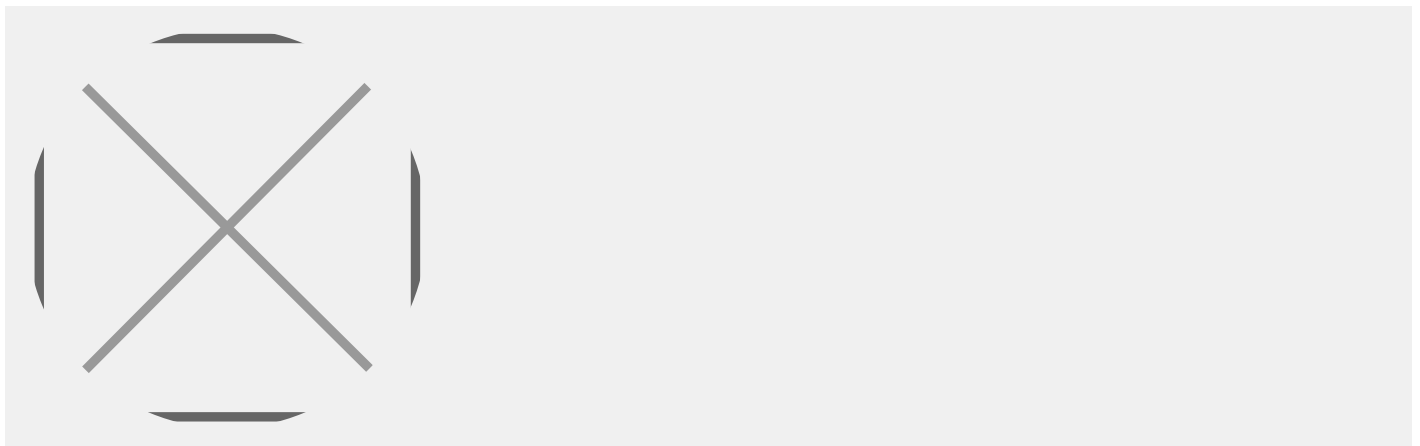


# Interview: Éric Gervais, Executive Vice President, Médunik Canada

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Tags: [Government Regulation](#), [medunik](#), [medunik canada](#), [orphan drugs](#), [Registration](#),

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*As the only country in the G8 without an orphan drugs act, the President of Médunik, a company focused on bringing orphan drugs into the country, talks about the desperate need for better legislation in this area for the benefit of patients, and the misconceptions of treating Canada as a part of the US when it comes to introducing a new product.*

**Médunik Canada was created in response to the need for medications for rare disorders. How did you take your experience from Duchesnay to create an entirely new company dedicated to this niche?**

Duchesnay's core business is obstetrics medications. Developing medications for pregnant women is a highly niche market; most pharmaceutical companies do not invest in this special population area due to the complicated nature of the research as well as the inherent liabilities in treating this group. Having led this company for the past 20 years, I can say that Duchesnay stands alone in this endeavor. Frankly, I do not know any other companies that invest in developing drugs for pregnant women.

I became involved in the rare disorders landscape twelve years ago as one of the founding members of the Corporate Council for the National Organization for Rare Disorders (NORD) in the US. I have worked with leaders in the orphan drug market, which consists mainly of small orphan drug companies. I think many would be surprised to learn that Canada does not have an orphan

drug act and that many Canadians suffer because they do not have access to medications that are available elsewhere in the world. There are approximately 200 orphan medications available in Europe or in the US that are not accessible in Canada. Therefore I worked diligently to convince the Boivin family to create Médunik Canada and invest in meeting the needs of Canadians living with rare diseases. The company's main goal is to bring to Canadians orphan medications that have been approved in other countries.

**How do you balance being Executive Vice President of both Duchesnay and Médunik Canada?**

It is a natural fit since in both companies we focus on making a difference in the life of Canadians with unmet medical needs. The main difference lies in the fact that Médunik Canada does not develop new drugs for orphan diseases, whereas Duchesnay develops new drugs, obtains patents and finds partners worldwide to commercialize its obstetrics products.

**Market access in Canada is difficult due to drug approval on a provincial rather than national basis. Given that long process, what added value can Médunik Canada bring to this challenge?**

Market access in Canada is indeed extremely difficult and challenging. In order to succeed, Médunik Canada must work with each province separately. Provincial governments pay for the drugs and decide individually on their reimbursement mechanism. It makes no sense that orphan drugs approved at the federal level may not be available in all provinces. This situation creates unfairness and unnecessary suffering. Although we do not have the solution, we believe there is a need for a shared vision to ensure that Canadians have access to those needed medications through federal-provincial collaboration. Orphan drugs can be expensive, especially for smaller provinces. Therefore, the federal government should allocate some dedicated funds to the provincial governments. Since some orphan diseases are more prevalent in certain provinces, such budget allocation should be flexible to enable them to provide the needed care to their constituents.

