GALDERMA

October 21, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
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Dear Mr. Douglas Clark,

Galderma Canada Inc. thanks the Board for the opportunity to provide its comments regarding the Board's proposed Guidelines Modernization initiative. Galderma is not a member of Innovative Medicines Canada or BIOTECanada; therefore, it welcomes the opportunity to provide its comments as an independent, mid-sized innovative company whose focus is on dermatology health. Galderma's corporate vision is to partner with healthcare professionals to provide innovative medical solutions to patients with skin health needs.

The Patented Medicine Prices Review Board (Board) is one component of the Canadian pharmaceutical policy framework to ensure non excessive pricing of patented medicines. However, the Board operates within a larger, more complex system of pharmaceutical pricing and reimbursement, which also involves federal, provincial and territorial governments, HTA agencies, the pan Canadian Pharmaceutical Alliance (pCPA) as well as the private sector companies, each of which employ strategies to ensure that cost-effective, affordable medicines remain available to Canadians.

The Board's expressed desire to modernize its Guidelines must take into account a realistic view of Canada's place in the global market for medicines, balance initiatives to contain cost without compromising innovation and availability of improved medicines to Canadians and avoid creating barriers to manufacturers to bring new therapies to Canada.

Galderma has provided detailed responses to the Board's stakeholder questions in Appendix A (attached). We would, however, like to make specific comments on the two key issues outlined below.

1. PATENT STATUS

The definition of patented medicine requires increased specificity and clarity. This will foster the certainty necessary for manufacturers to make the business decisions they must to properly evaluate whether or not to introduce a new product onto the Canadian market. For example, attempts by the Board to extend its jurisdiction to medicines which no longer fall within its jurisdiction by asserting that patents which relate to other medicines also "pertain" to the older medicine merely foster an atmosphere of cynicism. More importantly, however, these kinds of attempts at jurisdictional expansion create unpredictability. Unpredictability is anathema to business. Manufacturers may choose to avoid introducing new, improved medicines to Canada or they may find creative strategies to avoid filing patent applications in Canada. The fact remains that while any rational manufacturer wants more markets in which to sell their product, if conditions are too unpredictable and inimical to business in a given market, they may choose to forego that market entirely. Canada remains one of the smaller Western markets—a fact which this Board ignores at the peril of the people whose interests the Board

exists to serve. We submit that the Board's jurisdiction should be limited to medicines with patents that actually confer market exclusivity. The Board should not engage in jurisdictional 'creep' by seeking through protracted litigation to assert jurisdiction over medicines for which a manufacturer enjoys no commercial benefit by reason of a patent the manufacturer holds. Galderma supports streamlining of reporting obligations to medicines with patents listed on the Health Canada Patent Register, which forms the true basis of legal protection for market exclusivity.

2. SUCCESS OF EXISTING REGULATIONS AND GUIDELINES

In general, Galderma supports the Board's current Guidelines. The Discussion Paper does not make a compelling case that current prices of medicines in Canada are 'excessive'. Indeed as the Board reported in its 2015 Annual Report, the prices of patented medicines in Canada continue to be below the international median on average and price increases have not kept pace with CPI such that, in real terms, prices have decreased year on year.

The existing international price comparator countries, including the US, remain relevant and have historically been effective in establishing appropriate prices. Within this context, Galderma supports the continuing ability of manufacturers to take annual price increases linked to Canada's CPI. Importantly, and as noted at the outset, the Board is but one of several agencies (and governments) which, combined with market forces, affect prices and competition.

Galderma supports a stable and predictable market environment in which to do business and to introduce new pharmaceutical therapies. Any policy changes by the Board relating to non-excessive pricing of patented medicines must take a realistic view of the Canadian reimbursement system, including HTA, pCPA, PLAs and market factors such as generic competition which work together to ensure non-excessive pricing, cost-effectiveness and affordability of medicines in Canada. Care must be taken not to implement policy changes which destabilize the commercial-economic environment or adversely affect the viability of manufacturers to do business in Canada. Insufficiently considered changes in regulation may have the unintended effect of diminishing access to existing or new pharmaceutical therapies.

