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TECHNICAL REPORT 11

An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices

Summary Report

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Table of Contents

1 Introduction

A comprehensive framework for the regulation of medical devices in Australia was first introduced under the Therapeutic Goods Act 1989. The provisions of the Act have since remained largely unchanged. In recent years, however, a number of developments in Australia and overseas have led to debate about potential reforms to the way in which medical devices are regulated in Australia. In particular, the Industry Commission inquiry into the Medical and Scientific Equipment Industries (Industry Commission, 1996) strongly supported a move towards the adoption of the European Union model for conformity assessment in Australia. The National Competition Policy also places the unnecessary restriction of competition on the agenda for reform (Duckett et al, 1999).

The Health Economics Unit, at the Centre for Health Program Evaluation, was commissioned by the Therapeutic Goods Administration to provide an economic analysis of a potential move to a third party conformity assessment model for medical devices in Australia. Economic analysis was prepared based on a comprehensive review of the literature on medical devices, conformity assessment, regulated competition and health risks, and analysis of the potential costs and outcomes of a third party model in Australia. Fuller details and discussion are provided in the Full Report on this project (Peacock et al, 2001) which should be read in conjunction with the Summary Report.

2 Evidence from the literature

(i) The Medical Devices Industry and Conformity Assessment

The Medical Devices Industry is comprised of a high proportion of small firms, but production and employment is dominated by a number of large firms. Evidence suggests that substitution across medical equipment product classes is limited, and the market is highly segmented. The global market is dominated by the US, the EU and Japan, with Australia accounting for a little over 1% of the global market in medical equipment. Approximately 80% of the medical devices in Australia are imported, with 25% of imports from the EU, 53% from the US, and 10% from Japan, and 12% from other countries.

The EU and Australian models of conformity assessment are based on similar principles relating to the quality, safety, efficacy and timely availability of medical devices. The EU differs, however, in that it explicitly includes a trade goal to remove impediments to intra-EU trade. It is important to note that reflecting the EU setting, the EU model has sought to facilitate trade in addition to the traditional public health goal of promoting safety and effectiveness in its regulatory framework. In design, the EU and Australian models differ in two main respects:

- Manufacturers in the EU are free to choose from a range of conformity assessment bodies who are allowed to compete for business across the full range of classes of devices. In Australia, the TGA is the sole supplier of conformity assessment and there is no provision for competition

- EU manufacturers have a choice of routes to demonstrate conformity which do not require evaluation of each and every device, with greater emphasis on quality assurance systems audit. In Australia, manufacturers have no choice of the methods to demonstrate conformity, and large numbers of devices have to be evaluated on a case by case basis.

The recent signing of the EU-Australia Mutual Recognition Agreement and moves towards international harmonisation will reduce the costs of conformity assessment for importers and exporters and increase the speed with which products are approved. Under the Mutual Recognition Agreement, the EU and Australia are moving towards a model where conformity assessment carried out in Australia will be recognised in the EU, and vice versa.

(ii) Regulated Competition and Public Sector Services

Microeconomic reform of public sector services has focused on three main strategies in recent years: privatisation; managed competition and quasi-markets; and competitive tendering. All fall under a broad heading of regulated competition. The EU model of conformity assessment is a particular form of regulated competition where competition is allowed between third party conformity assessment bodies (Notified Bodies), which are regulated by government agencies (Competent Authorities). It is a model where conformity assessment service provision has been wholly or partially privatised, but the market remains under government regulation through the roles and responsibilities invested in Competent Authorities.

Evidence from the literature on privatisation does not provide definitive guidance on whether private ownership always promotes greater efficiency. A move from public to private provision can therefore neither be discarded nor conclusively supported, from the available evidence.

Most insight on specific aspects of the performance of industries where regulated competition has been introduced can be found in the evidence from competitive tendering models of regulated competition. Evidence falls under five areas: the size of cost savings; the sources of cost savings; changes in quality; transaction costs; and the effects of ownership verses competition. Cost savings from competitive tendering are between 9 and 14% across a range of industries, based on findings from a detailed meta-analysis of robust empirical studies (Hodge, 1996). Some industries, in particular refuse collection and cleaning, are better suited to competitive tendering and report cost savings of 20%. The quality and volume of services produced are easily observed in these industries.

