Comment on Reforms in the Medical Devices Regulatory Framework

To follow, please find comments on the proposed reforms:

Proposal 1 Reclassification of joint replacement implants

A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee, shoulder joint replacement implants from Class IIb to Class III medical devices

Comment

This proposal is not relevant to product supplied by DENTSPLY, therefore no comment is provided on this matter.

Proposal 2A Use of third party assessment bodies for Australian manufacturers

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

Comment

Although not directly relevant to DENTSPLY, as we do not undertake manufacturing activities in Australia, we support moves by the TGA that result in Australian medical device manufacturers being subject to the same regulatory requirements and processes as overseas manufacturers.

Proposal 2B Increasing pre-market scrutiny for implantable medical devices

(i) Devices requiring a TGA Conformity Assessment Certificate to be issued

Subregulation 4.1(2) of the medical device Regulations to be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.

Comment

As the proposal document indicates that medical devices covered by current classification rules 3.4, 5.2, 5.7 and 5.9 would be subject to this proposal, any change that would potentially widen the devices requiring a TGA Conformity Assessment Certificate to be issued (for example, to include classification rule 5.5) should be subject to further consultation. On the basis that this change would only apply to devices covered by the classification rules referred to above, DENTSPLY would support the change.

(ii) Applications to be selected for auditing

Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.

Comment

This proposal has been designed to address recommendations of the HTA review, in order to address perceived shortcomings of the TGA evaluation process to ensure the safety assessments undertaken (by the TGA) would satisfactorily inform the requirements of the 'downstream' HTA agencies. There seems to have been no consideration given to the basis for the recommendation in the proposed implementation of reform by the TGA, and the potential negative impact on other sectors of the market, such as dental devices.

This proposal has the potential to have a significant impact on the availability and affordability of dental implants in the Australian market, if this proposal is adopted in its current format and the current fee structure is maintained. Under the current fee structure, this proposal will result in increased regulatory costs, from $810 to approximately $4000 for each approval, an increase of a factor of 5. This has the potential to result in either increased costs to patients for this type of product in Australia as dental companies pass on this increased regulatory burden, or to a decrease in the range of products available to Australian patients if dental companies decide that the increased costs of bringing new dental implant products mean that the products are designated not commercially viable. Both of these outcomes would have a negative impact on the access of Australians to optimal oral healthcare that utilises new technologies. This outcome is not in keeping with the documented aim of the TGA 'to ensure that the Australian community has access, within a reasonable time, to therapeutic advances'.

As the need for this type of increased regulatory scrutiny of dental implants has not been established in the documentation provided by the TGA, DENTSPLY does not support this change in its current format, unless dental implants are specifically excluded.

The preferred position would be to adopt regular reviews of devices required to undergo an application audit and only add dental devices if safety or performance issues arise.

Proposal 2C Recognition of third party assessment bodies

(i) Confidence building for EU Notified Bodies designated under the MRA

That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

Comment

If third party certification is going to be accepted by the TGA in order to approve medical devices for supply in Australia, then it will be essential to the success of this change that all parties involved have confidence in certificates issued by third party assessment bodies. It

will be important in this process to clearly define the financial commitment required by both the TGA and the EC as part of the project management of this change, and to consult further with industry on how the financial commitment of the TGA will be funded.

(ii) Recognising Australian third party assessment bodies

That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

Comment

Although not directly relevant to DENTSPLY, as we do not undertake manufacturing activities in Australia, we support moves by the TGA that increase the choice of Australian medical device manufacturers seeking the services of an assessment body.

Proposal 3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

(i) Amend the way in which a kind of device is included on the ARTG

Comment

In its current format this proposal does not seem to fit into the basis of the TGA regulatory framework i.e. a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden. This proposal, if a fee is implemented for variation to lower class medical devices, will significantly increase the regulatory burden associated with the lowest risk medical devices, particularly for those companies that supply large numbers (thousands) of low risk devices. Each approval typically encompasses a number of devices, with the majority of new products launched in any given year falling into the category of new variants of existing devices, thereby attracting no fees.

In the information provided as part of this consultation, there is no detail provided of a clear demand for this information from either oral healthcare practitioners or consumers. While DENTSPLY does generally agree that the ARTG could be improved by linking an individual entry with 'models' of a particular device, this needs to be very carefully balanced against introducing a regulatory regime that is excessive for the task and adds unnecessary costs and potentially delays or prohibits the introduction of new low risk products to the Australian market.

The TGA must clearly define a 'model' and which changes would be considered significant enough to constitute a 'new model'. The definition of a 'model' is particularly difficult for the lower class medical devices. If a product name is taken as the model, and the product name is changed without a change to the device, does this constitute a new model? If a new variation of a medical device is produced but the name remains the same, how would this be captured? Is there to be a definition with respect to changes that impact the devices use, operation, efficacy or in any way affect patient health outcomes in the definition of a 'new

model'? This has implications for the amount and type of information provided to support the approval of low risk medical devices, and also potentially brings into question the definition of a 'kind' of medical device. The TGA's proposal has the potential to significantly increase the regulatory burden for businesses and has the potential to either increase the costs of low risk devices, or limit the availability of new and innovative low risk products.