Yours very truly,

W. Adams

Wendy Adams
General Manager
Galderma Canada Inc.

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Appendix A: Galderma Canada Inc. Response to PMPRB Stakeholder Input Questions

Question	Response
1. What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example: **a.** Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced? **b.** Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive? **c.** In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada? **d.** Conversely, if a drug's price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada? **e.** What economic considerations should inform a determination of whether a drug is potentially excessively priced?	• "Excessive" should be defined in the context of abuse of patent monopoly. The determination of whether a price of a medicine is "excessive" must logically always be a comparative exercise. That is, a comparison must be made to the price of medicines which treat the same condition (whether the prices of those medicines are domestic prices or international prices). One may arbitrarily specify a dollar amount and say that any price that is higher than that defined amount will be deemed to be "excessive", but that is a recipe certain to result in decisions by manufacturers not to bring their new medicines to market in Canada. Medicines may be very expensive, but "expensive" is not necessarily "excessive". The concept of "excessiveness" must, in logic, remain a comparative exercise. • (a) There are no economic metrics specified so it is not possible to comment in a meaningful way. However, in general, as noted in the comment immediately above, if the "agreed upon economic metric" is arrived at in an arbitrary fashion (for example, that any medicine priced above $100,000 per patient per year is excessively priced), this will without any doubt, result in the avoidance by manufacturers of Canada as a market for their new medicines. • (b) We suspect that this question is largely theoretical. A medicine that costs "exponentially more" than other medicines used to treat the same disease will not find a market *unless* the more costly medicine greatly improves clinical outcome. In short, we submit it would be imprudent to contrive any rule in this regard that does not take into account improvement in clinical effectiveness and situations in which existing medicines are comparators to new therapies. • (c) Galderma submits that it should not matter if a very costly drug treats only a small group of patients. Indeed, in general, one would expect that very result. The smaller the market for a medicine that is costly to develop, test, licence and market, the more expensive one expects the medicine to be. • (d) It is impossible to sensibly address this question unless the Board states what it means by

	"disproportionate". Moreover, there may be situations in which the use of a medicine is widespread in a population and may be "disproportionate" (in some unspecified fashion but, presumably, meaning that that medicine's penetration in the market is greater than any other medicine on the market). However, the *benefits* of that medicine may equally be *disproportionate* to the total "spend" on that medicine. For example, if one were to assume that it becomes generally accepted throughout the medical communities of Western countries that after a certain age, *everyone* should be taking a statin (because doing so demonstrably and unequivocally reduces the incidence of myocardial infarction and stroke), then notwithstanding the disproportionate "spend" on the statin, a rational actor would pay for the statin. It is impossible to generalize in this area. Every case turns on its own facts. It seems to us that any foray into 'proportionality' or 'disproportionality' is an invitation to complex and lengthy disputes. • (e) Where there is competition, e.g., multisource drugs, several similar drugs in a therapeutic class (e.g., statins), the Board should defer to competitive forces to moderate prices. If whatever the cost of a drug (in absolute terms or as a percentage of the total "spend" on medicines in any given period), the benefit that that medicine brings (whether in terms of costs-savings to the healthcare sector and reduced hospitalizations, reduced costs to society as a whole because of decreases in morbidity and mortality, reduction in work days lost or QALY years gained, etc.) is the other 'half' of the equation. It makes no sense to consider only the nominal cost of the medicine in question without regard to the benefits that medicine provides.
2. Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?	• The Board's question places the cart before the horse. The so-called "standard industry practice" is actually driven by price setting and review authorities around the world (like the Board). Their efforts compel manufacturers to insist that public prices in any given market not reflect the discounts and rebates that various review authorities may negotiate or mandate. The Board must recognize, however reluctantly, that it has little influence on this. Canada is a small market. If the Board seeks to compel disclosure of commercially-sensitive pricing information concerning other markets in which a

