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FULL OPENING STATEMENT

**Delivered by Sylvain Vigneault to the House Standing Committee on Industry,
Science and Resources: Inquiry into Developing Advanced Manufacturing in
Australia
25 July 2023**

Good morning, Chair and Committee Members.

Thank you for the opportunity to participate in today's hearing and thank you for your interest in Viatriis' experience as a local medicines manufacturer, manufacturing for over 40 years in Carole Park, Queensland.

I would first like to acknowledge the Jagera people and the Turrbal people of the Meanjin Nation, the traditional owners of this land, and pay my respects to Elders past, present and emerging.

I would also like to acknowledge the Jagera people, the traditional owners of the land in which we operate at Carole Park and pay my respects to Elders past, present and emerging.

My name is Sylvain Vigneault, and I am the Country Manager for Australia at Viatriis. Joining me today is Robert Elliot, Head of Operations, ANZ.

I'd like to make some opening remarks about Viatriis' Australian operations, and then touch briefly on three key recommendations that from our perspective are relevant to the Committee's inquiry.

Viatriis is a leading global healthcare company with a mission to empower people worldwide to live healthier at every stage of life. With our focus on sustainable access to medicine, we helped to supply medicines to approximately one billion patients globally last year. In Australia, Viatriis plays a key role as a supplier of medicines on the Pharmaceutical Benefits Scheme (PBS) and as a local manufacturer.

Since 1982, Viatriis and its precursors, Mylan and Alphapharm, have been manufacturing medicines at Carole Park in Queensland, where more than 600 of our 800 national employees work in manufacturing, each year producing more than 3 billion tablets and capsules for use in Australia and for export to countries around the world.



In Australia, we are proud to be the largest local manufacturer by volume supplying prescription medicines to the PBS. Of the 10,754 individual items on the PBS in 2022, ViatriS supplies 1,221 (or approximately 11%).

ViatriS brings together scientific, manufacturing and distribution expertise with proven regulatory, medical, and commercial capabilities to deliver high-quality medicines to patients in more than 165 countries. Our Australian site is part of a comprehensive global manufacturing network across approximately 40 different locations. This gives us the ability to manufacture at scale and have an incredible breadth of critical medicines to serve patient needs.

From EpiPen for anaphylaxis, antiretrovirals for HIV/AIDS, to Creon, a life-changing medicine for people living with cystic fibrosis, and our Resprim antibiotic range, every day we touch the lives of millions of Australian patients with a number of products, including many that are manufactured locally at Carole Park.

We are one of the few healthcare companies in Australia that has the capability to manufacture many prescription tablets and capsule medicines locally at scale.

However, the policy environment for Australian manufacturing is becoming increasingly challenging.

In order to maintain a sustainable industry, we believe it is critical the Australian Government further supports medicine manufacturers. To that end, we have three key recommendations to assist the Committee in its important work.

First: Australia would benefit from creating an ecosystem that enables medicine manufacturers to compete globally. As a result, ViatriS recommends the Australian Government revises its policies to better enable medicines to be manufactured for export.

- Currently, the existing Patents Act in Australia prevents manufacturers like ViatriS from manufacturing and exporting new generic medicines during the patent protection period of the reference drug, even when the drugs are not patent protected in the country of destination. Let me repeat, Australian medicine manufacturers can be prevented by Australian law from exporting generic medicines to countries where the patent for a drug has expired. This is contributing to an environment that restricts Australia's ability to compete globally on medicine manufacturing.
- This is not the situation in a number of comparative global jurisdictions. For instance, since February 2022 the European Union has a specific waiver system to allow European-based manufacturers to engage in these types of exports. Canada also has implemented this waiver. Our Australian laws are preventing Australian manufacturing sites from competing on a level playing field globally.
- In fact, in 2013, the Pharmaceutical Patents Review Report established by the then Parliamentary Secretary for Innovation, the Hon Mark Dreyfus QC MP,



found that this reform was necessary to ensure Australia can compete on a level playing field globally as a location for manufacturing of new generic medicines. Subsequently, the Productivity Commission in its 2016 report into Intellectual Property Arrangements considered this situation and came to the same conclusion¹. This is not a new proposal. It has been considered and recommended by a previous Australian government; the needed reform has just not been enacted.

- The Report also found that by keeping with the existing legislation, we are depriving the Australian economy of billions of dollars of potential export revenue from Australian-based generic manufacturers. Importantly, this legislative change would not impact Australia's current patent protection regime – Australian patents would continue to be enforced, and generic medicines would not launch in Australia until valid Australian patent protection ends.
- As an example of how this situation is impacting the competitiveness of Australian manufacturing, one of the critical medications we manufacture at Carole Park is metformin, used globally in the management of diabetes. There are a number of patent protected combinations of other medications with metformin sold in Australia. For certain combination products, relevant patents or patent term extensions are estimated to end in Europe earlier than in Australia. Under current law, Viatris' Carole Park site cannot manufacture generic versions of these combination products for export to the European Union until the relevant Australian patent or patent term extension expires. As a result, Australia is unlikely to be a viable option for a global company like Viatris to manufacture these products.
- Changing this law would contribute to removing barriers to Australian medicines manufacturing. If all relevant policies are aligned in support of medicines development, manufacturing and export, this would put Australia on a level-playing field with other competitive manufacturing locations. This could mean more highly skilled Australian jobs, more advanced Australian manufacturing and ultimately more revenue for the Australian economy.