Health service outputs and their quality characteristics are more difficult to observe, which limits the potential for regulated competition. Examples from the health sector are limited, do not provide definitive guidance, and are generally confined to domestic, catering and cleaning services. Other industries have not reported cost savings, or reported cost increases from competitive tendering. After completing one of the largest reviews to date, including a meta-analysis, of world wide experience with competitive tendering Hodge (1996) has questioned whether significant cost savings may be available from competitive tendering in the health sector, largely due to the inherent complexity of health services. A reasonable approach may therefore be to use Hodge's lower bound, 9%, as an estimate of potential cost savings in health services. Adjusting for the mix of industries studied may reduce this figure further, consequently the 9% figure may be taken as a generous estimate of the potential cost savings from competitive tendering in the health sector.

The literature does not offer definitive guidance on the source of cost savings from regulated competition. Cost savings may arise from increased productivity, through better management, more flexible working practices, increased innovation and more efficient use of capital. Equally, they may arise from reduced wages for workers, particularly for part time workers and women. The literature also offers no consensus on the effects of regulated competition on quality. There are a number of studies that report both improvements and reductions in service quality, with meta-analysis reporting no net change in quality over a range of international studies (Hodge, 1996).

(iii) Health Risks and the Regulation of Medical Devices

There are a number of considerations to take into account in assessing the potential for a regulated competition model in conformity assessment. These are as follows:

The National Competition Policy does not equate competition with public good (Duckett et al, 1999). Rather it requires a rational articulation of the objectives of regulation that restrict competition and an analysis of alternative means of achieving those objectives. The objectives set out in the Therapeutic Goods Act of quality, safety, efficacy and timely availability focus on public safety – on the trade-off between the risk of allowing a dangerous product (or one that does not offer a benefit) onto the market against the risk of preventing or delaying a beneficial product from being made available to the public.

Measurement of health related benefits from medical device regulation is not straight forward. The prevention of premature death is clearly of prime importance, but other benefits include the prevention of unnecessary morbidity and costs to society from device malfunctions. A focus on the mortality benefit, however, is sufficient to place the competition/public good issue in context. Literature based estimates of the value of reduced mortality risk suggest that there would need to be savings in excess of $3,000,000 per year if there was an expectation of one additional death a year as a result of a reduced role for government in the regulation of medical devices in Australia.

There may be potential increases in health risks under a move to a regulated competition model, with potential for larger variations in risk for high-risk (Class III) devices. Any potential decline in public confidence under a regulated competition model for Class I and II devices only, is likely to be smaller than any potential decline in public confidence under a regulated competition model for all devices (the EU model).

Public confidence may reflect public perceptions of risks that do not necessarily accord with objective evidence regarding the magnitude of those risks. Evidence suggests that the public places higher value on safety regulation which addresses catastrophic events, and small but alarming adverse events where risk is perceived to be largely outside the control of the individual.

(iv) Overseas Experiences with Conformity Assessment

Despite strong endorsement by the Industry Commission (1996) for a move to an EU style conformity assessment model in Australia, the EU reforms have not been evaluated, and their effects remain largely unknown. There do not appear to be plans to evaluate the system in the near future. Caution is warranted in importing solutions from overseas tailored to the cultures and institutional systems of other jurisdictions. The costs and benefits of moving to an alternative system need to be carefully assessed. Reflecting the EU setting, the EU model has sought to

facilitate trade in addition to the traditional public health goal of achieving safety and effectiveness in its regulatory framework. Most countries, including Australia, have focused on the public health goal alone.

3 Findings from Analysis of Potential Costs and Outcomes

(i) Options for Regulated Competition

Under a potential regulated competition model for conformity assessment in Australia it is envisaged that the roles and responsibilities of third party assessment bodies and the regulator of the market would be broadly similar to the EU model. Third party conformity assessment bodies would compete with each other for the pre-market assessment of devices and ongoing surveillance of quality systems. The regulator would accredit and audit conformity assessment bodies, develop and set standards, provide surveillance of the market, operate the vigilance system, and maintain registers of devices.

