Page No	Section	Comment
16	2(A)	Amgen supports the proposal to no longer require Australian medical device manufacturers to hold a TGA conformity assessment.
22	Part 3(i)	Amgen proposes that amendments to the way devices are included on the ARTG (i.e. how various models are supplied under the same ARTG entry) should apply to Class III and high risk devices only. The reason for this is that low risk devices may contain smaller items that could be considered different models (eg thermometers or needles of different gauges). The regulatory burden and ARTG burden to list different models, doesn't match the benefit obtained for such low risk items.
23	Proposal 3(ii)	While Amgen supports enhancing the identification process, clarification is sought. Due to space restrictions some devices contain insert cards only with the device (as opposed to printing directly on the device, device packaging or instructions for use) in order to be able to hold all the information necessary to comply with *Essential principles 13.2 Information to be provided with medical devices – location*. It is intended that the ARTG No. will also be printed on the insert card and not the devices in these instances.
26	Proposal 4	Amgen supports the initiative of publication of device product information (similar to AUSPARs) when applied to all higher risk medical devices only. For low risk devices this would appear to be of limited benefit. Amgen proposes information; such as submission evidence required to gain registration, instructions for use, risk/benefit, TGA's overall assessment; should be published. TGA should be the author. All rejected applications should be published as a source of information to guide potential new device applications