



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Plain English Guide
In Vitro Diagnostic Medical Devices (IVDs)
as included in the
draft Medical Devices Rule

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1. INTRODUCTION

In vitro diagnostic medical devices (IVDs) fall with the definition of a medical device. Consequently, under the Australian New Zealand Therapeutic Products Authority (the Authority) IVDs will be regulated as a subset of medical devices. The regulatory framework is aligned with the principles of the Global Harmonisation Task Force (GHTF) model.

The key features of the joint regulatory scheme for medical devices are:

- product licensing as the central point of control of supply of medical devices in Australia and New Zealand;
- prescribed essential principles for the quality, safety and performance of the medical device that must be complied with before the product can be supplied;
- device classification schemes based on different levels of risk for each class of device with five classes of medical devices other than IVDs, - Class I, Class IIa, Class IIb, Class III and Active Implantable Medical Device (AIMD); and four classes of IVDs, Class 1 IVD, Class 2 IVD, Class 3 IVD, and Class 4 IVD;
- a choice of procedures that can be employed by manufacturers to demonstrate initial compliance and on-going compliance with the essential principles. These procedures may include obligations on manufacturers for quality systems, type testing, and/or design examination depending on risk class of the device;
- the use of recognised standards to satisfy the requirements of the essential principles;
- a comprehensive post market surveillance including compliance testing and adverse event reporting and appropriate regulatory controls for the manufacturing processes of medical devices; and
- mechanisms of access to unlicensed devices.

Due to the unique nature of IVDs there will be several points of difference to other medical devices in the manner in which IVDs will be regulated. For example, IVDs will have their own classification system (IVD classification rules), there are some IVD specific essential principles and not all the conformity assessment procedures will apply to IVDs .

2. DEFINITIONS

Under the joint agency, a ***medical device*** is:

any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, including any diagnostic goods for *in vitro* use, intended by the person under whose name it is or is to be supplied, to be used alone or in combination, for human beings for the specific purpose for one or more of the following:

- i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
- ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
- iv. supporting or sustaining life;
- v. control of conception;

- vi. disinfection of medical devices;
- vii. providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;
- viii. and that does not achieve its principal intended action in or on the human body by pharmacological, chemical, immunological or metabolic means, but that may be assisted in its function by such means.

It should be noted that an accessory to such an instrument, apparatus, appliance, material or other article, whilst not being a medical device, will be regulated as a medical device.

An ***in vitro* diagnostic medical device or IVD** is considered to be:

a reagent, calibrator, control material, kit, specimen receptacles, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for *in vitro* use; and is intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for:

- (i) giving information about a physiological or pathological state or a congenital abnormality; or
- (ii) determining safety and compatibility with a potential recipient; or
- (iii) monitoring therapeutic measures.

This definition does not apply to a product intended for general laboratory use that is not manufactured, sold or presented for use as an IVD.

The ***manufacturer*** of a medical device is the person who accepts responsibility for the design, production, packaging and labelling of the device before it is supplied under the person's name.

A manufacturer of a medical device, may also be the person, who, with a view to supplying the device in their name, performs one or more of the following actions using ready-made products - assembles, packages, undertakes refurbishment of the device, processes the device, labels the device or assigns the device its purpose by means of information supplied.

However, a person is not taken to be the manufacturer of a medical device if the device is a customised medical device where the person assembles or adapts the device for an individual patient, the device has already been supplied and the assembly and adaptation is in accordance with the intended purpose of the device.

3. ESSENTIAL PRINCIPLES AND MEDICAL DEVICE STANDARDS

All medical devices are required to comply with the essential principles, which set out requirements relating to safety and performance characteristics of medical devices.

The essential principles are about identifying and mitigating risk and ensuring that devices are safe and perform as intended. They do not inherently specify how the principles can be satisfied or complied with. A principles-based set of requirements accounts for technological advances and changes in the application of medical devices.

There are three groups of essential principles:

1. General Principles, which apply to all medical devices:

- the use of a medical device must not compromise health and safety when used as intended and the residual risks of the device must not outweigh the benefits;

- the design and construction of a medical device have to conform with generally acknowledged safety principles;
- medical devices are to be suitable for the intended purpose;
- long term safety;
- medical devices are not adversely affected by transport or storage; and
- the benefits are to outweigh any side effects.

2. Particular Principles about Design and Construction:

- chemical, physical and biological properties;
- infection and microbial contamination;
- construction and environmental properties;
- medical devices with a measuring function;
- protection against radiation;
- medical devices connected to or equipped with an energy source;
- information to be provided with medical devices (labelling, instructions for use and advertising material); and
- clinical evidence.

3. Particular Principles for IVDs:

- analytical and clinical characteristics support intended use;
- traceability of values for controls and calibrators;
- variation in user technique and environment;
- information and instructions easy to understand;
- risk of error of device, specimen and results interpretation;
- quality control provisions.

The application of the particular principles will depend on the intended purpose and technology used in the medical device.

Both the general principles and the relevant particular principles must be considered, and if applicable, complied with, in order for a medical device to be considered to comply with the essential principles.

Medical Device Standards

Medical device standards orders for products and conformity assessment standards orders for manufacturing or quality management system processes may be determined by the Authority. Compliance with applicable medical device standards are not mandatory, but it is one way to establish compliance with essential principles. Other ways, including other relevant standards, may be used to demonstrate compliance with the essential principles.

To claim compliance with a medical device standard or a conformity assessment standard, the device must fall within the scope of the standard and the requirements of the standard must be explicitly applied.

Standards orders will usually reference international or Australian or New Zealand standards that were originally developed for voluntary use or as regulatory standards. Clauses of these standards may demonstrate compliance with one or more of the essential principles or one or more aspects of the conformity assessment procedures. It is equally possible that several clauses of a standard or multiple standards are required to demonstrate compliance with one essential principle or one aspect of a conformity assessment procedure. The relationship between clauses and essential principles and aspects of conformity assessment procedures will be set out in the Orders themselves. If a manufacturer chooses to use a medical device standard or conformity assessment standard, compliance cannot be claimed if relevant aspects of the clause or clauses have been ignored, or methods or requirements of a clause have been modified.

The requirements of a more specific standard will take precedence over a more general standard.

4. CONFORMITY ASSESSMENT PROCEDURES

‘Conformity assessment procedure’ is the term used to define the pre-market process that a manufacturer follows in order to demonstrate compliance with regulatory requirements. Conformity assessment procedures are obligations on the manufacturer. Depending on the procedure chosen, assessment of the final design, the controls implemented for production and the manufacturer’s courses of action may have to be assessed by the Authority or another acceptable conformity assessment body through arrangements with overseas regulators. In essence, the application of a conformity assessment procedure required for a medical device is commensurate with the level and nature of risk posed by the medical device to the patient or user. This ranges from manufacturer self-assessment, for the lowest risk medical devices, through to a full quality management system and product design dossier review, for conformity with the essential principles for the highest risk devices.

The following two conformity assessment procedures cannot be applied to an IVD:

- Part 4 Verification procedures; and
- Part 6 Product quality control procedures.