**You said that it is a myth that the best way to get an orphan drug on the Canadian market is through a North American deal. How did this myth come about, and what is the best way to get drugs here?**

Europeans often want to do North American deals, as opposed to separating the US and Canada. While this may seem simple, in reality, the best way to introduce a product in North America is through two separate deals. Big orphan drug companies that are established in Canada market

their drugs in our country; Canada is one of the top ten pharmaceutical markets in the world. However, the vast majority of companies that develop orphan drugs are small companies and do not understand the Canadian system very well. They tend to ignore Canada and do not seem to realize that there are patients to be treated here and a market to be served. For example, companies may perceive Canada's population of 34.5 million as small when, in fact, this is a substantially sized population. As an example, Canada is larger than Switzerland, Austria, Belgium or the Netherlands. Moreover, companies are afraid of price control and wrongly believe that Canada is a low-price country. They do not understand the PMPRB; a patented orphan drug has its price established by the PMPRB based on the median price of the top European countries such as Germany and France. Drug pricing in Canada is significant, but small companies are not aware of it or do not understand how it works. American companies tend to acquire licenses for the US, but do not invest the time to learn about the Canadian market and its reimbursement system. They compare Canada to the US whereas the Canadian system is much closer to the European system. The end result is that Canadians lose out by not having access to many drugs. I participate in various international conferences to explain how different the Canadian market is and why companies should think about making two separate USA-Canada agreements to ensure Canadian patients have access to their treatments.

**In 1983, the US passed the Orphan Drug Act; now Canada is the only G8 without an orphan drug policy. How can Médunik Canada work with various stakeholders including the government to ensure that such a policy is passed sooner rather than later?**

Canada is part of the G8 but does not lead in the orphan drug world. The US Government passed their orphan drug act 30 years ago, Singapore passed theirs 22 years ago, Japan 20, Australia 16, and the EU 13 years ago. I believe that Canadians are suffering due to unnecessary delays in analyzing the huge success other countries had with their respective orphan drug acts. Médunik Canada can help by expressing its views and let the Government of Canada know how much people living with rare diseases suffer. Health Canada has been developing an orphan drug regulatory framework for several years while Médunik Canada has been taking action. The company spends much of its revenues on travelling, meeting with CEOs of orphan drug companies, explaining that there is a worthwhile and profitable market in Canada, and that patients desperately need access to their drugs. Instead of relying on an orphan drug act, Médunik Canada works to improve drug access. Médunik Canada provides a turnkey solution to market a drug, obtain regulatory approval and promote it appropriately rather than just making it available through Health Canada's Special Access Program (SAP). If the Canadian government comes up with a good orphan drug act or regulatory package, offering exclusivity, it will help tremendously. But

Médunik Canada is not waiting for that to happen.

**How did Médunik Canada's partnerships with QOL Medical and Orphan Europe come about, and what makes Médunik Canada the partner of choice?**

To succeed in obtaining the Canadian rights for their products, our biggest challenge was to demonstrate the value of the Canadian market. Although Canada does not have an orphan drug act, the country offers 8 years exclusivity for new chemical entities. If the drug products are patented, Canada honors the patents. As to repurposed drugs, and there are many developed for orphan diseases, unfortunately Canada offers no protection whatsoever. It is tough to convince companies to bring a product to the Canadian market without protection against generics. Médunik Canada differentiates itself by its dedication and focus.

The company currently has six orphan products, which makes it the biggest orphan drug company in Canada in terms of number of products offered. The goal is to bring as many different orphan drugs as possible to the Canadian market. Médunik Canada is unique in that it focuses on Canada's needs as a whole rather than on one category of rare diseases. If we are able to provide oncology products for rare cancers, or drugs for metabolic disorders in children, we will. We will continue to work at making our partners' products available to Canadian patients in need of otherwise unavailable treatments. When discussing with a CEO, it is frustrating to hear that because Canada does not have an orphan drug act, he finds greater incentive to provide his drugs to South Africa, Thailand, Korea, or Australia rather than to Canada. Canada is among the top ten countries in the world for drug expenditure; nevertheless, many companies' products are not available here. Médunik Canada has to do a lot of education and create awareness in order to bring these medicines to Canada.

**If we were to return to Canada in another five years, what is your vision for the company then?**

I would like to be able to look back and see the number of products that we succeeded in making available to Canadians living with rare diseases. Canada has no direct access to 200 orphan products available elsewhere in the world and there are a dozen new products approved every year. There is a lot of work to be done. Therefore I would like to look back and see this number of drugs to be as large as possible. This is how I see that Médunik Canada really can make a difference.

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