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Recalls & Advertising Section
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Updating of the Uniform Recall Procedures for Therapeutic Goods

To Whom It May Concern

Thank you for the opportunity to respond to the consultation *Updating of the Uniform Recall Procedures for Therapeutic Goods*. Please find attached the IVD Australia response.

Yours sincerely

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IVD Australia Comments – Updating of the Uniform Recall Procedures for Therapeutic Goods (URPTG)

Issue	Recommendations	Support	Rationale/Comments
The URPTG does not address the initiatives implemented to increase transparency following the Blueprint	**Recommendation 1**: The URPTG be updated to allow the Sponsor's Customer Letter to be available through SARA	**No**	**IVD Australia does not support this recommendation as written** **IVD Australia supports this recommendation for consumer level recalls only** **If this recommendation was to proceed for consumer level recalls, industry should not be required to take on additional work towards publication of letters in SARA, eg, uploading final letters.** There are different levels of recall in the URPTG, some of which may not benefit from making publically available sponsor customer letters. Currently the TGA may send out a product recall through safety alert email updates where the recall action has been deemed consumer level. The information presented in the email update is included as a link in the SARA database and can be accessed by general consumers. This is in line with the intent of the transparency review and may be beneficial to update to include a copy of the sponsor customer letter as additional information. Where recalls are directed at Healthcare Professionals only, e.g. Laboratory IVD products, placing the Sponsor letter on the website is not the preferred option. Product recall letters are tailored to the professional responsible for the laboratory running the test and are technical in nature. As such the letters are unlikely to be understood by the general public and/or the reason for action will not impact individual consumers. The frequency of hospital level recall (corrections, etc) is higher than that of consumer recall due to the nature of the product and publication of letters to the general public may create a false perception of lack of safety in testing. Publication of such a Healthcare Professional only letter in a consumer forum may be confusing to the general public, leading to unwarranted fear and distress regarding use of the IVD tests in general. Publication of Hospital level recall letters is therefore not advised and any information published should be assessed so as to not impact the confidence of the general consumer in the IVD industry or cause them to not have tests performed which are critical for their health because of a recall of one lot of a product. Sponsors direct Healthcare Professional only letters to the specific customers impacted by the recall. This minimises unnecessary work and anxiety for non-impacted customers and also prevents destruction or return of unaffected kits where customers assume all product is affected instead of specific lots. Current requirements to notify CEOs of hospitals would be better revised to require the appropriate Department Heads of Hospitals, eg, Pathology Departments, be notified to ensure the appropriate personnel are contacted. Broadening the audience is of little benefit in a non-consumer environment.

The URPTG does not contain clear information on the procedures and processes for recall of all medical devices and biologicals	**Recommendation 2**: The URPTG be updated to ensure all product sectors and their current regulatory requirements are adequately covered	**Yes**	**IVD Australia supports these recommendations** It is important that the specific regulations applying to each sector be covered in the Uniform Recall Procedure. Any requirements for either the Medical Device or Biologicals section must be supported by a specific regulatory requirement. Implementation of the recall procedure should also be in line with the way businesses and customers function in this industry and not be based either on a consumer model and/or outdated technology.
	Recommendation 3: The URPTG be updated to include information on the procedures and processes for recall of biologicals		
The URPTG refers to the *Trade Practices Act 1974,* which has been superseded by the *Australian Competition and Consumer Act 2010*	**Recommendation 4**: The URPTG be updated to remove reference to the *Trade Practices Act 1974* and include references to the *Competition and Consumer Act 2010*	**Yes**	**IVD Australia supports these recommendation**s The URPTG should be in line with current consumer laws, this will reduce burden on sponsors who only supply to healthcare professionals.
	Recommendation 5: The URPTG be updated to remind sponsors that where they supply therapeutic goods that are also 'consumer goods' they have certain obligations under the ACL		

