SHPA response to Proposed new requirements for therapeutic vaping devices and accessories, March 2024

Consultation questions - Proposed new product requirements

2.1 Instructions for Use

12. Regarding the proposed instructions for use (IFU) requirements, what would be the impact on you as a manufacturer or sponsor to implement an IFU? If you are another stakeholder, do you have views about this change?

SHPA is broadly in support of the proposed product requirements for vaping devices and accessories which align with Australia's medical device labelling obligations.[1] Regarding the proposed requirement to state the 'intended purpose and the intended user of the device', SHPA would like to suggest that it is clearly highlighted in the IFU that vaping devices are for therapeutic uses only, as opposed to recreational use, and that the vaping device is to be used for the purposes of smoking cessation programs as directed by the user's health professional.

SHPA also recommends that supportive advice on smoking cessation is included in the IFU, such as including the Quitline number, as currently implemented for tobacco packaging in Australia. While the long-term effect of vaping is still being established through ongoing research, scientists and public health experts do not consider them safe.[2] With an alarming uptake of vaping particularly in younger people in recent years, creating a public health issue, it is important that ongoing regulatory reforms of vapes in Australia incorporates important messaging on the known and potential health risks of vaping, and where users can seek further support in their quit journey.

2.2 Labelling & Packaging

14. Regarding the proposed labelling and packaging requirements, what would be the impact on you as a manufacturer or sponsor to implement these requirements? If you are another stakeholder, do you have views about this change?

SHPA is supportive of the proposed labelling and packaging requirements, and recommends that the total active ingredient component, that being nicotine, should also be required to be clearly labelled on the packaging where appropriate. This would be in line with current medicines labelling and packaging requirements. These devices may be pre-filled and single use, similar to insulin auto-injector pens, and the same labelling and packaging requirements should be considered for therapeutic vaping devices.

Therapeutic vaping devices, whether they are re-usable or single-use, should not be designed to be aesthetically attractive or appealing, such as being shiny or glossy in the way illegal vaping devices can come across. Again, these devices should look like other medical devices that deliver a medicine that currently registered by the Australian Register of Therapeutic Goods (ARTG).

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References

[1] Therapeutic Goods Administration. (2024). Medical device labelling obligations. Available at: https://www.tga.gov.au/resources/resource/guidance/medical-device-labelling-obligations
[2] Therapeutic Goods Administration. (2024). About vaping and e-cigarettes. Available at: https://www.health.gov.au/topics/smoking-vaping-and-tobacco/about-vaping#:~:text=Health%20impacts%20of%20vaping%20devices,memory%20and%20changes%20in%20mood.