



Sanofi Consumer Healthcare
87 Yarraman Place
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RESPONSE TO TGA CONSULTATION

Consultation: Complaints Handling – Advertising of Therapeutic Goods to the Public

Version 1.0, May 2018

Date: 28-May-2018

Total number of pages: 5

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1 ABOUT SANOFI CONSUMER HEALTHCARE

Sanofi Consumer Healthcare Australia is part of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people they serve throughout the continuum of care. Sanofi's global portfolio includes diabetes and cardiovascular, vaccines, rare diseases, oncology and consumer healthcare businesses.

In Australia, Sanofi Consumer Healthcare is one of the country's largest vitamin, mineral and supplement manufacturers and distributors. We are also a large supplier of trusted over the counter medicine brands.

With a brand portfolio that includes Nature's Own, Cenovis, Ostelin, Betadine, Gastrolyte and Telfast, our products are found in more than 8500 pharmacies and grocery outlets nationwide.

Sanofi Consumer Healthcare is based in Brisbane's northern suburbs, where our \$80 million, 35,000 square, TGA licensed and GMP standard vitamin, mineral and supplement manufacturing facility is located. Sanofi Consumer Healthcare is the only large-scale vitamin, mineral and supplement business in Australia to be vertically integrated with full research, development, manufacturing and packing capability. In recent years, we have invested in excess of \$30 million in this site to grow our Australian manufacturing presence. This investment ensures we remain at the forefront of high quality research, development and manufacturing.

We employ approximately 400 people across Australia including scientists, allied health professionals, regulatory affairs specialists, and quality control experts, manufacturing technicians, engineers and warehouse staff.

2 OVERVIEW

Sanofi Consumer Healthcare (Sanofi) welcomes the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation on Complaints Handling – Advertising of Therapeutic Goods to the Public, dated May 2018.

Sanofi believes the approach being taken by the TGA for Complaints Handling is more objective and the priority based complaints handling model is appropriate and an improvement compared to the current model.

The current consultation document appears to be incomplete as the last page contains a heading with no further information stated thus the response is only on the information provided.

3 CONSULATION CONSIDERATIONS

3.1 SECTION 7.2 TRIAGING OF COMPLAINTS

In regards to vexatious complaints will this be defined within this guidance document?

3.2 OVERVIEW OF PROPOSED COMPLAINTS HANDLING MODEL ONCE A BREACH IS ESTABLISHED

For each nature of advertising breach explanation is it possible to include example/s for critical, high, medium and low to assist industry.

3.3 SECTION 8.5 CRITICAL PRIORITY CASES

Is it possible to expand or outline what will be the regulatory tools to enforce compliance, and also make reference to the relevant clauses of the regulations for the civil or criminal litigation.

3.4 MONITORING AND TREND ANALYSIS

Sanofi believes it may assist industry and consumers if the reporting of complaints was divided into where the complaint originated from such as consumers, industry and/or industry critics/academic medicine activists.

3.5 SECTION 12 THE TGA WEBSITE ADVERTISING HUB – 4. MAKE A COMPLAINT ABOUT AN ADVERTISEMENT

There is no information after this point and unable to make any further comment.

3.6 ADDITIONAL COMMENTS

Within the proposed consultation there is no mention of an Appeal mechanism on decisions made by the TGA against the sponsor, can this be added or referred to in this guidance document.