The Authority may, as part of a design dossier review, undertake performance testing of IVDs.

The common elements in most of the conformity assessment procedures are:

- Quality management system certification
Manufacturers of devices must define, implement and ensure effective controls on the manufacturing processes and have those controls assessed by the Authority. As compliance with the essential principles must be an objective of the application of the manufacturing controls they must be integrated into the quality management system or manufacturing process. Conformity assessment procedures implemented by the manufacturer of all but class I medical devices and Class 1 IVDs, are assessable by the Authority.

- Quality management system certification surveillance audits

Quality management system certification only remains valid when it is periodically inspected. A re- inspection audit is referred to as a surveillance audit. The audits ensure that the manufacturer is continuing to apply the approved quality system or manufacturing process to existing product and to any new product introduced since the previous surveillance or certification audit. A program of surveillance audits will be established for all manufacturers issued with quality management systems certification.

- Post-market monitoring system

A manufacturer must implement and maintain a post-market monitoring system to seek and assess information concerning the performance of devices after supply. Any reportable events must be conveyed to the Authority, either directly from the manufacturer or through the Australian or New Zealand sponsor.

When a conformity assessment procedure requires a quality management system the post production monitoring must be implemented as part of that system.

As part of the conformity assessment procedures, the manufacturer of a medical device will be required to make a declaration of conformity which, in most cases, declares that the medical device complies with:

- the applicable provisions of the essential principles;
- the classification rules; and
- the conformity assessment procedures;

before being supplied in Australia or New Zealand.

The declaration also requires the manufacturer to provide:

- their name and address;
- details of the:
 - scope of devices covered by the declaration (including product identification information);
 - quality management certification;
 - device classification;
 - device nomenclature code;
 - conformity assessment standards (quality management system standards);
 - medical device standards (product standards); and
 - other standards used to show conformity with the essential principles or elements of the conformity assessment procedures
- relevant conformity assessment procedure and the manufacture of the medical device covered by the declaration.

Special conformity assessment procedures apply to medical devices that have a special purpose, such as those that are exempt from a product licence (but not from the essential principles or conformity assessment procedures), intended for special and experimental use,

or custom-made devices for a medical practitioner, custom-made or customized devices for a specific patient.

a) Classification of Medical Devices

The classification of a medical device determines the conformity assessment procedure(s) a manufacturer can choose to ensure that the device is adequately assessed to conform to the particular requirements for the class of device. Higher-class devices will undergo a more stringent form of conformity assessment than lower class devices. Certification by the Authority or a designated notified body is required for higher risk devices.

Medical devices will be classified by the manufacturer according to the intended purpose of the medical device and the degree of risk involved to the patient, the public and the user.

The benefits of a rules-based classification system include:

- the immediate ability to deal with devices incorporating new technologies; and
- increased transparency, accountability and consistency in the regulation of medical devices in that all devices are subject to a level of scrutiny commensurate with their risks to individual and public health.

Classification of Medical Devices other than IVDs

The device classification will be determined using a set of rules which take into account the level of invasiveness in the human body, duration and location of use and whether the device is powered or not.

The five classifications of medical devices are those used in Australia and also in Europe and are based on the recommendations of the Global Harmonisation Task Force:

- Class I (low risk);
- Class IIa (low-medium risk);
- Class IIb (medium-high risk);
- Class III (high risk); and
- Active Implantable Medical Devices (AIMD; high risk).

The classification may change depending on the site of use, the addition of a medicinal component, or the intended purpose specified by the manufacturer.

Classification of IVDs

A separate classification system exists for IVDs to account for the special nature of this group of medical devices. The classification rules take into account the use of IVDs in establishing disease status, patient management, monitoring substances (including medicines), genetic screening and diagnosis, cell and tissue typing, and pregnancy and fertility testing.

The rules and the classes are aligned with the recommendations of the Global Harmonisation Task Force. The four risk classifications of IVDs are:

- Class 1 IVDs (low personal risk);
- Class 2 IVDs (low public health risk, moderate personal risk);
- Class 3 IVDs (moderate public health risk, high personal risk);

- Class 4 IVDs (high public health risk);

b) Conformity Assessment Standards

Conformity assessment standards may be determined by the Managing Director and set out in Orders. Compliance with applicable conformity assessment standards is not mandatory, but it is one way to establish that one or more parts of the conformity assessment procedures have been applied to medical devices.

5. ISSUING OF CONFORMITY ASSESSMENT CERTIFICATES

The Managing Director can issue a conformity assessment certificate in respect of a manufacturer of medical devices, signifying one or more of the following:

- that relevant quality management systems and manufacturing processes required by the conformity assessment procedures have been applied to the manufacture of the device;
- compliance with the essential principles for the device have been demonstrated; or
- compliance with other requirements of the conformity assessment procedures have been met.

A conformity assessment certificate may be required before a valid application can be made for a product licence for a kind of medical device.

A conformity assessment certificate issued by the Authority is required for:

- a manufacturer who manufactures medical devices in Australia and/or New Zealand; and
- medical devices manufactured outside Australia and/or New Zealand of the following kinds:
 - medical devices other than IVDs, that contain or are manufactured using cells, tissues or tissue derivatives of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only);
 - medical devices other than IVDs, that contain or are manufactured using cells, tissues or derivatives of microbial or recombinant origin and are intended for use in or on the human body;
 - medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;
 - medical devices that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on the patient in a way ancillary to the device.
- Class 4 IVDs

Conformity assessment certificates are not required for:

1. any of the following:
 - a Class I medical device that is not intended to be supplied in a sterile state or that does not have a measuring function;

- a Class 1 IVD
 - an exempt device
 - a device that is exempt for special or experimental uses
 - a device that is the subject of an exemption for a medical practitioner
 - a system or procedure pack, where all relevant conformity assessment procedures have been applied to the device/s and medicines or other therapeutic products are licensed
 - custom made medical devices, or
2. a manufacturer of a medical device of a kind mentioned in item 1, above.

When an application has been made for a conformity assessment certificate the decision to issue the certificate will depend on several factors:

- whether the application procedures have been followed;
- the application and satisfactory assessment of quality management systems, where required;
- satisfactory demonstration of compliance with the essential principles;

The Managing Director may, by written notice, require the applicant to

- provide further information related to the application within the specified time frame,
- provide samples of the device undergoing assessment. For specific Class 4 IVD's, performance testing by the Authority will be required as part of the design dossier review.
- allow an authorised person to inspect:
- the premises (including premises outside Australia or New Zealand) and equipment, processes and facilities that are being or will be used to manufacture medical devices of the kind in question; and
- any other kinds of therapeutic products being supplied in Australia or New Zealand on those premises.

After making a decision, the Managing Director must notify the applicant in writing and:

- if the decision is not to issue the certificate, state in the notice the reasons for the decision; or
- if the decision is to issue the certificate and all assessment fees that are due have been paid, issue the certificate to the manufacturer.

A conformity assessment certificate must specify whether it covers all medical devices manufactured by the manufacturer or only specified medical devices.