An acceptable alternative would be to list the 'product name' on the ARTG entry for a medical device, with the allowance made for a number of names to be included under a single ARTG entry where all are the same kind of device. Variations could be automatically added and subject to audit, as Class I applications are currently. The frequency of application audits could be set according to the classification level of devices, with higher class device variations audited more frequently than the lower class devices. This would allow the oral healthcare professionals and consumers, in addition to the TGA, the ability to link a particular device with a TGA approval without imposing significant regulatory compliance burden in association with the improvement.

As this change has the potential to impact our entire range of (thousands of) medical devices, the ability to update details of current approvals within a timeframe of 1 year is unrealistic. A timeframe of 2 years is more realistic.

(ii) Enhance the ability to identify devices that have been approved by the TGA for supply in Australia

Comment

The TGA have incorrectly assumed that this change should not adversely impact on regulatory costs as sponsors are already required to publish contact details on the information that accompanies a medical device. This is an erroneous and potentially dangerous assumption, as the two pieces of information are not linked.

The majority of the medical devices that DENTSPLY sell in the Australian market are sold in packaging and with information that meet the requirements of a number of markets e.g. the European and Australian markets, because the Australian dental market is small and Australian only products are not financially viable. In these instances, the inclusion of the ARTG number may necessitate Australian only packaging and therefore special production runs for the Australian market. The strongest consideration needs to be given to any change that will mean Australian specific labeling as our market volume means that it is not commercially viable to produce small quantities of dental devices labeled specifically for our market. This would then jeopardise supply to the Australian market, with the potential to severely impact healthcare professionals and consumers through inability to access currently approved products. In the unlikely event that a manufacturer should agree to manufacture devices with Australian specific labeling in small production runs, then due to the small volumes manufactured, prices would be significantly increased. This has the potential to compromise the affordability of dental care in Australia, as price increases across the entire range of low risk dental devices are passed on to consumers.

Logistically, the addition of any change to the information that accompanies a medical device requires liaison with the manufacturer to update new artwork. This artwork is then required to be reviewed, approved and implemented. Typically, in order to reduce the costs

associated with implementation, time is also allowed to use up the old labeling and then implement the updated labeling once old stock is exhausted. A twelve month timeframe to implement changes to the labeling of thousands of device, with numerous manufacturers is impossible. Should this proposal be implemented, a five year timeframe would be required or supply of product that remains in the market is likely to be interrupted simply due to an inability to meet the requirement to have an ARTG number on the information that accompanies a medical device.

The TGA's proposal, if adopted in its current form will jeopardise the supply of low risk dental devices to the market and potentially impact the availability and affordability of oral healthcare to both professionals and consumers in Australia, limiting the ability of all Australians to access basic dental devices.

The consultation paper indicates that this change is expected to enable healthcare providers and consumer to easily identify medical devices approved for supply, and assist in cross-referencing the device with the ARTG record. If the TGA implement proposal 3(i), as outlined above with the inclusion of product names on the ARTG, then the need for 3(ii) would be removed. DENTSPLY support the implementation of proposal 3(i) utilising product names, over proposal 3(ii) as the preferred way of enabling healthcare providers and consumers to identify medical devices approved for supply and the preferred way of enabling the TGA to cross-reference a device with the ARTG record to avoid any impact on the access of all Australian to affordable oral healthcare.

Proposal 4 Publication of device product information on the TGA Website

Comment

The information published on the TGA website in relation to medicines in Australia is related to the evaluation and approval process. Similarly, the PI and CMI documents are documents that are developed specifically for the Australian market, and are reviewed and approved by the TGA as part of the evaluation of the medicine. In addition, changes to these documents are also required to be approved by the TGA. In keeping with this basis, only information that is reviewed and approved by the TGA, and is required to be updated with the TGA should be made available on the TGA website. As such, the type of information should be directly linked to the information that is submitted and approved for the higher risk classification devices, such as Class III and AIMD devices, and therefore only these devices should be included in such a scheme. DENTSPLY would support a scheme for increasing the information available for higher risk classification devices, but does not support a scheme for lower risk devices.

As outlined above, the majority of the dental devices that DENTSPLY supply to market are manufactured overseas, therefore any scheme that would require documentation to be reviewed for publication both here and overseas would significantly increase compliance costs associated with low risk dental devices, once again escalating costs of oral healthcare services to the Australian consumer, and having an impact on the affordability of these services in Australia.

If the TGA is to publish information on rejected application, then it would need to be limited to reasons related to safety and/or efficacy, as it is for medicines. This is the only type of

information that is easily understood by those unfamiliar with the details of device approvals. Currently, medical device applications for lower risk medical devices can be rejected for other reasons e.g. on the basis of incorrect allocation of a GMDN code or an apparent difference between a GMDN code definition and an intended purpose for a device. This type of information would not be in the public interest, particularly if the device was subsequently approved.