Health risks associated with medical devices are not uniform, and devices have been classified into four main categories: In-vitro diagnostic (IVD); Class I - Low risk; Class IIa – Medium Risk (non-hazardous and low risk surgical devices); Class IIb – Medium Risk (potentially hazardous and higher risk surgical devices); and Class III – High Risk (including active implantable medical devices).

Three options for regulated competition have been suggested and were considered in the analysis:

Option A Conformity Assessment for all medical devices to be undertaken by the private sector.

Option B Conformity Assessment for medium to low risk IVD, Class I, IIa and IIb medical devices to be undertaken by the private sector, Conformity Assessment for Class III and high risk IVD devices to be retained by the TGA.

Option C Conformity Assessment for low risk IVD, Class I and IIa medical devices to be undertaken by the private sector, Conformity Assessment for Class III, high risk IVD and Class IIb devices to be retained by the TGA.

There are three reasons for retaining some higher risks under the jurisdiction of the TGA under options B and C. Firstly, there may be economies of scale in the conformity assessment of higher risk devices. Secondly, there is a strong public interest argument for the retention of higher risk devices under direct TGA control. Thirdly, there are practical reasons related to the level of expertise and reputation of the Competent Authority to maintain its involvement in conformity assessment.

(ii) Prospects for Regulated Competition

Our review of the evidence and theory in the literature suggests a set of conditions under which regulated competition may be considered favourable. These are when:

- The magnitude and specificity of the physical assets (human and physical capital) required for the provision of services are relatively small, thereby reducing sunk costs and barriers to entry into the industry.

- Monitoring of service provider performance is relatively straightforward: outputs and their quality characteristics are observable ex ante and ex post; regulatory and monitoring systems are already developed and in place.

- The availability of competitive supply in the market, both actual and potential, is large.

- Information asymmetries do not exist between incumbents and potential entrants into the market. Information asymmetries are more likely when output is not clearly observable and monitoring is difficult.

These conditions relate to the objective of increasing efficiency in service delivery through the introduction of competitive forces. A second objective may also be deemed desirable to foster an Australian industry in conformity assessment. Therefore, a fifth consideration may also be included in assessing the prospects for regulated competition in Australian conformity assessment:

- There is potential to foster an Australian industry in conformity assessment, and for exporting services provided by the private sector.

There is no rigorous evidence on the potential availability of private sector expertise in Australia. In this situation, expert opinion represents the main way in which information may be gathered. Such evidence is subject to bias, however, and should be treated with caution. Opinion and judgement varied significantly between private sector and TGA sources as to the potential availability of expertise. The private sector considered strategies to provide expertise were available (e.g. through strategic partnerships), but the TGA suggested these may overestimate the potential availability of expertise.

A key issue is one of determining how a private sector conformity assessment market may develop in Australia if there is a shortfall in private sector expertise. In the short run, a shortfall in expertise may result in a dislocation of conformity assessment services, with the private sector unable to meet the demands of the medical devices industry. This would result in delays in devices reaching the market. This may be avoided by the phasing in of private sector conformity assessment, with the TGA and private sector bodies operating in tandem until the market "matures". During this period, the regulator of the market would have to be especially vigilant to ensure quality in conformity assessment is not compromised. Issues around a "level playing field" may also arise.

Where conformity assessment is more complex, and devices of a particular type are assessed infrequently, private sector bodies may have difficulties in finding appropriately qualified staff to

perform the required tasks. This suggests that the private sector may also face some difficulties in assessing high risk devices with highly specialised assessment requirements, but may face fewer difficulties in assessing low risk devices.

For the above and other reasons, there may be scale economies in the provision of conformity assessment for higher risk devices. These devices require higher levels of skills and equipment specificity, which may reduce contestability for these devices. There is, however, no published evidence on the size of any scale economies.

