HCASA
Health Consumers Alliance of SA Inc

Consumers at the centre of health in South Australia

Response to TGA Consultation – Changes to a number of definitions and the scope of the medical device regulatory framework in Australia

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Health Consumers Alliance of South Australia (HCA)

HCA is the peak body for health consumers in South Australia. We are a member-based, independent, not-for-profit organisation, funded by SA Health. We work with consumers and health services to position consumers at the centre of care. Health consumers are people who use, or are potential users of health services, including their family and carers.

HCA's mission is to engage consumers and health services to achieve high quality, safe, consumer-centred care for all South Australians. We seek to promote and strengthen the voices, wellbeing, rights and leadership of health consumers.

We advocate that consumer engagement policy and practice is embedded across the SA health care system. This includes public, private and non-government health service providers.

We believe that consumer engagement results in better planning and policy-making. This leads to better health outcomes and community wellbeing.

Specific comments have been provided (tracked) within the draft document (refer second attachment in email). HCA has made two specific recommendations for inclusion in relation to strengthening the health literacy and consumer centred care language and process within the policy (below).

General Comments

Health Consumers Alliance of South Australia Inc (HCA) acknowledges that regulation, and definition of medical devices is complex, in part due to the diverse and wide range of devices from simple, minimally invasive items to life-sustaining components. HCA is also mindful that regulation of non-medical devices may affect their cost, quality, and availability in the health care system and this needs to be taken into account when considering the impact to consumers as a balance of cost, access and safety.

HCA is concerned with ensuring consumers have access, as quickly as possible, to new and improved medical and non-medical devices (such as contact lenses). Simultaneously, ensuring mechanisms and protections must be in place to prevent devices from entering or remaining on the market that are not safe or have significant potential for harm or increased health risk when used inappropriately by lay persons.

HCA also acknowledges that consumers may be confused at times about when it is appropriate/safe to have non-medical procedures (eg cosmetic fillers) performed by lay person and when this should be performed by a health practitioner. Further, with the availability of many of the mentioned non-medical devices online, consumers may purchase and self-administer 'treatments' assuming they are safe.

HCA recognises it is in the public interest to regulate non-medical devices, where there is evidence that such devices are associated with health risk or harm and may result in the need for health care intervention to reduce or resolve the risk/harm. It is noted that changes to the current Australian legislation would need to be made to, in effect, give the TGA authority over devices that do not have a medical purpose. A key question for consideration arises therefore about whether such regulation is the purview of the TGA or whether further consideration should be given to more rigorous industry-based regulation. Further, what consultation has been had with the predominant 'lifestyle and beauty' industry in relation to this proposal?

Should the TGA amendments be agreed to - HCA does not - agree or support the TGA be given similar powers as the European Union medical device regulation, to amend the list of product groups in *Annex XVI* or add new groups of products without consumer consultation (even if there is a public health imperative). The criteria and definition of such non-medical devices should not however, be expanded without further consumer consultation.

Potential risks of overregulation of non-medical devices may have unforeseen outcomes. Although there is room for improvement, uniformly increasing the hurdles in the regulatory process risks raising costs without any real increase in patient safety. Consumers have the right to be self-determining in the choices they make about whether or not to have non-medical procedures eg cosmetic enhancements. It is necessary that consumers however have access to credible information to assist their decision-making about the risks/adverse events of such devices, and clear information about the knowledge, skills and qualifications of those who administer procedures related to use of such devices. Over-regulation of non-medical devices may precipitate consumers making decisions to seek cheaper, more accessible options (eg overseas).

HCA recommends the TGA address: What potential is there for devices outlined in *Annex XVI* to include unforeseen products that should not be regulated (as they do not pose the same level of risk/harm as other products) and may have the effect of overregulating the system?

HCA in principle, supports the regulation (ie regulation by the TGA or industry-based regulation) of such non-medical devices under *Annex XVI*. However, HCA recommends that consideration be given to devices being classified according to the risk they pose to consumers and that devices that pose low-risk be exempt from registration or can be legally marketed upon registration alone ie do not require further or premarket review or testing. This may reduce the risk of unforeseen/low-risk products from being captured by regulation. Further, if all devices listed in *Annex XVI* require manufacturers to register their facilities and list their devices with the TGA and follow general controls requirements – what costs are being transferred to consumers (directly and indirectly)?