The URPTG does not provide for direct communication with private hospitals and there are gaps the list of stakeholder organisations in Appendix 5 of the URPTG	**Recommendation 6**: A mechanism is developed that ensures timely information being provided to private hospitals such as through private hospital associations such as the Australian Private Hospital Association and the Catholic Hospital Association	**No**	**IVD Australia does not support this recommendation** **If recommendation 6 were to proceed, the whole list of stakeholders would need complete revision as currently NO IVD users/stakeholders are covered. See Table below.** IVD Australia sees little benefit in expanding the lists of stakeholders to be contacted by TGA or in notifying the Private Healthcare Associations for IVDs. The contacts listed in Table 1 are predominantly pharma contacts and therefore irrelevant for IVDs. The experience of the IVD industry is that these letters rarely reach the appropriate personnel for whom they are intended (ie: the Pathology laboratories) through these mechanisms. Where the notifications do percolate through within the public sector, it predominantly results in IVD device companies spending time reassuring unaffected customers, having customers discard unaffected product and generally creating additional work for all involved. It also creates a broader negative perception around both the product and the sponsor where often minimal product is impacted. If recommendation 6 were to proceed, the whole list of stakeholders would need complete revision as currently ***NO IVD users/stakeholders*** are covered. See Table 1 below.

Group 1 (for all medicine and medical device recall actions)

Contact details	
Chief Pharmacist Joint Health Command Department of Defence CP3-6-154 Campbell Park Offices CANBERRA ACT 2600 P: 02 6266 3924 E: DOSMAD.JHC@defence.gov.au (Also receives blood recall actions)	Recall Coordinator Recalls & Hazard Assessment Product Safety Branch Australian Competition & Consumer Commission GPO Box 3131 Canberra ACT 2601 P: 02 6243 1262 E: recalls@accc.gov.au
Chief Medical Officer Australian Antarctic Division Department of the Environment 203 Channel Highway Kingston TAS 7050 F: 03 6232 3310 E: polarmedalerts@aad.gov.au	National Manager P: (02) 6141 8394 Pharmaceutical Benefits Branch Department of Human Services E: pbs.listings@humanservices.gov.au Alternate P: PBS Helpdesk: 13 22 90 E: CO.PBS.Help.Desk@humanservices.gov.au
Ms Pattie Beerens, Executive Director E: pbeerens@bconsulting.net.au National Pharmaceutical Services Association 71B Grosvenor Street, South Yarra, VIC 3141 (Medicine Recalls Only)	Pharmaceutical Benefits Division Department of Health E: pbac@health.gov.au
Ms Kerren Hosking NPS MedicineWise Level 7/418a Elizabeth Street Surry Hills NSW 2010 PO Box 1147 Strawberry Hills NSW 2012 P: 02 8217 8796 F: 02 8217 8765 E: khosking@nps.org.au	Medsafe, Ministry of Health Wellington New Zealand Kathy Daly (all recall notices) E: recalls@moh.govt.nz P: +64 4 819 6894 Sonia Varma (medicines & blood products) P: +64 4 819 6833 Robert Jelas (medical devices) P: +64 4 819 6881

	Recommendation 7: The *TGA* review the list of stakeholder organisations in Appendix 5 of the current URPTG to ensure that it is comprehensive	**Yes**	**IVD Australia supports this recommendation**
The URPTG does not adequately address that the URPTG applies to mandatory recalls	**Recommendation 8**: The URPTG be updated to explicitly state that the recall procedures and processes in the URPTG also apply to mandatory recalls	**Yes**	**IVD Australia supports this recommendation** The same framework should be followed regardless of the mechanism by which the recall is initiated.
Harmonisation with New Zealand	**Recommendation 9**: In order to provide a clear message to market and consistency between Australia and New Zealand, The TGA introduce the new terms 'Health Professional Level' and 'Product Alert'	**Yes**	**IVD Australia supports this recommendation, however raises a caution** IVD Australia agrees in principal with the introduction of these terms from New Zealand. In particular, the use of the Product Alert category for use with Consumer-based actions is important where the removal of the product from the market may pose a greater risk than leaving it in place. Care may be needed to ensure the term "Product Alert" is not confused with the term "Safety Alert" as the terminology is similar but the definition of each is significantly different. For HCP level recalls, particularly in the IVD sector, generally these are adequately covered by the product correction or product recall category, particularly if Recommendation 10 is adopted. It is the laboratories responsibility to determine if the Clinician who orders a test needs to be informed should a recall or product correction action take place. A Health Professional Level classification is useful for devices used by consumers and may be useful for Point of Care testing situations in the future where non-laboratory personnel are involved in the testing.
The term "Recall for Product Correction" causes confusion as the product does not need to be returned to the sponsor / manufacturer	**Recommendation 10: In order to provide a clear message to stakeholders, the term 'Product Correction' should be included in the URPTG**	Yes	**IVD Australia supports this recommendation** This recommendation is highly supported by the IVD industry and IVD Australia. The majority of actions which must be taken in the field for this type of product require only a change in use by the laboratory or other healthcare professional. There is no requirement or need to return the product to the sponsor and the product may continue to be used under revised conditions. The use of the term "Recall for Product Correction" has led in the past to significant confusion to customers, unnecessary destruction of product, and in some cases, return of product to sponsors making it unusable.

