

Dear Sir/Madam

Thank you for the opportunity to comment on the above.

Overall this Company is supportive of the changes outlined in Proposals 3 & 4 which are the areas of impact for STS Health, an importer and sponsor of medical devices manufactured in Europe.

I do however need to point out the areas of concern that this Company has as follows: -

1. Manufacturers are constantly making minor technical changes to devices to rectify faults or improve performance so we ask that the threshold that is determined for what constitutes a "new model" is set at an appropriate level. If the bar is set too low, then we may not be able to source the relevant paperwork from manufacturers to satisfy TGA requirements on time, or even at all. This may cause frustration, delay and loss of revenue.
2. We are concerned about the increased compliance costs associated with the proposed changes. The proposals in their current form will result in a very large initial on-off cost and significant ongoing costs.
3. The depth of information required (from a commercial sensitivity aspect) when product information is made available to be viewed by competitors is of concern; as is what recourse reputable businesses have if the information provided by less scrupulous competitors is inaccurate or misleading (will the TGA have a surveillance unit that verifies the information, for example?)
4. The proposals, if adopted, substantially alter the existing regulatory arrangements for all businesses.
5. We are concerned about the potential for repackaging and relabelling that may be required depending upon where the ARTG number must appear under the new arrangements. Special manufacturing runs may be required for the Australian market significantly adding to costs.
6. The proposed transition time is likely to be too short given the requirement to source documentation from an overseas manufacturer.

Thank you again for the opportunity to comment on the proposed changes.

With kind regards,

John Waghorne

Sales Manager

STS Health

PO Box 1223 Osborne Park WA 6917

T (08) 9244 4628

F (08) 9244 4639

john.waghorne@stshealth.com.au [mailto:stshealth.com.ausales@stshealth.com.au](mailto:john.waghorne@stshealth.com.au)

www.stshealth.com.au