The conformity assessment certificate commences on the day specified on the certificate.

An application for a conformity assessment certificate lapses if the applicant:

- does not provide information required for the certificate to be issued;
- does not provide, if requested, a reasonable number of samples of the kind of medical device to which the application relates;
- the applicant fails to provide information relating to a kind of medical device to which the application relates within 10 working days of the day specified in a notice from the Managing Director;
- information provided by the applicant in relation to the application is false or misleading;
- the applicant fails to allow an authorised person to carry out an audit; or
- the applicant fails to pay an assessment fee for the application within the specified period, after being notified of the decision to issue a conformity assessment certificate.

The applicant for a conformity assessment certificate may give the Managing Director written notice that the applicant wishes to treat the application as having been refused if the applicant has not been notified of a decision within a prescribed period. In which case it is considered that the Managing Director had decided not to issue the certificate.

a) Statutory Timeframes for Conformity Assessment Certification Applications

At commencement of the joint scheme, statutory timeframes will apply to conformity assessment applications for Class III or AIMD medical devices.

After the application is accepted for assessment, a decision to grant or to refuse a conformity assessment certificate will be made within 255 working days of receipt of the application.

The penalty to the Authority for not completing applications within statutory timeframes will be the forfeit of 25% of the application fee to the applicant.

Assessment timeframes and associated penalties will be applied to individual applications rather than to overall performance of the Authority.

b) Conditions on a Conformity Assessment Certificate

When a conformity assessment certificate is issued to a manufacturer of a medical device by the Authority, conditions will be imposed on the certificate. Breaching any of these conditions may lead to the suspension or revocation of the certificate.

The following standard conditions will be imposed automatically when a conformity assessment certificate is issued:

- Entry and audit powers

The manufacturer will allow an authorised person to:

- enter premises, at any reasonable time, including premises outside Australia or New Zealand, at which the manufacturer, or any other person deals with the medical devices covered by the certificate; and

- inspect those premises and the equipment, processes and facilities used to manufacture the medical devices, and to take samples of the devices; and
- to see and copy any requested documents relating to the medical device, compliance with the Essential Principles or the manufacturer's quality management system.

- **Review**

The manufacturer will cooperate with any review by the Authority of the application of quality management systems, the compliance with the essential principles and any other conformity assessment procedures specified in the Rules, relating to the certificate.

- **Notification of substantial changes**

The manufacturer will notify the Authority, in writing, of any plan for substantial changes to the:

- quality management systems; or
- product range; or
- the product design

- **Fees**

Any prescribed fees for a review of a conformity assessment certificate will be paid when they are due.

Additionally, the Managing Director may impose special conditions on a conformity assessment certificate at the time it is issued or subsequently and may also vary or remove existing conditions.

Additional conditions, imposed on a conformity assessment certificate issued by the Authority, may include:

- conditions on the medical devices covered by the certificate; or
- conditions on the manufacturer's quality management system; or
- new conditions at the request of the manufacturer or the Authority; or
- varying or removing existing conditions, at the request of the manufacturer or the Authority, if the medical benefits do not outweigh the residual risk/s of death, serious illness or serious injury, as determined by the application of current risk analysis and assessment procedures, at the request of the manufacturer or the Authority.

c) Revocation or Suspension of a Conformity Assessment Certificate

The Managing Director may revoke a conformity assessment certificate or suspend a certificate for a period of time. In certain circumstances, a conformity assessment certificate can be revoked with immediate effect.

(i) Automatic Revocation

The Managing Director must revoke a conformity assessment certificate if the conformity assessment certificate has been suspended and the period applying to the suspension expires before the suspension is revoked.

(ii) Revocation with Immediate Effect

In certain circumstances, the Managing Director may revoke a conformity assessment certificate with immediate effect, in which case the sponsor must immediately cease import, supply or export of the product. In certain circumstances, the product may also be recalled.

The Managing Director may revoke (with immediate effect) a conformity assessment certificate for a medical device if the manufacturer requests in writing the revocation of the conformity assessment certificate.

(iii) Revocation after Notice of Proposal to Revoke

If the Managing Director decides that a conformity assessment certificate should be revoked and the legislation does not provide for the certificate to be revoked with immediate effect, the Managing Director must advise the manufacturer of the intention to revoke the certificate and give the manufacturer the opportunity to respond to the proposed action.

The Managing Director may revoke a conformity assessment certificate for a medical device if:

- The conformity assessment procedures have not been applied to medical devices of a kind to which the certificate applies;
- The certificate holder refuses or fails to comply with a condition to which the certificate is subject;
- The Managing Director has given the manufacturer of the kind of medical device a notice requesting information or documents relating to that kind of medical device or a quality management system to which the certificate applies and the manufacturer fails to comply with the notice within 10 working days of the day specified in the notice;
- The manufacturer in respect of whom the certificate is issued no longer manufactures any of the kinds of medical devices to which the certificate applies;
- The manufacturer is not a fit and proper person to hold a conformity assessment certificate;
- A person who is participating in managing the manufacturer's affairs is not a fit or proper person to participate in managing the affairs of a manufacturer in respect of whom a conformity assessment certificate is issued; or
- A person who has effective control over a manufacturer is not a fit or proper person to have effective control over a manufacturer in respect of whom a conformity assessment certificate is issued.

In these circumstances, before making a decision on a proposal to revoke a conformity assessment certificate, the Managing Director must:

- inform the manufacturer in writing of the intention to revoke the certificate and set out the reasons for such an action; and
- give the manufacturer reasonable opportunity to make submissions in response to the proposed action; and
- consider submissions made by the manufacturer in relation to the proposed action.

(iv) Limiting Revocation to Some Kinds of Medical Devices

The Managing Director may limit the revocation of conformity assessment certificates to some kinds of medical device, or some medical devices of the kinds, to which the certificate applies.

If the revocation is limited, the Managing Director must vary the certificate so that it no longer applies to the medical devices revoked.

(v) Date of Effect of Revocation of Conformity Assessment Certificates

The revocation of a conformity assessment certificate, or variation of a conformity assessment certificate in cases of limited revocation, has effect:

- where revocation or variation is immediate, from the day on which the notice of revocation or variation is given to the manufacturer in relation to whom the certificate is issued; or
- where specified in the notice.

(vi) Suspension

Suspension of a conformity assessment certificate leads to suspension of product licences for the kinds of medical devices to which the certificate applied, pending provision of additional information by the manufacturer to enable the Managing Director to determine whether or not the conformity assessment certificate should remain valid or be revoked.

The suspension may be limited to some medical devices of that kind.

The Managing Director may suspend a conformity assessment certificate for a medical device if the Managing Director is satisfied that there are grounds for revoking the certificate.

The Managing Director may suspend (with immediate effect) a conformity assessment certificate for a medical device if the Managing Director is satisfied that the suspension is necessary as the medical benefits do not outweigh the residual risk/s of death, serious illness or serious injury.

The Managing Director must notify the sponsor in writing if he/she decides to suspend a conformity assessment certificate.