Additional Recommendations:

- The requirement for postal notification to be sent is out-of-step with the manner in which the majority of customers wish to be notified of recall/product corrections. Hard copy letters are much slower to reach customers and are often misdirected. This problem will only increase as Australia Post seeks to reduce the level of standard postal service and/or increase the costs of next day delivery.
  - Although the language of the URPTG is prescriptive and ostensibly mandatory; the TGA has for some time allowed electronic communication as well. **IVD Australia recommends** the option to alternatives to postal notification be specifically included; with the proviso that industry can ensure that the intended recipients receive the notifications (see email extract below – from the TGA to a member company in response to an enquiry).

    In reviewing the effectiveness of recall action communication strategies the Recalls Unit has identified that the dissemination of information via methods other than post can lead to more timely and efficient communication… To this end the Recalls Unit considers that it is appropriate for recall letters to be sent via email or other electronic means. For electronically distributed letters it is recommended that a read receipt or other means of validating the receipt of the letter is used (in addition to the Return Form). In the event that the electronic letter was not opened it is expected that other means of communication are promptly implemented. For example, hard copy letter or telephone confirmation.

    You are correct in pointing out that this method does not comply with the implicit instructions in the URPTG, however, as a <u>non-legislated agreement with industry</u> [emphasis added] *there is always potential to allow deviations from the standard recall procedure, so long as these changes do not adversely affect the recall procedure. In the case of electronic transmission of letters, the Recalls Unit believes that this will allow for a swifter dissemination of the recall information and in many cases reduce the burden of recall actions on the Sponsor. Please note that it is not mandatory for electronic letters to be sent. It is expected that the next edition of the URPTG will include information on appropriate electronic methods of communication.*

  - Currently URPTG in Section G prescribes that the size of the envelope should be 220 x 110 mm. IVD Australia strongly recommends that if postal notification is required, it being for more general "Post-office approved" envelopes. In addition, the highly prescriptive requirements around the style and printing of recall letters should be removed and replaced with a more general requirement that the envelopes be distinctive and indicate urgent attention required. Given the general move away from postal notifications being the primary method of contact this would reduce the burden on sponsors with minimal loss in effectiveness.
  - The required addressees on recall letters as defined in the URPTG are inappropriate for the majority of IVD products and do not ensure the letter reaches the appropriate user, in most cases the laboratory. See Extract below. **IVD Australia recommends** that, for IVD-related letters, it is more appropriate to be sent to the 'Senior Scientist/Chief Pathologist' as for Human Blood and Tissue recalls (see below). It is important to note here that Point of Care and Self Testing IVDs would be the exception here: for Point of Care tests, a broader audience may be required; and for Self-testing IVDs, where the action is conducted at a consumer level, these types of notifications are usually not required.

Addressing of recall letters and envelopes

i. Medicine Recalls

For hospitals, address to:

'Chief Pharmacist'.

In the case of a clinical investigational medicine, address to:

'Clinical Investigator' and 'Chief Pharmacist' (a copy of the letter to each) in the institutions in which the clinical investigations have been performed.

In the case of radiopharmaceuticals a copy of the letter should be sent to the head of each relevant department of nuclear medicine and pharmacy (e.g. 'Director of Nuclear Medicine').

ii. Medical Device Recalls

In the case of medical devices in a hospital, address to:

'Chief Executive Officer'

and marked to the attention of the head of the appropriate department. In the case of a clinical investigational device, address to:

'Clinical Investigator'

and if appropriate:

'Chief Biomedical Engineer'

and/or:

'Director of Nursing'.

iii. Human Blood and Tissues

'Senior Scientist and/or Pathologist'

and if appropriate, the Recipient's Surgeon.