Under any form of regulated competition a third party body may cease activities (i.e. go out of business) leaving unmet commitments to manufacturers. These commitments and actions arising from services paid for, but not provided, are generally not insurable. Whilst this may be less than ideal from the manufacturer's point of view, financial losses to the manufacturer should be restricted to the transaction costs required for its new conformity assessment body to familiarise itself with the product etc. From a political perspective, however, the implications of private sector bodies going out of business may be compounded as any failure, however small, may reduce confidence in government policy within the community.

An important consideration is the question of what weight should be placed on fostering the development of a private sector industry, and allowing that industry a "chance to prove itself". If the longer term benefits from regulated competition, in terms of enhanced efficiency and the establishment of a new industry are large enough, then any short term difficulties in establishing the private sector expertise may be outweighed by the long term gains.

There is some potential for a private sector conformity assessment industry to export services. The long term effects of the Mutual Recognition Agreement on conformity assessment, however, are unknown, limiting ability to estimate potential exports to the EU. Similarly, there is potential for exports to the Asia-Pacific region, but estimates of the size of this potential cannot be made at present. Whether Australian conformity assessment bodies would have a significant presence in the world market would depend upon their performance and efficiency relative to overseas conformity assessment bodies.

(iii) Impact on the TGA and regulating the market

Reform of the regulation of medical devices in Australia to introduce private sector conformity assessment would have implications for the organisation, roles and responsibilities of the TGA. Additional costs would arise associated with evaluating and monitoring the competency of private sector conformity assessment bodies. Based on UK experience the incremental costs of regulating the conformity assessment market are likely to be of the order of 1.5%. In assessing the costs and benefits from a third party conformity assessment model, the incremental costs of regulating the market must be offset against efficiency gains from the private provision of services that are currently provided by the public sector. The estimate of a potential 9% cost saving in health services under competitive tendering includes the incremental costs of regulating the market. That is, incremental costs, on average, were more than offset by efficiency gains.

The TGA currently operates on a full cost-recovery basis, with its regulatory oversight and post-market surveillance functions covered by user fees and charges. It is reasonable to expect this policy to continue under a move to a third party assessment model. Who bears the burden of these fees (i.e. third party bodies, manufacturers, or consumers) will depend on the nature of the

conformity assessment and medical devices markets. An uncompetitive conformity assessment market and a large publicly funded program for purchasing medical devices will see a significant part of the burden passed back onto the public sector and the public.

There is potential for the TGA to lose a significant number of staff to third party bodies. This may be up 50-60% of the current skills base, which may affect the ability of the TGA to regulate the market. No published evidence is available from the EU, or elsewhere, on the potential size of the movement of staff from the public to private sector. Moreover, no published evidence is available on whether staff movements have compromised the ability of competent authorities to perform their regulatory functions. Despite the possible magnitude of this movement of staff, the TGA predicts, based on its current experience in regulation, that the remaining level of staffing and skills would be sufficient to effectively perform regulatory functions (TGA, personal communication). Anecdotal evidence from the UK Medical Devices Agency suggests the UK regulator did not experience significant problems from staff losses due to the introduction of the EU model. Under models of regulated competition where higher risk devices are retained by the TGA for conformity assessment the potential drain on TGA may be reduced as the size of the private sector market will be smaller.

Adoption of a model that retains higher risk conformity assessment within the TGA would enhance the ability of the TGA to regulate the market as the TGA will maintain a greater level of expertise in conformity assessment as well as oversight of the market. This may improve the development and quality of conformity assessment in both the public and private sectors in the long term. Maintenance of high levels of expertise would ensure the credibility of the TGA as a strong and effective regulator.

Third party conformity assessment bodies have a potential for conflict of interest between safe-guarding public health and financial viability. A conformity assessment body would be required to perform this regulatory role and compete to supply conformity assessment services to manufacturers. A third party conformity assessment body may therefore have incentives to ensure a favourable outcome for manufacturers that conflict with its regulatory functions.