Before suspending a conformity assessment certificate because it is likely there are grounds for revoking the certificate, and if the Managing Director would be required to give notice of an intention to revoke the certificate, then he/she must:

- inform the manufacturer in writing of the intention to suspend the certificate and set out the reasons for such an action; and
- give the manufacturer reasonable opportunity to make submissions in relation to the proposed action; and
- consider submissions made by the manufacturer in relation to the proposed action.

Where the suspension is necessary as the medical benefits do not outweigh the residual risk/s of death, serious illness or serious injury, the notice takes effect on the day on which the notice is given. In all other circumstances, suspension of a conformity assessment certificate is to take effect no earlier than 20 working days after the day on which the notice was given.

The period of suspension must not exceed 6 months. The period of suspension may be extended by up to an additional 6 months if the manufacturer is able to show that he/she has taken steps to remove the grounds for suspending the certificate. The period of suspension cannot be extended a second time (i.e. it cannot be extended beyond two suspension periods, to a maximum of twelve months).

The suspension has effect until:

- it is revoked by the Managing Director; or
- the end of the suspension period specified in the notice; or
- if the period of suspension was extended by the Managing Director, the end of the extension period.

The Managing Director may revoke a conformity assessment certificate suspension:

- on his/her own initiative; or
- if the manufacturer in relation to whom the conformity assessment certificate was issued or the person who applied for the certificate (if not the manufacturer) applies in writing to the Managing Director.

The Managing Director must revoke the suspension if satisfied that:

- the ground on which the conformity assessment certificate was suspended no longer applies; and
- there are no other grounds for suspending the conformity assessment certificate.

If the Managing Director revokes a suspension, he/she must advise the manufacturer in writing within 20 working days after making the decision to revoke the suspension.

If, after an application by the manufacturer, or the person who applied for the certificate if not the manufacturer, the Managing Director decides not to revoke the suspension, he/she must advise the person in writing of his/her decision, giving reasons for the decision, within 20 working days of the decision being made.

d) Validity of a Conformity Assessment Certificate

Once issued, a conformity assessment certificate will remain valid for five years after the date of issue. At the end of this period, it will be re-issued for a further five years based on satisfactory compliance and audit history.

The manufacturer must ensure that the manufacturer data profile including the declarations required for fit and proper person are accurate and up to date at the time of each interim surveillance audit.

All declarations must be in a form approved by the Managing Director.

The Managing Director may vary the terms of a conformity assessment certificate, as a result of his/her consideration of the renewal application or as a consequence of an audit.

The Managing Director may refuse to renew a conformity assessment certificate, if the manufacturer fails to provide, or refuses to provide, adequate declarations.

The Authority may revoke a conformity assessment certificate at any time if the manufacturer provides false information or makes false declarations.

6. ISSUING OF PRODUCT LICENCES

a) The Product Licence

A medical device may only be

- imported into Australia or New Zealand; or
- exported to a third country from Australia or New Zealand; or
- supplied in Australia or New Zealand

by, or with the written approval of, the holder of a product licence (the sponsor) issued by the Managing Director of the Authority, unless specifically exempted.

The *sponsor* of a medical device is a person who imports, or arranges the import of, the product; or who exports, or arranges the export of, the product; or who, in Australia or New Zealand, manufactures the product, or arranges for another person to manufacture the product, for supply (whether in Australia, New Zealand or elsewhere). A sponsor does not include a person who imports, exports or manufactures the product; or arranges the importation, export or manufacture of the product; on behalf of another person who, at the time of the importation, export, manufacture or arrangements, is a resident of, or is carrying on business in, Australia or New Zealand.

A sponsor intending only to export a medical device from Australia and/or New Zealand to a third country may obtain a special type of product licence, an ‘export only product licence’.

A product licence will be granted on the basis of an application submitted to the Authority, including certifications made by the sponsor, a copy of the manufacturer’s declaration of conformity and, in most cases, a conformity assessment certification.

To maintain a product licence, a sponsor must ensure that the manufacturer continues to meet the obligations placed upon him by the legislation and hence that the certifications made by the sponsor at the time of application remain true. Any significant changes by the manufacturer to any of the information upon which the conformity assessment certification was issued must be subject to further assessment and approval. In many cases this will not affect the validity of the product licence if the manufacturer has met their obligations. Any change to a detail recorded on the product licence must also be the subject of an additional application and approval by the Authority.

A register of product licences will be maintained by the Authority.

Generally, a product licence will be a dual-country licence, i.e. it will permit the import into, export from and supply in both Australia and New Zealand of the medical device that is the subject of the product licence. The only exceptions will be:

- single country licence, which will be issued only in those exceptional circumstances where one country has decided to depart from the joint regulatory scheme in relation to a particular therapeutic product or type of product or where the Authority deems such a restriction necessary; and
- export only licence, which will be issued if the sponsor intends only to export a product from Australia and/or New Zealand to a third country.

The product licence document will provide a summary of the particulars of the product(s) that is/are the subject of the licence and set out or refer to the conditions, subject to which the licence has been granted. The product licence will include:

- the date of its commencement;
- the licence number for the kind of medical device;
- particulars about:
 - the licence holder;
 - the manufacturer;
 - the device nomenclature code;
 - the medical device classification;
 - in the case of Class III medical device, a Class AIMD medical device or a Class 4 IVD – the unique product identifier;
 - the intended use of the kind of medical device;
 - the country, or countries, in which the licence has effect;
 - the conditions subject to which the licence is granted;
 - other information, if any, that may be relevant to the issuing of the licence.

(i) Product Licence Identifier

When the Managing Director issues a product licence for a medical device, a unique licence identifier is to be assigned.

When the Managing Director groups multiple medical devices on a product licence, a single, unique product licence identifier is to be assigned to the group.

(ii) Provisional Product Licence

In exceptional circumstances, and in consultation with the applicant, the Managing Director may issue a provisional product licence for a medical device for a time-limited period subject to conditions and further assessment of the medical device prior to completion of the provisional authorisation period.

A provisional product licence may be issued where there is insufficient clinical evidence available substantiating conformity with the essential principles but the Authority considers that there is a clinical need for the medical device to be available such as the prevention or treatment of a life-threatening disease or condition, and the medical device offers a likely superior therapeutic benefits to patients over existing treatments. This allows limited access to a medical device where the potential benefit is considered greater than the risk of non-treatment.

The Managing Director will be able to impose conditions on a provisional product licence including that:

- (a) the licence holder must continue to obtain clinical evidence to substantiate conformity with the essential principles and provide evidence on at least an annual basis;
- (b) restrictions can be placed on the use of the devices to certain persons, such as medical practitioners and/or certain target patient populations;
- (c) the licence holder is responsible for ensuring that these restrictions are adhered to as a condition of licensing;
- (d) the licence holders must also ensure that any advertising or promotion of the medical device is in compliance with the Rules and has written approval of the Authority.

