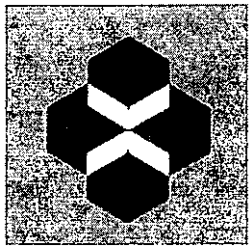

DYNEK
Surgical Excellence

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

December 2010

Dynek response to the Discussion Paper
"Reforms in the Medical Devices Regulatory Framework"

Summary
Dynek seeks resolution to an injustice in the present system regarding Third Party Conformity Assessments. This company is being penalised unfairly for getting its CE Mark from a (now) designated Notified Body 8 years before the TGA had the authority to perform conformity assessments. Because Dynek is proudly an Australian manufacturer it is charged twice for the privilege of employing Australians in a value-adding enterprise – once by its designated EU Notified Body SGS UK, and again by the TGA.
If the TGA has done enough "confidence-building" to regard SGS UK as sufficiently worthy to accept its assessments of European medical device manufacturers for supply to the Australian market, why should SGS's assessment of an Australian manufacturer be any less acceptable?
While the TGA's costs may be marginal for the profitability of multinationals seeking to dominate the Australian device market, they are unjustly punitive for Australian manufacturers. There is a grave danger that the imposition of excessive and avoidable costs will either drive manufacturing off-shore, or force domestic companies to cease operations.
By default, government policy runs the risk of favouring market power over domestic innovation and entrepreneurship.

Background Information
This response is structured along the lines of the TGA's Discussion Paper. It first gives some background on Dynek (the respondee), and our motivations in responding. There follows some brief comments on Recommendation 8 of the Health Technology Assessment (HTA) Review. Lastly, the Devices Regulatory Reform Proposals raised by the TGA are assessed.

- Dynek is an Australian manufacturer of surgical sutures, operating in Adelaide since 1974. Our products include five Class III invasive devices (Vilene®, Radene®, Biovek®, Plain catgut, and Chromic catgut) and four Class IIb invasive devices (silk, nylon, polyester and polybutester);
- Dynek has a history of zero product recalls;
- Dynek gained its CE Mark to access export markets eight years before the TGA was approved as a Conformity Assessment Body. For this reason, the company has many years of experience working with the designated EU Notified Body 0120, SGS UK;
- SGS is a global corporation, employing in excess of 50,000 people world-wide, with a physical presence and recognised brand in most global markets. By comparison, the TGA "brand" has

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comparatively limited global recognition, and is not recognised in some of Dynek's export markets;

- The Therapeutic Goods (Medical Devices) Regulations 2002 requires that a TGA Conformity Assessment Certificate is held by manufacturers who manufacture medical devices in Australia, before the devices can be included on the ARTG;
- Under present regulations Dynek must pay twice for the privilege of manufacturing in Australia, once to SGS for certification and surveillance audits, and again to the TGA;
- Dynek responded to the TGA Consultation Paper regarding Use of Third Party Assessment Bodies for Australian medical device manufacturers, seeking relief from the anti-competitive anomaly of doubling-up of conformity assessments and Full Quality Assurance audits imposed on Australian manufacturers;
- SGS audits of Dynek are conducted by an auditor with extensive prior experience as QA Manager for a manufacturer of surgical sutures. By comparison, TGA auditors have knowledge of Standards and regulations, but little to no direct experience of device manufacture;
- The EU-Australia Mutual Recognition Agreement can scarcely be called "mutual" when the TGA charges non-Australian manufacturers for access to the Australian Market, while access to the UK (a major EU devices market) for Australian products is free of charge (see Annex 1)
- The TGA's prices are uncompetitive. They may offer no barrier to large multinationals seeking to sell product in the Australian market. However, the recent judgment in ACCC *versus* Baxter illustrates how financial muscle and market power might be used to the detriment of smaller manufacturers (see Annex 2), especially Australian manufacturers offering a less extensive product range.