There is potential for regulatory capture of the TGA under regulated competition. The evidence does not suggest that the creation of independent authority would avoid this problem however, and separation of the roles of the TGA may be inefficient. Firstly, there are no guarantees that an independent authority would be any more or less impartial or subject to regulatory capture than the TGA. Evidence from the use of independent authorities does not provide definitive guidance on this issue and the purported benefits of qangos have been questioned in recent years. Conversely, the TGA has demonstrated its ability to remain neutral in regulating the market. Secondly, an independent authority would be costly to set up, both in terms of time and resources, and it may be more cost-effective to leave those functions within the TGA. There may be an inefficient duplication of skills between the independent authority and the TGA. The regulatory function of the TGA in medical devices has synergies with its regulatory functions in other therapeutic goods. In some cases, therapeutic products are a combination of medical devices and other medical interventions under the jurisdiction of the TGA. A separation of the regulatory body for medical devices may result in increased regulatory costs through difficulties in co-ordinating regulation between the TGA and the independent body. Furthermore, there may be economies of scale and scope in the regulatory function, with synergies in skills, training, and regulatory development between medical devices, pharmaceuticals, and other therapeutic goods.

(iv) Costs and Outcomes from Private Sector Conformity Assessment

Estimates of the potential size of a private sector conformity assessment market are pivotal in determining whether a regulated competition model should be adopted in Australia. The estimates of potential market size are based on EU conformity assessment requirements and the components of EU fees for conformity assessment. They do not include all TGA functions and activities that make up the revenue base of the TGA. Specifically, the estimates exclude functions of the TGA that relate to other regulation and public health activities, including: annual charges for products on the ARTG; manufacturing license charges; and fees for clinical trial notification. These activities are not included as part of conformity assessment under the EU model.

TGA estimates of the costs of conformity assessment indicate that the current size of the conformity assessment market for all classes of devices is between $390,000 and $1,300,000 per year. The market for higher risk devices (Class III/AIMD and IIb) is worth between $136,000 and $725,000 per year, with the market for lower risk devices (Class I and IIa) worth between $254,000 and $571,000 per year. These estimates do not include the potential for exporting conformity assessment services, but the potential market for conformity is nonetheless very modest.

Potential cost savings from regulated competition, using a 9% estimate of reductions in costs, are small. Cost savings are estimated to lie between $22,000 and $117,000 per year. Greater cost savings are estimated for Option A, between $35,000 and $117,000 per year, where all devices may be assessed by third party bodies. Cost savings for Options B and C, where regulated competition is introduced only for certain classes of devices, are estimated to lie between $31,000 and $94,000 per year. The upper bounds for these estimates imply a potential doubling of the medical devices market, a scenario which is unlikely in the short term. Potential cost savings from the introduction of regulated competition will therefore almost certainly be lower than $100,000 per year.

(v) Postal Survey of Key Stakeholders

A postal survey was developed to seek opinion and comment on many of the issues discussed in this report from conformity assessment, medical device industry, government, and consumer bodies. The survey was sent to 186 stakeholders, with 56 responses received (response rate of 32%). Given the sample was not random, and showed a heavy skew towards responses from medical device industry representatives, findings from the survey must be interpreted cautiously. Tentative aggregate findings included:

- Performance of the TGA: the conformity assessment role is performed somewhat better than the regulatory oversight role. The TGA is viewed favourably in both roles, with conformity assessment rated as ‘good’ and regulatory oversight as ‘average’.

- A new model for conformity assessment in Australia: approximately two thirds of respondents thought the EU model would work well in Australia. There was no strong preference between the TGA or an independent authority as the regulator. Almost three-quarters of manufacturers indicated they would use a private sector conformity assessment body. Two thirds would prefer to use an EU body based in Australia.

- Public health risks: the fully privatised model for conformity assessment was seen as having greater risks than either a partially privatised model or a wholly public sector model. Risks were not perceived to be great on average for all models.

- Availability of private sector expertise: a wide range of potential private sector conformity assessment bodies were suggested. Just over a quarter of the sample thought a private sector market would actually be financially viable, with one half of respondents unsure. Three quarters thought private sector expertise was available for low risk products, and almost one half for high risk products.

- Attributes of a good conformity assessment body: just over one half of respondents thought these attributes were more likely to be held in the private sector. However, between 30-40% of respondents thought problems would arise with confidentiality, independence, or impartiality in private sector conformity assessment bodies.