A provisional product licence would be granted for an initial period of two years, during which time the licence holder of the medical device must submit data to the Authority to support their application for a full product licence. The provisional licence holder will need to provide a periodic report to the Authority on the progress in obtaining this data. It will be possible to extend the period of validity for a period of no more than two years. If the required data are not submitted within the two-year extension period, the provisional product licence will lapse and the medical device will no longer be able to be supplied.

The provisional product licence may be revoked at any time if a post-marketing clinical study fails to verify clinical benefit or post-marketing restrictions are inadequate to assure safe use of the medical device.

Assessment of the additional data required to support the granting of a full product licence will incur an additional assessment fee.

(iii) Kind of medical device

Generally, a separate product licence will be issued for each new kind of medical device. The circumstances in which a medical device is a new kind of medical device will depend on the type of device, its classification and the nature of the difference or change.

Medical devices are taken to be of the same kind if they:

- have the same sponsor;
- have the same manufacturer;

- have the same device nomenclature system code¹;
- have the same medical device classification; and
- are the same in any other characteristics necessary to identify the device and any variants.

b) Obtaining a Product Licence

Before a person can supply a medical device in Australia and/or New Zealand they are required to make an application for a product licence, unless the device is exempted from this requirement.

To obtain a product licence for a new medical device, the sponsor will be required to submit an application to the Authority, in a format approved by the Managing Director and accompanied by the prescribed fee. A sponsor must have a presence in Australia or New Zealand and the resources to implement post-market requirements in relation to the product.

In making an application for a product licence, the applicant must certify that:

- the manufacturer has determined that the devices of the kind concerned are medical devices;
- the device is intended for a purpose specified by the manufacturer;
- the device has been correctly classified by the manufacturer in accordance with the relevant classification rules;
- the device has been declared to conform with the essential principles, and the sponsor is either in possession of sufficient information to substantiate compliance with the essential principles or has procedures in place to ensure that the information can be obtained from the manufacturer within the prescribed timeframe;
- an appropriate conformity assessment procedure has been applied to the device and the sponsor is either in possession of sufficient information to substantiate the manufacturer's declaration of conformity with the essential principles or has procedures in place to ensure that the information can be obtained within the prescribed time;
- the advertising material relating to the device complies with all applicable requirements;
- the device does not contain any substances that are a prohibited import for the purposes of the *Customs Act 1901* (Cth) and the *Customs and Excise Act 1999* (NZ);
- the information included in or with the application is complete and correct;
- the applicant is a resident of or carries on business in, Australia or New Zealand.

In most cases, the manufacturer of a medical device will be required to hold a conformity assessment certificate. The certificate and the manufacturer's declaration of conformity will need to be presented as part of the application process for a product licence.

¹ Global Medical Device Nomenclature (GMDN) codes are used for grouping procedures. The GMDN is a collection of internationally recognised terms to accurately describe and catalogue medical devices, providing generic device descriptors and for the purposes of data exchange, vigilance activities and commercial identification.

A product licence for a medical device will usually be issued automatically once an effective application is submitted with the required certifications and declarations. However, applications may be selected for an application audit and, in the case of IVDs, for a technical file review, by the Authority. This involves the Authority checking some or all aspects of the application and certification.

If the application is an effective application (i.e. is made in accordance with an approved format and complies with the requirements in relation to certifications) and is not selected for audit or technical file review, the Managing Director will issue a product licence for the device.

If the application is successful, conditions will then be imposed on the licence holder, for example to allow an authorised person to enter premises at any reasonable time to inspect premises and take samples of device products.

Penalties may be imposed if the product licence conditions are breached.

If the application is selected for auditing, the Managing Director may consider all or some aspects of when making a decision to issue or to refuse a product licence:

- whether the application is a proper application; and
- whether the certifications made by the Sponsor are correct.

(i) Priority Assessment

The Authority may give priority to the assessment of product licence applications with respect to a new medical device that is intended for the treatment or diagnosis of a serious, life-threatening or severely debilitating disease or condition.

Priority will only be given if the treatment potentially offers a major benefit over currently available treatments or diagnoses.

For an application to receive priority status, the sponsor will be required to make a commitment to give priority to providing information to the Authority. Failure of the sponsor to respond adequately to questions within agreed timeframes may result in loss of priority status.

The circumstances in which priority status can be granted and the timeframes to apply will be outlined in guidelines.

c) Conditions on a Product Licence

Conditions may be imposed on product licences for medical devices. These will be appropriate to ensure that the relevant requirements continue to be met throughout the life of the product. The product licence cannot be used to impose any conditions relating to the price of the product.

(i) Standard Conditions

The legislation will set out conditions that will apply to all licensed medical devices or to specified types and/or classes of medical devices.

Standard conditions relating to entry and audit powers, delivery of samples, availability of information and advertising material will apply to all licensed medical devices and require the sponsor to:

- allow an authorised person from the Authority to enter, at any reasonable time, any premises, including premises outside Australia and New Zealand, at which that person, or any other person deals with the medical devices. This is required so that the authorised person can inspect the premises and medical devices and to take samples. If requested by the authorised person the sponsor will also need to produce any documents relating to the medical device and to allow the documents to be copied by the authorised person;
- if requested to do so by the Managing Director, supply a reasonable number of samples of a medical device for testing purposes, together with any other materials reasonably considered necessary to allow testing to be performed. The samples are to be appropriate for the proposed testing purpose, supplied at the sponsor's expense and delivered to the Authority within the period specified within the request and in accordance with any other requirements specified in the request;
- have sufficient information to substantiate compliance with the essential principles and give this information to the Authority, if requested, or has procedures in place to ensure that the information can be obtained from the manufacturer;
- have possession of sufficient information to substantiate that the conformity assessment procedures have been applied to the medical device and give this information to the Authority, if requested;
- have possession of relevant information relating to any changes to the medical device including the product range, the quality management system, or manufacturing processes or the manufacturer of the medical device and give this information to the Authority, if requested;
- give information to the Authority about any malfunction or deterioration in the characteristics or performance of the medical device or any inadequacy in the design, manufacture, labelling of the device, instructions for use or advertising materials for the medical device, or any use in accordance with, or contrary to, the use intended by the manufacturer that:
 - led to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 10 working days after becoming aware of the event or occurrence, or
 - led to a serious threat to public health, within 48 hours of becoming aware of the event, or
 - that might lead to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 30 working days of becoming aware of the event;
- give information to the Authority to confirm whether or not a medical device complies with essential principles;
- give information to the Authority to confirm whether or not a certificate that certifies compliance with the essential principles or the application of relevant conformity assessment procedures, and which was issued by a body other than the Authority and was used to support an application for a product licence, has been restricted, suspended, revoked or is no longer valid;

- give the manufacturer of the medical device information relevant to the manufacturer's obligations under the conformity assessment procedures, especially the requirements for post-market monitoring, and whether the medical device complies with the essential principles; and
- ensure advertising material used is consistent with the intended purpose for the medical device.

(ii) Specific Conditions

In addition to the standard conditions, the Managing Director may impose specific conditions as part of the decision to issue a product licence.

