18th February 2019

Medical Devices Branch
Therapeutic Goods Administration

RE: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia.

Ego Pharmaceuticals is a world-leading Australian manufacturer of both cosmetic and therapeutic skin care products. More than half a dozen of our products across multiple ranges fall into the category of Medical Devices- Class 1. It is our belief that the introduction of a unique device identification system is unnecessary for lower risk medical devices and could have a significant impact on their production.

While we believe that this proposed system would be beneficial for medical devices of class 2 and above, and for class 1 medical devices that are sterile or have a measuring function, the majority of class 1 devices do not need this extra system due to the low risk posed to the user and the rigorous testing and surveillance that is already in place.

At Ego, our medical devices (which are class 1 and are not sterile, nor do they have any measuring function) are manufactured according to Good Manufacturing Practice (GMP), undergo extensive stability testing, and are subject to rigorous post market surveillance. In addition, as with all of our products, our medical devices are thoroughly tested for efficacy and safety.

Introducing a mandatory unique device identification system for all medical devices would ultimately be another hurdle to clear for devices such as ours that represent the lowest possible risk to the consumer. Such a system would have a significant impact on the production of these devices, both in terms of the monetary cost and the time taken to implement it.

While we understand that such a system has obvious benefits for higher risk devices, it simply would not be practical to apply it to all medical devices. A possible alternative would be to implement this system for medical devices in class 1 which are sterile or have measuring functions and all class 2 and above devices while exempting the low risk class 1 devices. Another solution would be to make a unique identification system optional for the low risk class 1 devices.

At Ego, we take every care to ensure that all of our products are safe, efficacious and produced to the highest possible standard. To that end, the systems and safeguards we have in place are more than sufficient, and the introduction of an unnecessary additional step in the production process would be of no benefit to our employees or our consumers.

Yours sincerely,

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