CS EXECUTIVE GROUP

AUSTRALIA
Toll Free 1800 077 860

MELBOURNE (HEAD OFFICE)
L4, 566 St Kilda Road
Melbourne 3004
T 03 9516 0100
W csexecutivegroup.com

ABN 14 007 098 295

29 April 2019

TGA Consultation: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

RESPONSE FROM CS EXECUTIVE GROUP INC. CHEMSKILL

On behalf of sponsors we represent, we wish to submit a response to this consultation regarding the proposed new medical device classification for substances introduced into the body via a body orifice, in order to raise the question how this future classification would apply to saline nasal wash solutions.

The new classification rule proposed to be included in Schedule 2 of the Australian Medical Device Regulations, to align with the EU Medical Device Regulation Rule 21 states that a:

Medical device that is composed of a substance or of a combination of substances that is intended to be introduced into the human body via a body orifice or applied to the skin and that is absorbed by or locally dispersed in the human body is classified as …

• *Class IIa if the device is applied to the skin or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities*

This proposed reclassification will potentially impact on our client's products, which are somewhat different to the "saline nasal solution sprays" discussed in the consultation document as cited in the table below.

Device	**Current classification**	**Proposed classification**
Saline nasal solution sprays Saline nasal solution sprays are intended to penetrate, clear, clean, and sometimes hydrate the nasal passages and sinus cavity for preventive or symptomatic nasal care.	**Class I** *(transient use invasive medical device not intended to be connected to an active medical device)*	**Class IIa** *(applied in the nasal cavity and achieve their intended purpose on that cavity)*

There are a number of saline nasal irrigation sprays currently included on the ARTG, typically under GMDN code 44844 (Irrigation fluid, nasal) or GMDN code 44845 (Irrigation kit, nasal), where a solution is used to penetrate, clear and clean the nasal passages and sinus cavity, and can be self-administered for postoperative, preventative or symptomatic nasal care.

CS EXECUTIVE GROUP

AUSTRALIA
Toll Free 1800 077 860

MELBOURNE (HEAD OFFICE)
L4, 566 St Kilda Road
Melbourne 3004
T 03 9516 0100
W csexecutivegroup.com

ABN 14 007 098 295

In these devices the irrigation solution is typically sprayed up the nostrils by means of a hand-activated spray pump pack to irrigate the nasal passages and sinus cavity. The solution usually collects at the back of the sinuses, typically drains via the pharynx and is swallowed.

We would request the consultation to consider the appropriate classification for a product scenario where a saline sinus rinse solution is introduced into the nostrils as a stream of liquid via a squeeze bottle, rather than aspirated into the nostrils via a spray pump pack. The solution is then expelled either from the nostrils or from the mouth, rather than being swallowed.

In the case of such a product, the solution being "*introduced into the human body via a body orifice"* could be perceived as not being either *"absorbed by or locally dispersed in the human body",* but rather expelled after performing its intended function.

We wish to raise the question whether the TGA would consider such a medical device to be covered by the current scope of the proposed new classification rule.

[redacted]