Conditions may relate to:

- the manufacture of the product;
- the custody, intended purpose, supply, disposal or destruction of the product;
- the keeping of records relating to the product, including records relating to the tracking and location of the devices after their supply;
- matters dealt with in the essential principles;
- other matters relating to the product that the Managing Director thinks appropriate.

The Managing Director may also, by a notice given in writing, impose specific conditions on an existing product licence or vary or remove existing conditions. If the imposition or variation of the condition is necessary to prevent imminent risk of death, serious illness or serious injury, it will have immediate effect. In any other case, it will take effect no earlier than 20 working days after notice is given to the sponsor.

d) Product Licence Variations

The Managing Director will be able to vary the terms of a product licence. The legislation will set out the circumstances in which a change to a medical device results in a new kind of medical device. Other changes will be treated as product licence variations.

The Managing Director may vary the terms of the product licence, following a request by the holder of the product licence or at his/her own initiative, if the particulars on a product licence are incomplete or incorrect. If the only effect is a change in the intended purpose the Authority may vary the licence in accordance with the request.

The sponsor of a medical device must apply for variation of a product licence if the sponsor becomes aware that previous certifications are now known to be false, or they do not possess information required to be held.

e) Suspension and Revocation of Product Licences

The Managing Director may suspend or revoke a product licence in the event that the sponsor fails to comply with relevant regulatory requirements, including the product licence conditions, or the Authority receives new information on the safety, quality or performance

of a medical device, which makes such an action necessary. In certain circumstances, a product licence can be revoked with immediate effect.

(i) Automatic Revocation

The Managing Director must revoke a product licence if:

- (1) the product licence has been suspended and the period applying to the suspension expires before the suspension is revoked; or
- (2) a conformity assessment certificate applying to that kind of device is revoked.

(ii) Revocation with Immediate Effect

In certain circumstances, the Managing Director may revoke a product licence with immediate effect, in which case the sponsor must immediately cease import, supply or export of the product. In certain circumstances, the product may also be recalled.

The Managing Director may revoke (with immediate effect) a product licence for a medical device if:

- (1) satisfied that there would be an imminent risk of death, serious illness or serious injury if the devices that are the subject of the licence continue to be available for supply or export;
- (2) devices of that kind are no longer therapeutic products;
- (3) devices of that kind are no longer medical devices;
- (4) devices of that kind become exempt devices;
- (5) the sponsor requests in writing the revocation of the product licence;
- (6) the Managing Director is satisfied that a statement made in or in connection with the product licence application or related certifications was false or misleading;
- (7) the annual charge for the product licence is not paid within 20 working days after it becomes payable;
- (8) the sponsor does not comply with a direction or requirement made under the Advertising Rule in relation to advertising; or
- (9) there is a serious breach, involving the kind of device, of the advertising requirements applicable under the legislation and the Managing Director is satisfied that the breach is significant and that, as a result of the breach, the presentation of devices of that kind is misleading to a significant extent;
- (10) the sponsor fails to comply (within 10 working days) with a request for information or documents made by the Managing Director for the purpose of ascertaining whether medical devices of that kind should have been licensed; or
- (11) the sponsor fails to comply (within 10 working days) with a request for information or documents made by the Managing Director for the purpose of ascertaining whether medical devices of that kind are being supplied, imported or exported from Australia or New Zealand.

The Managing Director must notify the sponsor in writing of a decision to revoke a product licence with immediate effect.

(iii) Revocation after Notice of Proposal to Revoke

If the Managing Director decides that a product licence should be revoked and the legislation does not provide for the licence to be revoked with immediate effect, the Managing Director must advise the sponsor of the intention to revoke the licence and give the sponsor the opportunity to respond to the proposed action. Before making a decision on a proposal to revoke a product licence the Managing Director must consider submissions made by the sponsor in relation to the proposed action.

The sponsor may continue to import, supply or export the product until such time as the Managing Director notifies the sponsor in writing of the decision to revoke the product licence.

The Managing Director may revoke a product licence for a medical device (following a notice of proposal to revoke) if:

- (1) the medical devices are no longer of the same kind as the medical device described in the product licence;
- (2) the sponsor has failed to comply with a condition of the licence;
- (3) the sponsor fails to comply with a notice given by the Managing Director requiring the sponsor to provide information or documents in relation to the kind of device, within 10 working days from the day specified in the notice;
- (4) the Managing Director is satisfied that the medical benefits of the kind of device do not outweigh the residual risk;
- (5) the Managing Director is satisfied that any certification, in relation to the application for issue of the licence is no longer correct; or
- (6) the sponsor has failed to notify the Authority of a change in ownership of the licence.

(iv) Suspension

Suspension of a product licence will stop further import, supply or export of a product pending provision of additional information by the sponsor to enable the Managing Director to determine whether or not the product licence should remain valid or be revoked.

The Managing Director may suspend a product licence for a medical device if:

- (1) the Managing Director is satisfied that:
 - the medical benefits of using the medical devices that are the subject of the licence do not outweigh the residual risk; and
 - it is likely that the manufacturer of the devices will, within the period of the suspension, be able to take the action necessary to ensure that the devices do not cause death, serious illness or serious injury if they continue to be available for supply or export; or
- (2) the Managing Director is satisfied that it is likely that there are grounds for revoking the licence.

The Managing Director must notify the sponsor in writing if he/she decides to suspend a licence.

Before suspending a product licence because it is likely there are grounds for revoking the product licence, and if the Managing Director would be required to give notice of an intention to revoke the licence then the notice:

- would inform the sponsor of the reasons for the suspension;
 - would specify the period of the suspension;
 - may include conditions to be complied with by the sponsor as a prerequisite to a decision whether to withdraw the suspension.
-
- Before suspending a product licence, the Managing Director must:
 - give the sponsor reasonable opportunity to make submissions in relation to the proposed action; and
 - consider submissions made by the sponsor in relation to the proposed action.

In all other circumstances, suspension of a product licence is to take effect on the day on which the notice is given to the sponsor.

The suspension may be limited to some medical devices of that kind.

Duration of Suspension

Suspension of a product licence takes effect on the day on which the sponsor is notified of the decision.

The suspension has effect until:

- it is revoked by the Managing Director; or
- the end of the suspension period specified in the notice; or
- if the period of suspension was extended by the Managing Director, the end of the extension period.

Withdrawal of suspension

The Managing Director must revoke the suspension if satisfied that:

- the ground on which the product licence was suspended no longer applies; and
- there are no other grounds for suspending the product licence.

The Managing Director may revoke a product licence suspension:

- on his/her own initiative; or
- if the sponsor of the product applies in writing to the Managing Director.

If the Managing Director revokes a suspension, he/she must advise the sponsor in writing within 20 working days after making the decision to revoke the suspension.

