

WC: Well first of all, this has to do with the broader issue of the US reimportation proposals and the issue of cross-border shopping. The short answer for us is that our jurisdiction applies to sales at the factory gate, sales by manufacturers, so if a manufacturer is selling in Canada, then we have jurisdiction with respect to the price they are charging. If they are selling outside Canada for export purposes, we don't. We don't report that now and we don't have jurisdiction over it.

I think the Remicade case could turn out to be a pivotal case.

— Wayne Critchley

I think that what you're talking about, and I have to speculate a little bit because it's only recently that firms have started to come to us on this issue, is the question of Internet pharmacy. We don't have jurisdiction over sales by pharmacies, so on the face of it, it's not obvious what the issue is, or would be, for us. Having said that, I think we all have to recognize that the cross-border issue is an issue for industry. If there are questions that they have about how our guidelines or regulations work then we have an open door to hear from them and to sit down and see if there is a need to clarify or review in any way how our system works.

To put this in a totally different context, I used to hear it said (fortunately I don't hear it much anymore) that our guidelines prevent companies from lowering their prices or offering discounts. Of course that's hogwash. I would be very concerned if anyone were to

say that our guidelines somehow impede appropriate distribution policies of manufacturers. They shouldn't and I don't see why they would. If there are concerns about it, then I hope manufacturers will bring those to our attention so we can understand them and clarify the issues if necessary.

PRA: *We also haven't talked about non-patented medicines yet. Can you comment on the concern about where prices for off-patent drugs are going?*

WC: We've already discussed the changes over the last 15 years for patented drugs: Canadian prices used to be among the highest in the world, but they are now below the median. Prices for all drugs in Canada used to increase at rates well above the overall rate of inflation. We have had price stability in Canada for the past decade, very much in line with European countries, and this is a change. One thing that does not appear to have changed is the pricing of non-patented drugs. By this I mean prices for both non-patented single-source drugs supplied by brand name manufacturers, and multiple-source drugs, whether they are the brand name version or a generic version. There are an increasing number of studies that appear to show that the prices of these drugs in Canada are higher relative to foreign countries. That's an issue that we are reporting. I don't have any views about what one does about that, but we are reporting it.

PRA: *Finally, I realize that evolution has been a big part of what we've already talked about today. May I ask if you, personally, have a vision for the Board's future, and its place in the system?*

WC: I'd like to pick up on the point about greater collaboration in the area of pharmaceuticals management. We have seen great progress and that's very positive. I think we are going to see a continuing evolution in that direction — whether it's through creating a new forum such as Romanow's National Drug Agency or whether it's through continued evolution and development of existing mechanisms. The key thing is we continue to do more work to develop better approaches to assessing prices of drugs so that prices in Canada are not out of line compared to other places. But also, and very importantly, by continuing to promote and facilitate evidence-based decision making, to promote the cost-effective utilization of drugs, and doing that in a very transparent and open way. We need to give greater confidence to citizens that health care money is being spent wisely and appropriately, that people are getting value for money. This is tremendously important in an area such as pharmaceuticals where we have more information but we still don't have full information. Decisions on medications are taken by patients and physicians and others — a number of people are involved — so it's very important that we have as much transparency and as much openness as possible. My vision, in terms of the Board, is that I see it continuing to evolve and play an important role in those areas.

The Working Group did not agree on whether R&D performance should be taken into account in reviewing the price of a drug.

— Wayne Critchley

PRA: *I want to thank you for your time and your frankness.* PRA

Chris Jones is president of Management Tools, a health care consultancy specializing in market access and health policy initiatives for clients in industry, government and health care service delivery.