Review of the Discussion Paper

(i) Recommendation 8 – The HTA Review

Recommendation 8 of the HTA Review made the following four recommendations.
That the Therapeutic Goods Administration (TGA) in the context of international harmonisation:

a) Continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on to the ARTG and marketing in Australia;
b) Respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;
c) Increase the rigour of assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and

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d) Develop protocols for infonnation sharing with other HTA agencies through the Single Entry Point (SEP), subject to commercial-in-confidence constraints on the outcomes of its safety assessments.

Recommendation 8a) is correctly framed by the opening line of this Recommendation, i.e., "in the context of international harmonisation". The TGA's role, as *independent* and with *sole responsibility* must be exercised with due regard to the regulatory expertise of non-Australian Conformity Assessment Bodies/Notified Bodies and international harmonisation of regulations. In addition, Discussion Fora with the TGA have explained that some of the emphasis on "*sole*" relates to the decision hierarchy across multiple Federal Government (Canberra) departments for medicines and devices.

Recommendation 8b) demands examination of the TGA's response to feedback from its consultation processes. The issue of whether the TGA has "listened" adequately to feedback will be addressed later in this response.

Recommendation 8c) would seem to be in direct contradiction of the TGA's stated purpose for the HTA Review, i.e., "to reduce unnecessary regulatory burdens on the (health) sector". A blunderbuss approach must be avoided when implementing steps to "increase the rigour of assessment of higher risk medical devices". Any such "increased rigour" should be focused on "problem devices" and justified (to avoid it becoming a "licence to print money") rather than adopting the catch-all approach of scrutinising all Class IIb and Class III devices. In addition, the recommendation stresses rigorous review "prior to market entry", but opens a Pandora's Box for post-market regulatory demands and surveillance (with associated cost-implications), leaving this point unanswered. Caution would suggest that Recommendation 8c) should not be acceptable to the sector until the detail of consequential post-market surveillance of defined high risk devices has been resolved.

Recommendation 8d) side-steps one of the major issues confronting Australian medical device manufacturers, i.e., the disconnect between HTAs and State government procurement offices. The recent judgment in ACCC *versus* Baxter (Annex 2) identifies the ability (and practice) of procurement offices in State government health departments to stand outside the Trades Practices Act when making purchase decisions on medical supplies. Uncompetitive pricing policies of the TGA will be a disincentive for smaller national and international companies to develop and register products on the ARTG, thus by default facilitating abuse of market power and stifling national innovation and entrepreneurship.

(ii) Devices Regulatory Reform Proposals
TGA Proposal 1
Dynek has no input to this proposal.

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

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The interpretation of this Proposal is that it enables implementation of Proposals 2B and 2C.

Dynek's concern is that for this company any concessions granted in Proposal 2A are nullified in Proposal 2B. Proposal 2A raises the possibility that some manufacturers " *... may opt to utilise (recognised Notified Body) CE certification to support their ARTG entries.*"

Proposal 2B would seem to withdraw this option for Dynek's Class IIb and Class III products.

TGA 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 be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.*

(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.*

The wording of this proposal stresses "pre-market scrutiny". Dynek's products have already been approved for market. Thus it is unclear whether our products fall within the sphere of Proposal 2B, or whether they will be accepted onto the ARTG using our CE Mark certification, in accordance with Proposal 2A.

If the TGA's intention is to emphasise approval-for-market rather pre-market scrutiny, then Proposal 2B leaves Dynek in a worse position than it was in prior to initiation of this Consultations activity, i.e., we pay for SGS certification and surveillance audits, we still pay for TGA's duplication of the same activities, and in addition we may have to pay "Application Audit fees" for four Class IIb products, adding between $12,000 and $22,640 to regulatory costs.

In other words, the central issue for Dynek in the Consultation Paper "**Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia**" (December 2008) may have been overlooked.

TGA 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.*

(ii) Recognising Australian third party assessment bodies *That further consultation be undertaken to investigate the development of a system whereby Australian based assessment*

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bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

Proposal 2C (i) is unjust and inconsistent. As set out in Annex 1 and the EU – TGA MRA ...