If, after an application by the sponsor, the Managing Director decides not to revoke the suspension, he/she must advise the sponsor in writing of his/her decision, giving reasons for the decision, within 20 working days of the decision being made.

f) Exemptions from Product Licensing

Certain medical devices or kinds of medical devices will be exempted from product licensing in specified circumstances and may be subject to applicable conditions. These exemptions include, but are not necessarily limited to:

2. Medical devices used in life-threatening or otherwise grave cases² provided:
 - the patient (or their guardian) has given informed consent to the device being used;
 - at the time the device is used, the medical practitioner responsible for using the device signs a statement in relation to the patient in the form approved by the Managing Director and sends a copy of the statement to the Authority within 20 working days; and
 - the device is used in accordance with the direction of the medical practitioner who requested its use and in accordance with good clinical practice.
3. Medical devices imported into Australia or New Zealand for use in the treatment of the importer or the importer's immediate family provided the importation is not prohibited under Customs legislation. In the case of a medical device other than an IVD that contains or is manufactured using, tissues, cells or tissue derivatives of animal origin that have been rendered non-viable or are of bacterial or recombinant origin, the importer must obtain written permission from the Managing Director before importation can take place. Written permission from the Managing Director must also be obtained if the device incorporates a stable derivative of human blood or plasma.

In the case of a medical device classified as Class IIa or higher or an IVD that is a Class 2 IVD or higher, the quantity imported in one importation must not be more than the amount required to give 3 months treatment using the device according to the treating medical practitioner's directions. The total amount imported in a 12-month period must not exceed 15 months' supply.
4. Medical devices that are exported from Australia or New Zealand provided they are not for commercial supply and do not contain a substance the exportation of which is prohibited under Customs legislation in the exporting country. This exemption does not cover medical devices intended for use in clinical trials on humans.
5. Samples of medical devices imported into, exported from, manufactured in, or supplied in Australia or New Zealand for any of the following purposes:
 - submission to a regulatory authority; or
 - subjection to developmental or quality control procedures; or

². defined as a person who is seriously ill with a condition that is reasonably likely to lead to the death of the person within a matter of months; or has a medical condition that, in the absence of immediate treatment, is likely to lead to the imminent loss of an arm, leg, hand or foot of the person; or an organ of the person; or the person's sight

- examination, demonstration or display, with notice to the effect that the device is not available for general supply unless it is the subject of a product licence; or
- subsection to analysis or laboratory testing procedures.

Medical devices covered by this provision can not be supplied for use in or on a human being. If this provision relates to an IVD, the IVD may not be used for the release of patient results.

6. Medical devices imported into Australia or New Zealand solely for the purpose of export that remain subject to Customs control in the importing country and that are not subject to any process of manufacture in Australia or New Zealand.
7. A custom made medical device that is specifically made in accordance with a request by a health professional specifying the design characteristics or construction of the medical device and is intended to be used only in relation to a particular individual or intended to be used by the health professional to meet special needs arising in the course of their practice. Custom made devices will be exempt from having a product licence, but would need to meet the essential principles as far as possible and comply with the conformity assessment procedures for custom made devices.
8. Medical devices imported by a member of a group of persons visiting Australia or New Zealand, provided that:
 - the medical devices are intended to be used and are used only for the treatment of a member or members of the group;
 - the group of persons is either:
 - a group of persons visiting Australia or New Zealand to participate in a national or international sporting event; or
 - members of the military forces of another country visiting Australia or New Zealand for military training; or
 - a group of persons including the Head of State or Head of Government of a foreign country and senior Government officials of that country who are visiting Australia or New Zealand
 - the devices are destroyed at the end of the visit or removed from Australia or New Zealand;
 - a member of the group takes responsibility for the control and custody of the devices while the group is in Australia or New Zealand;
 - that person carries a list, in English, of the name of the quantity and nature of each device imported, and keeps a record of the use of the devices while the group is in Australia or New Zealand; and
 - the list or record is be provided to a customs officer or other authorised person on request.
9. Medical devices imported by a medical practitioner or a member of a medical team accompanying a person to Australia or New Zealand who has a critical illness and is under the direct care of the medical practitioner or team. The devices must be for use in the treatment of the person with the critical illness and their importation must not be prohibited under Customs legislation.
10. Medical devices on a ship (including a yacht or other marine vessel) or aircraft visiting Australia or New Zealand if they are part of the medical supplies of the ship or aircraft. The devices must be for use in the treatment of a passenger or member of the crew of the ship or aircraft and their importation must not be prohibited under Customs

legislation. The quantity of the devices imported must be consistent with the quantity required for the treatment of the passengers or crew. The devices must not be removed from the ship or aircraft whilst it is in Australia or New Zealand.

11. Medical devices that are the subject of an approval given in emergency situations. This exemption may be used to enable medical devices to be stockpiled as quickly as possible in preparation for dealing with a potential threat to public health, or made available urgently in order to deal with an actual threat to public health caused by an emergency.
12. Medical devices for which the Managing Director grants an approval to enable the medical device to be used for the treatment of a person or for experimental purposes in humans (*see also Part F3: Clinical Trials and Access to Unlicensed Therapeutic Products*).
13. Medical devices used under a written authority from the Managing Director for a specified medical practitioner to use specified unlicensed medical devices or kinds of medical devices in the treatment of specified recipients or classes of recipients. Conditions may be imposed on this kind of authorisation.
14. Medical devices for which the Managing Director has granted an exemption in the interests of public health where he/she is satisfied that no licensed product that could act as a substitute is available, or any such product is in short supply.

Any medical device that is exempt from product licensing requirements and is imported into Australia or New Zealand and held under the direct control of the sponsor, must be:

- supplied only in accordance with the relevant notification, approval, authorisation or medical practitioner's direction; and
- kept in a warehouse or a properly secured area under the control of the sponsor.

If not used within 12 months of importation, the device must be destroyed or returned to the consignor of the device within one month of the end of that period. The sponsor must keep records relating to the source of supply of the device, and if the device is destroyed, the sponsor must keep records relating to the destruction. The sponsor must provide copies of the records to the Managing Director on request.

If a person supplies a medical device that is exempt from product licensing and the Managing Director is satisfied that the medical device does not conform to an applicable standard or is not fit to be used for its intended purpose, then the Managing Director may issue a notice requiring the person to take steps to recover any unused device. The notice may also specify how and when the device is to be recovered.

7. OBTAINING INFORMATION

The Managing Director may obtain information about medical devices or the manufacture of medical devices or applications pertaining to medical devices.

The Managing Director may, by a notice in writing, request information or documents relating to:

- the application of conformity assessment procedures;
- compliance with essential principles;

- whether the devices comply with conditions (if any) imposed on a conformity assessment certificate;
- whether the devices comply with every requirement (if any) relating to advertising;
- compliance with other requirements; or
- whether devices of that kind are being supplied in Australia or New Zealand, imported into Australia or New Zealand or exported from Australia or New Zealand.

The Managing Director may, in relation to kinds of medical devices exempt from product licensing, seek information or documents relating to the distribution of, and other matters relating to, medical devices that are exempt from product licensing.

The notice must specify a reasonable period in which the sponsor is to comply. The notice may specify the form in which the information is to be supplied to the Authority.

8. POST MARKET SURVEILLANCE INCLUDING ADVERSE EVENT REPORTING

The Authority will have systems, procedures and strategies in place for the reporting of problems with medical devices.