- Prospects for the medical devices industry: on aggregate, responses indicated that prospects were 'average to good' both in the near and more distant future.

Results highlight differing opinion on the merits of the EU model in principle, and its practical translation into the Australian context. On aggregate, it was suggested that the EU model would be good for Australia, manufacturers would use private sector bodies, a wide range of potential sources may exist for private sector expertise, and that expertise is available at least for lower risk devices. On the other hand, the fully privatised model is seen as having greater public health risks and there is significant uncertainty over the financial viability of a private sector market. There is also some doubt over whether there is sufficient expertise available for high risk devices, and there may be problems with respect to confidentiality, independence and impartiality in the private sector. These opinions mirror many of the arguments presented elsewhere in this report.

Findings also indicate a significant divergence in opinion between government/health professionals associations, and industry/university sectors. Government/health professionals view the performance of the TGA more favourably, view prospects for the EU model in Australia less favourably, and place greater emphasis on the TGA as the regulator. Government/health professionals also view the potential financial viability of the private sector and availability of private sector expertise less favourably, and place greater emphasis on potential problems with private sector bodies. These findings suggest a real difference in opinion may exist between groups of stakeholders on a range of key factors. These differences warrant further examination through analysis and more formal evaluation of the performance of the TGA relative to other models of conformity assessment.

4 Conclusions and Recommendations

The Industry Commission Inquiry into the medical and scientific equipment industries (Industry Commission, 1996) endorsed a move to the EU model of conformity assessment in Australia. Recommendations essentially covered two major aspects of conformity assessment:

- the processes used to demonstrate conformity of medical devices; and
- the finance and organisation of the provision of conformity assessment services.

The first of these aspects has already begun to be addressed in Australia. The signing of the EU-Australia Mutual Recognition Agreement has opened up a range of new processes by which manufacturers may demonstrate conformity for devices marketed in the EU. Similarly, moves towards global harmonisation are seeking to extend and develop conformity assessment processes further in collaboration with international industry and government agencies.

This study sought to examine the second of these aspects: the potential for a move to a regulated competition model for the conformity assessment of medical devices in Australia. The findings of our analysis do not support the recommendations of the Industry Commission report for a move to a regulated competition model in Australia.

Examination of the evidence and theory from the literature suggest there are three persuasive a priori reasons why the conformity assessment of higher risk devices should be retained under the jurisdiction of the public sector.

There is a strong public interest argument for the retention of higher risk devices under direct TGA control. Individuals may not view catastrophic risks in the same way as small risks and risks over which they have some control. There is therefore a case for treating products with a potential risk of catastrophic consequences differently to those products with small risks. Even where there is little evidence of a substantial increase in risk to the public, there may be strong opposition to changes in the regulatory structure for devices perceived as having potentially catastrophic health consequences.

By retaining some elements of conformity assessment, the TGA will maintain expertise in conformity assessment. This expertise would enhance the ability of the TGA to regulate the market, improve the development and quality of conformity assessment in both the public and private sectors in the long term, and would ensure a minimum level of training and development of skills and techniques. Furthermore, to be regarded as a strong and effective regulator, the TGA would need highly qualified and experienced staff who understand the conformity assessment task in detail.

It is likely that there will be economies of scale in the conformity assessment of higher risk devices. The specificity of tasks involved, and the relatively small numbers of higher risk devices assessed, particularly for Class III devices, is highly likely to make TGA provision of services more efficient than the private sector.

Recommendation 1

It is therefore recommended that the Therapeutic Goods Administration retain responsibility for the conformity assessment and regulation of high risk devices, in particular Class III devices.

Evidence from the literature on regulated competition reveals significant variation in potential cost savings from regulated competition. The best estimate in health services may be expected to be in the region of 9%, but may be lower in some cases due to the inherent complexity of health service provision. These cost savings are low in comparison to those found under regulated competition in some other industries. This makes the potential size of the conformity assessment market critical in determining whether regulated competition is worth pursuing in the Australian context.