- UK's Medicines and Healthcare products Regulatory Agency (MHRA) does not require any additional registration for products that have already been registered with another EU Competent Authority;
- The MHRA does not require any additional fees to be paid in respect of importing of CE marked medical devices, irrespective of their classification;
- Dynek's understanding of the Mutual Recognition Agreement between the EU and the TGA is that the TGA is regarded as if it were "another EU Competent Authority";
- So, UK's MHRA has adequate confidence in any European Competent Authority to give access to the UK market for CE marked devices;
- It has adequate confidence in the TGA's ability as a Competent Authority to permit entry of devices given a CE Mark by the TGA;
- The TGA has adequate confidence in "designated" EU Notified Bodies to recognise their assessment of European manufacturers of medical devices for entry to the Australian market;
- But the TGA does not have confidence in the *same* designated EU Notified Bodies when assessing Australian manufacturers.

The logical basis for Proposal 2C(i) is further undermined when Proposal 2C(ii) is considered. If the TGA is capable of devising a system whereby (currently non-existent) Australia-based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers, then why hasn't it put effort into resolving the anomaly of use of third party conformity assessment bodies during its ...
"seven years' experience with the medical devices regulatory framework, based on the GHTF model"?

If a model can be devised for the TGA to accept the assessments of Australia-based assessment bodies, why has it not already instituted such a parallel system for existing EU Notified Bodies during its last seven years of experience with the regulatory framework?

The recent release of the TGA document "*TGA Risk based approach to audit frequency*" (available for downloads at <http://www.tga.gov.au/docs/html/audit-freq.htm>) will exacerbate the costs associated with TGA audits. The explanations offered by the TGA for introducing *a* more frequent audit regime show little understanding of the costs associated with making any substantial change to a process involved in medical device manufacture (staffing, procedure, equipment or location), and the validation of that change. For Dynek, the baselessness of the supposition regarding changes in key staff as a driver for increased audit frequency is illustrated by the duration of employment of key production staff, several of whom have been with Dynek for over 20 years (see Annex 3).

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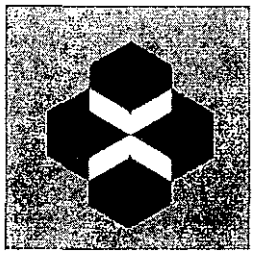

DYNEK
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TGA Proposal 3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices:
(i) amend the way in which a kind of device is included on the ARTG; and
(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

The TGA's Proposal 3 (i) is to itemise the devices and/or various models that are supplied under the same ARTG entry. Dynek requires clarification on this proposal. We manufacture sutures. These are entered onto to the ARTG as a single entry according to suture material type, e.g., silk, nylon, polyester, polybutester, polyvinylidene fluoride, polyglycolic acid, surgical catgut. A full listing of all Dynek "models" for these sutures would embrace the combination of all needle types (cutting profiles, wire diameters, needle lengths, etc) with all suture thread sizes (lengths and diameters).

Such a list would exceed 9000 "models", and would do little to achieve the TGA's stated aims for this proposal. In addition, should the TGA opt to charge for these additional listings, or changes in them, the cost would be prohibitive.

The TGA's Proposal 3 (ii) would require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device. (label, IFUs, or packaging).

Dynek makes two comments here. First, consideration needs to be given to the available space on device labels, and any stipulations on minimum font size for ARTG numbers. Secondly, manufacturers are likely to hold considerable stock of existing packaging/IFUs (ordered in units of thousands), and TGA's proposed implementation times must give consideration to the time taken for manufacturers to work through existing stocks.

TGA Proposal 4 - Publication of device product information on the TGA Website
This proposals bears no relationship with the HTA Recommendation 8, but seems to be on the TGA's "wish-list". It represents "bigger government", which means bigger cost. And we all know who pays for that. The question remains whether it delivers bigger benefit.
The web link examples from the FDA lead to a single page entry for typical data on a medical device, but representative information on summary safety and efficacy data lead to a 26 page document!

What is unclear is who commits the time and expense in preparing, updating and validating these documents.