	manufacturer does business, a rational manufacturer will always weigh the harm to its business as a whole caused by the disclosure of such sensitive information versus the harm caused to its business in any specific market in which it does business.
3. In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?	• The PMPRB should consider all factors (not just any one) in determining if medicines are excessively priced. In Galderma's view, section 85(1) does a good and workmanlike job of outlining reasonably relevant considerations in the determination of whether or not a given medicine is "excessively" priced.
4. Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e. the US, the UK, Sweden, Switzerland, Germany, France and Italy)?	• The Board's mandate is tied to "excessive". It is not evident how a price that is anything but 'high' relative to other Western countries can be considered excessive. • The prices of patented medicines in Canada have consistently remained below the international median on average. • Maintaining the US as reference country is important due to its proximity to Canada and because in many cases the US is the only reference country.
5. Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?	• A decision as to whether or not a medicine is appropriately priced in Canada should be unrelated to the amount of research and development that a specific company or the industry as a whole conducts in Canada. • It is unrealistic to expect that a country with a small population and possessing a modest scientist cohort and research infrastructure can command R&D expenditures to be made in Canada in order to permit a manufacturer to obtain a fair price for its medicine in a small market like Canada. • Moreover, the Board has consistently underreported the R&D actually conducted by or on behalf of manufacturers in Canada by relying on the definition of what constitutes eligible R&D that are almost 30 years old.
6. What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the	• No alternatives have been proposed in the discussion paper. However, the Board's question suggests ignoring clinical effectiveness which, for obvious reasons, is not a good approach. • The Board's mandate is to police "excessive" prices, not

outset and address questions of high relative prices, market dynamics and affordability?	to set "fair" or "affordable, or "socially responsible" prices, etc. The Board exists to prevent a form of so-called 'patent abuse', not to conduct some broader form of economic regulation of the drug market.
7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?	• 'Traditional' smaller molecule (low cost/day) treatments are still needed and unnecessary for same amount of scrutiny as higher priced drugs e.g. specialty biologics. • There maybe opportunity for streamlining of reporting of traditional molecules particularly those that are multi-source or subject to competition by similar drugs. • Provinces and the pCPA already control the prices of these products. • We do point out that "increased oversight" for newer treatments that are expensive (such as monoclonal antibodies), may discourage their introduction into Canada.
8. Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?	• Manufacturers need price certainty when deciding to commercialize products in Canada. • Periodic re-benchmarking introduces uncertainty and to the extent it happens it must be predictable and clearly defined. • If price ceilings are to be revised there must be the opportunity to increase and not just decrease price—and increases not limited to CPI unless decreases are similarly limited. • Additional mechanisms exist to control price over time such as initial pricing review policy, HTA and pCPA negotiation process. • Once listed price control continues to occur through provincial pricing policies, and re-negotiation of PLAs. • For practical purposes generic entrants set a ceiling on prices.
9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?	• Galderma does not discriminate between provinces and customers. Rather provinces and customers' price requirements are determined by their policies and the value they see in the product. • In any event, 'price discrimination' should be considered a form of 'excessive pricing' only if there no valid reason for the price differences.

10. Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?	• Definition of a patented medicine requires certainty and should be tied to actual market exclusivity and clear definition of patented medicine (e.g., the Patent Register). • The Board should not engage in jurisdictional creep by seeking through protracted litigation to gain jurisdiction over off-patent medicines. • The Board should not control pricing when there is generic competition.
11. Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?	• All changes must be prospective and current prices should be 'grandfathered' in order to maintain industry stability and predictability. To do otherwise would be exceedingly unfair. • A policy change to significantly change a patentee's obligations will be disruptive to the pharmaceutical market place resulting in fewer newer medications brought to the market and decreasing the choice available to physicians and patients. • Any future policy change that the Board undertakes should consider other market forces such as HTA, pCPA which operate to influence pharmaceutical pricing. • Galderma supports a balanced approach to avoid duplication of work and the negative health-related consequences for Canadians.
12. Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?	• A clear definition of patented medicine should be enshrined in the Patent Act and should be consistent with the definition established for the Patent Register.