The potential conformity assessment market size was found to be modest for Australia. This reflects the relatively small size of the Australian medical devices industry as a whole, which is approximately 1% of the world market. The potential conformity assessment market size was found to be between $390,000 and $1,300,000 per year. The potential cost savings were therefore found to be very modest, estimated to be between only $22,000 and $117,000 per year. Even allowing the potential size of the private sector conformity assessment market to be presented in a very optimistic light, cost savings would almost certainly be less than $100,000 per year.

Literature based estimates of the value of reduced mortality risk suggest that there would need to be savings in excess of $3,000,000 per year if there was an expectation of one additional death a year as a result of any changes. The potential cost savings are very small in relation to this potential cost. Monetary estimates of the value of reduced morbidity risk are not readily available from the literature. However, if there was an increase in morbidity from one additional adverse event for one individual from the introduction of regulated competition, this may also outweigh any cost savings.

There are a number of potential difficulties and concerns with the implementation of a regulated competition model in Australian conformity assessment. These concerns may result in additional costs and/or reduced quality of services (increased health risks), which would reduce the cost-effectiveness of a regulated competition model. Concerns and difficulties include:

- a lack of consensus on whether private sector expertise will be available for the conformity assessment of medical devices;
- a potentially significant drain on TGA expertise that may lead to some difficulties, at least in the short run, in regulating the market;
- there may be economies of scale in the provision of conformity assessment that the private sector cannot exploit to the same degree as the TGA, or will be used to raise prices under monopoly power; and,

- a third party conformity assessment body may have incentives to ensure a favourable outcome for manufacturers that conflict with its regulatory functions.

These additional factors are difficult, at present, to quantify. However, the overriding and decisive consideration is the trivial magnitude of the potential benefits from regulated competition, and the likelihood that these would be very quickly exceeded by even a modest increase in administrative costs. Loss of scale economies, private sector failure to deliver the product, or increased mortality and/or morbidity would result in a large net loss from the introduction of regulated competition.

Recommendation 2

It is therefore recommended that a regulated competition model for third party conformity assessment should not be adopted at present in Australia..

The Industry Commission recommended the establishment of an independent statutory authority to regulate the market. The main thrust of the argument is that a statutory authority provides greater safeguards against regulatory capture. By investing the responsibilities of the regulator of the market in the hands of a body which is not directly under the influence of either manufacturers or the government, the approach seeks to reduce the possibility of conflicts of interest between the regulator and other key actors. There are two main issues that mitigate against the use of an independent authority in conformity assessment, however.

- First, there are no guarantees that an independent authority would be any more or less impartial or subject to regulatory capture than the TGA. Evidence on the use of independent authorities does not provide definitive guidance on this issue and the purported benefits of QANGOs have been questioned in recent years. Conversely, the TGA has demonstrated its ability to remain neutral in regulating the market.

- Second, an independent authority would be costly to set up, both in terms of time and resources, and it may be more cost-effective to leave those functions within the TGA. There are likely to be economies of scale and scope in the regulatory function, with synergies in skills, training, and regulatory development between medical devices, pharmaceuticals, and other therapeutic goods.

Recommendation 3

It is therefore recommended that the Therapeutic Goods Administration retain its current roles of conformity assessment body and regulator of conformity assessment in Australia and that an independent statutory authority not be created.

The remaining argument for a move to a regulated competition model is to foster the longer term development of a private sector industry in conformity assessment in Australia. If the longer term benefits from regulated competition, in terms of enhanced efficiency and establishing a new industry are large enough, then any short term difficulties in establishing the private sector expertise may be outweighed by the long term gains. Therefore, there is an argument to give the private sector “a chance to prove itself” in the longer term. To assess whether longer term benefits are available, evidence is needed on the performance the EU regulated competition model and on the effects of the EU-Australia Mutual Recognition Agreement and moves towards global harmonisation.

Evidence on the performance of alternative regulatory models is sparse. This perhaps reflects the relative infancy of medical device regulation, and the evaluation of regulatory policy in general. Despite strong endorsement by the Industry Commission (1996) for a move to an EU style conformity assessment model in Australia, the EU reforms have not been evaluated, and their effects remain largely unknown. Caution is warranted in importing solutions from overseas tailored to the cultures and institutional systems of other jurisdictions. The costs and benefits of moving to an alternative system need to be carefully assessed, and desirably, piloted before adoption. The need for such caution is emphasised by the mixed success of moves to competitive tendering, and especially when the quality of the product is difficult to assess.