Response to Attachment 2 - *Use of Third Party Conformity Assessment Bodies for Medical Devices Manufactured in Australia*

It is the view of this respondent that the TGA has paid little regard to the feedback to the questions it posed in the Third Party Conformity Assessment paper.

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Appendix 2 of the current paper summarises the responses to the seven (7) questions raised in the earlier consultation paper.

Question 1 - *Do you think TGA should continue to be solely responsible for undertaking conformity assessments for devices that contain a designated material?*

The TGA's summation ... *"that manufacturers of high-risk medical devices and their products containing a designated material should continue to be subject to review by the TGA prior to market entry"* is contrary to the (almost universal) feedback from industry, conformity assessment bodies and professional organisations.

Question 2 - *Do you think TGA should continue to be solely responsible for undertaking conformity assessments for Australian made devices intended to be supplied in Australia? If so, why? If not, who should do this?*

The overwhelming feedback from industry, conformity assessment bodies and professional organisations was for alternative conformity assessment bodies to be able to provide assessment services for entry of medical devices to the Australian market.

Question 3 - *Do you think TGA should be solely responsible for undertaking conformity assessments for any or all classes of medical device? Should CABs be permitted to undertake assessments of any or all classes of medical device?*
Again, predominant feedback was that this should not be the sole responsibility of the TGA.

Question 4 - *Do you think a CAB should issue certificates for acceptance, or otherwise, by the TGA or should they produce a report of their findings for the TGA to consider prior to issuance of a certificate? Should the approach be the same for all classes of device?*
Feedback is reported as being "balanced".

Question 5 - *Should TGA have a role in designating Australian CABs? If yes, why? If not, who should perform this function?*
Respondents overwhelmingly thought that the TGA should have a role in designating Australian CABs.

Question 6 - *Should TGA retain responsibility for making the final decision to allow supply of a medical device into the Australian marketplace? If yes, why? If not, who should hold this responsibility?*

The overwhelming view of stakeholders was supportive of the TGA retaining responsibility for making the final decision to allow supply of a medical device into the Australian market.

Certainly, from the point of view of this respondent, this response was given to mean that someone (a single entity) needs to hold and control the register (ARTG). Being chief monitor over the ARTG is not

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the same as holding sole responsibility for performing conformity assessment for (high risk) devices seeking access to the Australian Market. Nor does it mean that the only pathway to the ARTG for Australian manufacturers should be via a conformity assessment from the TGA.

Question 7 - *Are there other matters you wish to be considered in relation to conformity assessment for medical devices?*
Multiple responses were given.

In the view of this respondent the TGA's *In Summary – Reforms in the Medical Devices Regulatory Framework* (relating to responses to questions) was not balanced, nor representative. As such, it forms a poor foundation for making the proposals identified in the current Discussion Paper.

Yours sincerely
Dynek Pty Ltd

Tim Kaethner PhD
Quality Assurance Manager

Annex 1

Suspected fraud involving impersonation of British authorities
11 November 2010
It has been brought to the Agency's attention that a number of manufacturers and their stakeholders groups have been approached via email from the British Health Agency (11Kb) stating that there are additional fees payable to manufacturers and importers of medical devices and medicines and supplying an extract from the UK Health Gazette (172Kb). We would like to bring to your attention that:

Medical devices
The MHRA is the Competent Authority and designating authority for medical devices in the UK and as such administers the provisions of the Medical Device Directives. This includes the registration for Class I medical devices and IVD Medical Devices for manufacturers or Authorised Representatives based in the UK.

In the UK we do not require any additional registration for products that have already been registered with another EU Competent Authority, although for In Vitro Diagnostic devices we ask that a copy of the registration form submitted to the other member state Competent Authorities is supplied to us in order to comply with Article 12 of the IVD Directive , this activity does not incur payment of our statutory fees.