To conclude our first point, creating a supportive policy environment to enable Australian manufacturers of generics and biosimilars the opportunity to compete globally could support Australian jobs and the sustainability of Australian medicine manufacturers.

¹ [Intellectual Property Arrangements - Inquiry Report \(pc.gov.au\)](https://www.pc.gov.au/reports/indicators/ipa), p 310-312, and p 549-550.



Our second recommendation is that the Australian Government could strengthen the local medicine manufacturing industry by developing a strategic partnership and dialogue with Australian medicine manufacturers.

- Maintaining a strong global supply chain is an integral component of access to medicines, given no country can meet all its medicines needs through domestic production alone. In Australia, as is the case globally, medicines supply is not always aligned with demand, which means some Australian patients are at risk of not having access to certain medicines. While there are many causes of this misalignment, developing strategic partnerships between the Australian Government and medicines manufacturers could increase predictability for supply and demand of critical medicines, mitigating risks of disruption.
- ViatriS is committed to a productive dialogue across Government and industry, and actively participates in ongoing dialogue about medicines supply with the Therapeutic Goods Administration. It is our view that identifying solutions to the systemic causes of vulnerabilities in Australia's medicines supply chain and to supporting Australian competitiveness as a global manufacturing base requires a broad lens across all of government.
- In a broader strategic partnership, the Government may be interested in identifying the medical products that it wants to have domestic capability to manufacture at some level, while still maintaining an open market for competitive global supply. The French government has recently announced a similar plan, with the intention to reinforce or create local production critical medicines.
- As an example of how partnership could increase capacity for greater medicines availability, in 2022 we announced a grant from the Federal Government's Modern Manufacturing Initiative for a further expansion at our Carole Park manufacturing facility, with the potential to take the site's annual medicine production to more than four billion doses.
- We saw the benefits of this partnership yesterday in the Delta Suite at our site in Carole Park, which will lead to an increase in capacity of more than 1 billion tablets of critical medicines.
- The Government may benefit from considering additional incentive programs that would further enhance domestic facilities, such as our Carole Park site. Investing in expansion of our local manufacturing capability could allow us to rapidly respond to patient needs now and in the future and continue to be a critical part of the ViatriS global manufacturing network, supporting Australian exports.



- In addition to leveraging local manufacturers' domestic capabilities, a strategic partnership would provide the opportunity for Government and industry to identify areas where the highly skilled Australian workforce can be expanded through STEM capability development and job training. In the Australian context, we have a unique opportunity to partner with the Government from the earliest stages of this.
- We saw yesterday the valuable partnership between industry and universities in developing a STEM pipeline of graduates. You also heard the challenges domestic manufacturers have in recruiting experienced STEM staff. We are happy to play our part in upskilling graduates to experienced manufacturing roles, but a broad-based industry staffed with experienced people is necessary both for Viatris and for other medicine manufacturing, and the Government has a key role to play in enhancing education and workforce training.
- **To conclude our second point, a partnership between Government and medicine manufacturers could better enable us to build long-term sustainable capabilities and jobs in Australia.**

Our final recommendation is that the Australian Government reviews its policies to consider the sustainable availability of critical generic medicine in Australia with respect to comparative global markets.

- Broad factors in the external environment are impacting the cost to supply medicines in Australia. In situations of constrained global supply, local pricing is a key point to ensure a robust supply of finished products, and the materials to make finished products. The challenge of increasing sourcing and production costs is particularly relevant for generic medicines with low margins and high complexity.
- A recent challenge for Australian manufacturers has been the increasingly unsustainable pricing of generic medicines set by the reimbursement authority. The impact of such pricing has set Australian generic pricing significantly below global benchmarks, creating challenges for ongoing access to supply of inputs and materials in times of constraint. While these challenges exist for generic medicines sold in Australia regardless of their manufacturing location, this is compounded for generic medicines manufactured in Australia, where production and labour costs are also high compared to some other geographies.



- We urge the Australian Government to look at medicines pricing policies through a perspective of health investment and economic development. We suggest the government could consider developing an Australian Manufacturing Impact Statement on any government decision that would affect Australian medicine manufacturers, and more broadly, an evaluation of the impact of cost-containment decisions on the sustainable availability of medicines for Australian patients.
- **To conclude our final point, maintaining viability of generic medicines in a global marketplace is a critical element of ensuring a sustainable PBS that enables products to be available when patients need them, and to support continued investments in Australian manufacturing.**

Mr Chairman, thank you again for the opportunity to address your Committee today. We appreciate your consideration of our recommendations to further enhance advanced manufacturing in Australia. My colleague Robert Elliot and I are happy to answer any questions you may have.

ENDS