The long term effects of the Mutual Recognition Agreement and global harmonisation on conformity assessment are not known, limiting the ability to estimate potential trade flows in conformity assessment. Australian conformity assessment bodies may have some potential to export conformity assessment services, particularly to the Asia-Pacific region. Conversely, there is significant potential for Australian manufacturers to import conformity assessment from EU Notified Bodies, especially for the CE marking of devices to be marketed in the EU. Whether Australian conformity assessment bodies would have a significant presence in the world market would depend upon their performance and efficiency relative to overseas conformity assessment bodies.

Without evidence on the performance of the EU model and on the effects of the Mutual Recognition Agreement and global harmonisation, a move to a regulated competition on the basis of fostering a new private sector industry cannot be justified on the grounds of sound empirical analysis. Sound empirical evidence and analysis is vital to ensure potential reforms are capable of delivering their purported benefits. In light of this lack of evidence, the most prudent approach is to gather evidence and information when and where it becomes available, and to use the findings to inform future policy development.

Evidence on the performance of the EU model, and the effects of the Mutual Recognition Agreement and moves towards global harmonisation, should be evaluated in light of the conditions specified above which are necessary for the introduction of regulated competition.

Recommendation 4

It is therefore recommended that the prospects for a regulated competition model for third party conformity assessment be reviewed in the future when there is more evidence on the performance of the EU model; the reasons for its success or failure; the effects of the EU-Australia Mutual Recognition Agreement; and the availability of private sector expertise.

There are a number of ways in which the TGA may realise efficiency gains without the introduction of a regulated competition model. Some of these initiatives have already been implemented with some evidence of reduced costs and improved quality of services. Examples include:

- the implementation of DEAL (electronic application lodging system for medical devices);
- the development of a quality system for conformity assessment; and
- the implementation of the Mutual Recognition Agreement, in particular for increasing efficiency for listable devices covered under the agreement.

There is, however, a lack of rigorous evidence on the costs and benefits of these initiatives to estimate the magnitude of efficiency gains. More rigorous evidence would ideally consist of a formal economic evaluation of changes in practices and policy. Options for economic evaluation include cost-benefit analysis, cost-effectiveness analysis, and program budgeting and marginal analysis. In practice this cost-benefit analysis may prove too resource intensive in its own right, however. An acceptable substitute for cost-benefit analysis may be a cost-effectiveness or program budgeting and marginal analysis study of the impact of initiatives on the costs of delivering services and on the volume and quality of those services.

In addition efficiency gains may be realised through the introduction of competition in adjacent markets. The threat of competition for conformity assessment from EU Notified Bodies may lead to improvements in efficiency in Australia irrespective of what model of regulation is chosen for the future. If the threat of competition from the EU is perceived to be real, this may lead to further initiatives to raise efficiency in the TGA, or risk losing business to the EU. The EU model will provide financial and quality information for benchmarking the performance of current TGA practices. Benchmarking TGA performance, together with sound internal evaluation processes would represent a potentially much more cost-effective method of raising efficiency than regulated competition.

To undertake further initiatives to raise efficiency, and to evaluate those initiatives, accurate and timely information is required. In particular information linking the costs and activity of the TGA broken down by class of devices is vital to improving efficiency. At present it is extremely difficult to estimate the relative size of expenditures and volumes of activity by types of devices in a meaningful way. This type of information is crucial for managing the effective and efficient delivery of conformity assessment services. Furthermore, this type of data should be routinely employed in evaluating initiatives that may have effects on the costs and quality of conformity assessment.

Recommendation 5

It is therefore recommended that the Therapeutic Goods Administration continues to seek efficiency improvements through more cost-effective strategies for reform, and that these strategies be subjected to more formal evaluation, and supported by accurate and timely cost, activity and outcome information.

5 References

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