The MHRA does not require any additional fees to be paid in respect of importing of CE marked medical devices, irrespective of their classification, and we are not aware of the British Health Agency being a UK government body. We are therefore investigating this matter. If you receive any further information regarding this matter you may forward it to our Compliance Unit by email at devices.compliance@mhra.gsi.gov.uk

Medicines
The MHRA is the UK regulatory authority responsible for assessing the safety, quality and efficacy of medicines,

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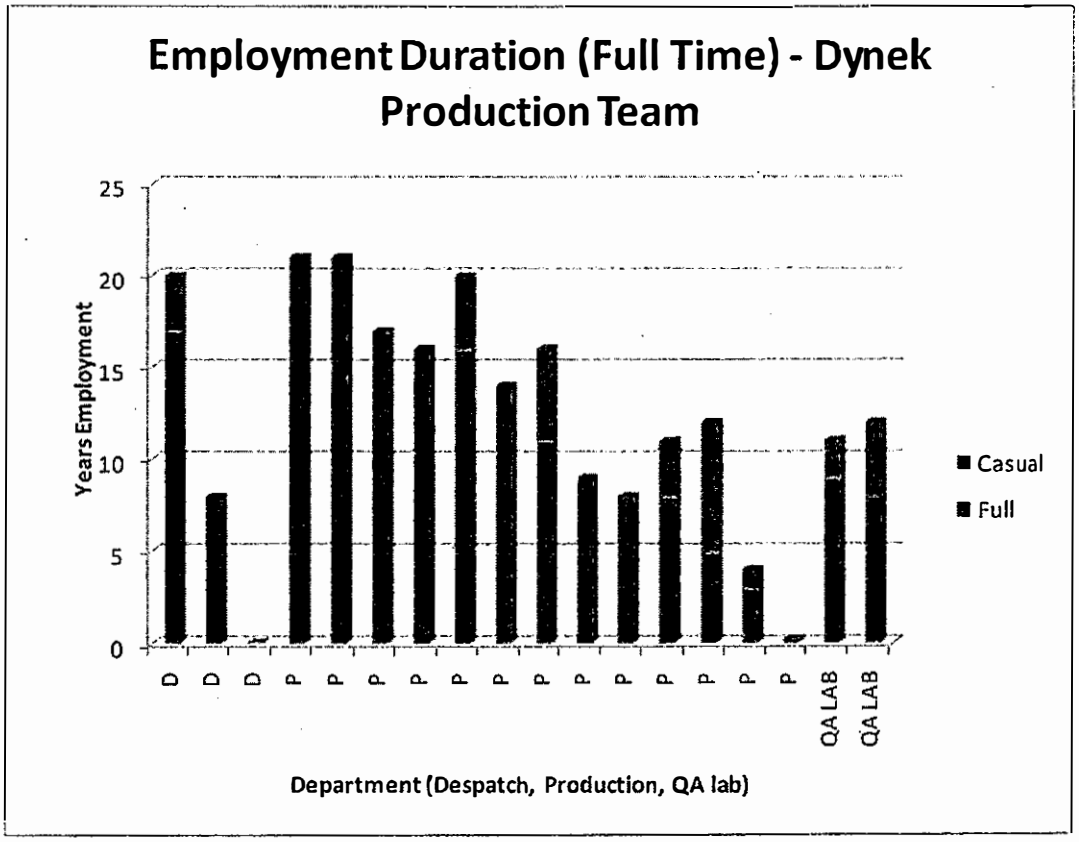
and authorising their sale or supply in the UK for human use. Companies selling medicines in the UK must hold a marketing authorisation for each product and any company importing medicines for sale in the UK must have an appropriate wholesale dealer's licence issued by the MHRA.
All fees are payable directly to the MHRA as described in the fees section on our website.

http://www.mhra.gov.uk/Howweregulate/Devices/Devicesregulatorynews/CON099898

Annex 2

1) http://www.austlii.edu.au/au/cases/cth/FCAFC/2008/141.html
2) http://www.dlaphillipsfox.com/article/42/Government-Alert---ACCC-v-Baxter-Healthcare---derivative-Crown-immunity-confined
3) http://www.theaustralian.com.au/national-affairs/agency-used-drug-firm-guilty-of-breaches/story-fn59niix-1225934048076

Annex 3



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