Australian Government
Department of Health

DEPUTY SECRETARY

Dr Ken Harvey
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Dear Dr Harvey

SBS Insight program recording on complementary medicines, 6 February 2019

Thank you for your email of 7 February. I stand by the statements I made during the recording of the SBS Insight show. Both in your email - and during the show's recording - there were a number of assertions you made and data you quoted regarding TGA's compliance activities that were quite inaccurate and misleading. This included your interpretation and explanation of the TGA advertising and complementary medicines compliance data that is routinely made publicly available on our website.

Advertising compliance statistics

Regarding advertising compliance, during the SBS Insight recording you made the assertion that 98 % of advertising complaints have been found to breach the Advertising Code (i.e. found to have broken the relevant laws). This is not correct.

Advertising complaints relating to complementary medicines (and other therapeutic goods) are triaged into four categories after an initial review by the TGA. Categorisation depends on a number of factors. For example, if there is the potential for damage to individual or public health, or there have been repeat complaints about a product the complaint is categorised as either medium, high or critical for review by the TGA.

Complaints in each of these categories – which formed about 30 % of the cases in the last 6 months – are examined thoroughly by compliance staff. If there is sufficient evidence to indicate a breach, compliance action is taken - which can include legal directions notices, fines through infringement notices, interlocutory injunctions or civil penalty or criminal offence proceedings.

For the 70 % of complaints in the "low level category" no official finding of a breach or otherwise is made as a formal investigation of these complaints has not been carried out; there is insufficient evidence to support any finding. The advertiser is contacted in writing and the issues in the complaint communicated to the advertiser in some detail. They are

provided with a reminder of their obligations under the Advertising Code. A clear focus on the cases where health and safety may be impacted or there is potential for repeated non-compliance is the most appropriate use of our resources given that we anticipate having to manage 2,000 advertising complaint cases in a full year.

I hope that this explanation clarifies why your assertion that 98 % of advertisements referred to the TGA are found to breach the Code is not correct and could also create unnecessary alarm with consumers.

Percentage of listed medicines found to lack evidence

At the SBS recording it was asserted that 75–80 % of complementary medicines audited failed compliance and that it was due to a lack of evidence to support the efficacy claims made. This interpretation is also incorrect.

As I emphasised, there are a range of reasons that the product may fail audit and the most recent figure of products which failed audits was about one third. The figure of 39 % for 2017/18 in the table you have copied from the TGA report supports my statement. It is not true to assert "that TGA postmarketing compliance reviews show a much higher rate of compliance breaches than (I) stated" as I did state that the overall non-compliance rate was 75%.

While it is true that 75-80 % of the audited products (many of which come from targeted reviews of particular types of products suspected of poor compliance) are found to breach at least one of a list of requirements, the TGA compliance audits do result in more than two thirds of these products returning to being compliant. The remainder of the products are cancelled – either by us or the sponsor company – which in either case removes these products from the market. It is clear that TGA's compliance efforts do have significant impact.

TGA GMP requirements

Describing the system as "TGA's occasional inspection of manufacturing facilities" is most inaccurate and shows a lack of understanding of Australian regulatory requirements. It suggests that such inspections are held on an *ad hoc* basis and are not conducted on a systematic basis. In fact, there is a requirement in law for any facility providing complementary medicines for the Australian market to manufacture them to medicinal quality standards and to have successfully passed a GMP inspection prior to putting them on the market. There is also a legal requirement for ongoing regular inspection of the manufacturing for all products, even if no problems have ever been identified at the particular facility manufacturing those products..

Australia has the tightest manufacturing quality standards in the world – for example TGA does not even accept United States FDA inspection results for complementary medicines and instead we pay to fly TGA inspection teams to the US for week-long detailed inspections of US-based complementary medicine manufacturing facilities.

The table you have reproduced from TGA's public report states that there was about 20 % of products with manufacturing quality compliance breaches reported annually. These manufacturing compliance breaches were almost all minor – for example, something as

minor as storing empty cartons for shipping product in an unlocked room is classified under the international code as a GMP inspection breach.

TGA also conducts regular inspections of prescription medicine manufacturing facilities and almost every inspection will identify some compliance breaches. We act immediately (e.g. product recall etc.) if there are critical deficiencies identified but the overwhelming number of breaches identified in GMP inspections are minor in nature – such as the company not changing computer passwords on equipment often enough.

A small number of products – none in 2017/18 and 22 in 2016/17 do fail compliance reviews for safety reasons. One of the most common "safety" failures is not that the products contained an unsafe substance, but rather that they contained a scheduled substance that is routinely permitted in an over-the-counter supermarket or pharmacy medicine but not by law in a listed complementary medicine.

On rare occasions there are findings of a forbidden substance in a medicine. For example, in the last few months we have had two recalls of complementary medicines that contained detectable (albeit low) levels of a forbidden substance. In that period we have also had recalls globally of a range of prescription medicines for hypertension that contained low levels of another toxic contaminant. These are not examples of regulatory failure; rather they are signs of the regulator doing its job.

Choosing particular garlic and cranberry products

You assert that TGA "fails to check for clinically active ingredients in often complex herbal products". Again, I submit that this indicates a lack of understanding of the regulatory scheme. For your convenience, I have attached the detailed and publicly available information on the regulatory requirements for clinical evidence on complementary medicine products. For example, if the medical literature is used to support a claim made about a particular garlic extract then the evidence must be on the same plant part, extracted the same way, at the same dose and in the same patient population.

In conclusion, there are a number of non-compliant complementary medicine products that are detected by TGA's programs, and the compliance issues are subsequently resolved or the products cancelled as a result of these efforts. I am concerned, however that your exaggeration and significant misrepresentation of the extent of compliance breaches can undermine the objective of improved public health and safety for which we both strive.

Yours sincerely

John Skerritt
9 February 2019

cc. Ms Glenys Beauchamp, Secretary, Department of Health
Ms Jenny Francis, Principal Legal and Policy Adviser, HPRG, Department of Health