A comprehensive adverse incident monitoring program will operate in Australia and New Zealand under the directorship of the Authority, and this program will monitor the safety of medical devices supplied in Australia and New Zealand.

Manufacturers and sponsors will be required to report adverse events involving their medical devices to the Authority within statutory timeframes that depend on the seriousness of the incident³. The Authority will review all adverse event reports and undertake investigations if required.

Post market surveillance of medical devices by the Authority will include the compliance testing of medical devices and an audit by the Authority of technical files and certification. Manufacturers and sponsors will be required to actively monitor the performance of their products in the market place. Manufacturers will be required to have in place systems to review experience from the use of a device once it is approved for use, and to implement appropriate corrective actions. At any time while a product licence has effect, as soon as a manufacturer or sponsor becomes aware of particular information in relation to the licensed product, the manufacturer or sponsor must inform the Managing Director in writing.

The particular information that must be reported with respect to medical devices includes information relating to:

- any malfunction or deterioration in the characteristics or performance of a kind of device; or
- any inadequacy in the design, production, labelling, instructions for use or advertising materials of a kind of device; or

³ Health care professionals and consumers are also able to report voluntarily adverse events to the Authority.

- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in the person's health.

Additionally, the manufacturer or sponsor must report information that:

- relates to any technical or medical reason for a malfunction or deterioration in the characteristics or performance of a device that has led the manufacturer to take steps to recover devices of that kind that have been distributed; or
- indicates that a device of that kind does not comply with the essential principles; or
- indicates that a certificate used to signify compliance with the essential principles or the application of relevant conformity assessment procedures to a particular device, has been restricted, suspended, revoked or is no longer in effect.

The Rules may provide for circumstances where sponsors are not obliged to provide certain types of information, even though it is of the particular type listed above.

Unless otherwise specified in the Rules, it will be an offence if a sponsor fails to provide the particular information listed above within the period specified in the Rules. Adverse event reporting by healthcare professionals and consumers will remain voluntary. Provisions will be put in place to maintain the confidentiality of the reporting scheme.

If an application for a product licence is withdrawn or lapses, the Managing Director may give the applicant written notice requiring the applicant to inform the Authority in writing whether the applicant is aware of any information of a kind mentioned in the list above. A person must comply with the requirements of a request of this kind within 25 working days of receiving the request and must not provide information that is false or misleading.

In addition, sponsors will be required to provide usage data for licensed products either annually or on request.

The Managing Director may seek advice regarding adverse event reporting from the relevant expert advisory committees.

Other features of the adverse event monitoring program include international information exchange between regulatory authorities and between inter-governmental agencies within Australia and New Zealand.

9. RECALLS AND PUBLIC NOTIFICATION

Recalls (including hazard alerts) will be classified by the Authority, in consultation with the sponsor where appropriate, according to a classification system, as follows:

- *Class I recalls* occur when defects in medical devices are potentially life-threatening or could cause a serious risk to health;
- *Class II recalls* occur when defects in medical devices could cause illness or mistreatment, but are not Class I; or

- *Class III recalls* occur when defects in medical devices may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

The Managing Director may, in writing, impose requirements relating to medical devices on a sponsor, if the medical devices are supplied while licensed and:

- do not conform with essential principles applicable to the device; or
- the conformity assessment procedures have not been observed in the manufacture of the device; or
- the Managing Director is satisfied that the quality, safety or performance of a device is unacceptable.

The requirements may be one or more of the following:

- recover the medical devices that have been distributed;
- inform the public or a specified class of persons that the circumstances referred to above have occurred in relation to the medical devices;
- publish information relating to the manufacture or distribution of the medical devices; or
- advise the Authority of the destruction etc., of the recalled medical devices.

Requirements may also be imposed on the sponsor of a device if the product licence has been suspended or revoked.

Requirements may be imposed on persons supplying medical devices that are exempt from product licensing if:

- the devices do not conform with essential principles applicable to the devices; or
- the conformity assessment procedures have not been observed in the manufacture of the devices; or
- the Managing Director is satisfied that the quality, safety or performance of a device is unacceptable.

Requirements will also be imposed on persons manufacturing, importing, exporting or supplying medical devices that do not have a product licence and are not exempt from product licensing requirements. Additionally requirements will be imposed on persons manufacturing, importing, exporting or supplying counterfeit products.

In addition, the Managing Director may impose requirements on a person if the person supplies or has supplied medical devices that have been, or could possibly have been, subject to actual or potential tampering.

The Managing Director may limit recall requirements to the kind of medical device affected by the recall.

The Managing Director may require the medical device affected by the recall to be recalled permanently or, where corrective action may be undertaken, to be recalled temporarily until supply may recommence.

If a medical device is supplied that is exempt from product licensing requirements and it does not conform to essential principles applicable to a device of this kind, then the Managing Director may require the person supplying the device to recover the device.

The Authority will be able to order a previous sponsor, or a current sponsor if the previous sponsor cannot be identified or is insolvent, to undertake a recall of a medical device if the previous sponsor was the sponsor at the time of the distribution of the device.

The Authority will be able to instigate a mandatory recall procedure in cases where the sponsor is unwilling or unable to conduct the recall voluntarily. Where the Authority undertakes a recall, it may recover costs from any party involved in the sale or supply of the medical devices, as appropriate.

When requirements are imposed under this provision, the Managing Director must publish a notice setting out the particulars of the requirement.

10. FURTHER ISSUES SPECIFIC TO THE REGULATION OF IVDs

a) In-house IVDs

It is proposed that the regulation of IVDs manufactured “in-house” will be incorporated into this regulatory framework following further consultation and the implementation of the framework for commercial IVDs.

An in-house IVD is one which is developed within a laboratory or laboratory network and is not supplied in a commercial context. An in house IVD is defined as an IVD that is:

- 1) developed *de novo*; or
- 2) taken or modified from a published source; or
- 3) modified from a commercial or other validated assay system, where the modifications would be likely to change the performance characteristics against the sample population on which the original validation was performed; and for use in that particular laboratory or laboratory network.

Commercial IVDs being used for a clinical application purpose other than that originally intended by the manufacturer are also classed as in-house IVDs and will be regulated as such.

b) Access to IVDs for Self-testing

IVDs intended for self-testing are tests that are used in the home or a similar environment that are not carried out under the supervision of a health care provider. It is the intention of the Authority that certain types of self-testing IVDs will be prohibited from supply. These include

- (a) Self-testing IVDs used to test blood and tissues for pathogens or diagnose notifiable infectious diseases;
- (b) Self testing genetic tests; and
- (c) Self-testing IVDs used to test for serious disorders, such as cancer and myocardial infarction.

This aspect of the framework has not yet been incorporated into the legislation. Pending further legal instruction, it is the intention of the Authority that it will be included in the final version of this Rule.

c) IVDs for Non-therapeutic Use

IVDs for non-therapeutic use include tests for parentage and kinship testing, drug tests used in sport and tests for alcohol and illicit drugs. These tests will fall outside the scope of the joint regulatory scheme for therapeutic products because they are not intended for therapeutic use.