Appendix 6: Guidance on Legal Issues

This appendix has been included to provide responses to commonly asked questions about legal issues.

1. Recall Powers

Are there mandatory powers of recall in the medicines legislation?

Yes, but in practice almost all recalls occur as voluntary actions undertaken by sponsors, with oversight from the regulator (Medsafe). This is also the common practice internationally.

There are provisions in the Medicines legislation relating to the mandatory recall of medicines and medical devices.

- Regulation 50(1)(a) of the Medicines Regulations 1984 provides that if a notice is in force under section 35 or 37 of the Act, the Director-General may issue an order directing the withdrawal from sale of a medicine or medical device or any portion of the produced quantity of a medicine or medical device if the Director-General believes on reasonable grounds that withdrawal is necessary to protect the public.

- Regulation 50(1)(b) of the Medicines Regulations 1984 provides that the Director-General may issue an order directing the withdrawal from sale of a medicine or medical device or any portion of the produced quantity of a medicine or medical device that does not conform to the specifications claimed for that medicine or medical device.

2. Pharmacy Issues

Is it lawful to provide a replacement supply of a medicine that is being recalled to consumer level without a new prescription?

Yes, in almost all circumstances the replacement supply can be provided under the cover of the original prescription.

A new prescription is not required to authorise the replacement of a recalled product:

- with unaffected stock of the same medicine. In this context, “same medicine” means a medicine of the same brand name, dose form and strength as the recalled product

- with another brand of the medicine that has the same active ingredient, dose form and strength as the recalled medicine. Brand substitution should only occur if this is requested in the recall letter in order to deal with a situation where unaffected stock of the recalled product is not available.

NOTE: If brand substitution is requested in the recall letter but the original prescription has been marked “no substitution”, the pharmacist will need to get authorisation from the

prescriber for the brand switch (regulation 42(4) of the Medicines Regulations 1984 would apply).

The pharmacist needs to be able to access details of the original prescription in order to be satisfied that replacement supply is appropriate and that what is being supplied is in keeping with the original prescription.

This will be straightforward when the consumer returns to the pharmacy where their medicine was dispensed to seek their replacement medicine.

When this does not happen, the pharmacist will need to use the information on the dispensing label of the container being returned by the consumer to make contact with the dispensing pharmacy and confirm the details of the original prescription before providing the replacement medicine.

If it is not possible to confirm those details (eg, because the customer does not have the container from the original dispensing pharmacy and cannot remember where it was dispensed) a new prescription will be required.

A new prescription is required to authorise the:

- dispensing of a different medicine to a consumer who has returned their recalled medicine. This would occur in situations where unaffected stock of the recalled medicine or a generic version of that medicine is not available. The requirement would be stated in the recall action letter. The advice for consumers published by the sponsor would advise consumers of the need to obtain a new prescription before returning the recalled medicine

- replacement of recalled product (with unaffected stock of the same medicine or a generic version of the medicine) where the consumer is not known to the pharmacist and the details of the original prescription cannot be confirmed from records held in that pharmacy, the pharmacy where the recalled medicine was dispensed, or by the original prescriber.

What should a consumer be told about how to obtain replacement medicine when contacted by their pharmacist or prescriber?

The consumer should be asked to bring any unused medicine with them in the container in which it was dispensed and, if possible, return to the pharmacy where the medicine was dispensed in order to receive replacement stock.

What amount of medicine should be dispensed to a consumer when giving a replacement supply?

An amount equivalent to that still left in the container in which the medicine was dispensed should be supplied unless that is impractical (for example in the case of eye drops, metered dose inhalers, tubes of cream, etc,)

In such cases a replacement original pack should be provided. A record of details from the original dispensing label should be kept in the pharmacy for audit purposes.

Should a new container and label be used for the replacement medicine?

Yes. The new label should contain the new date of dispensing, quantity supplied, unique identifier for this supply and state that this is a replacement dispensing.

3. Privacy Issues

Can a health professional request contact or other details for a consumer who needs to be contacted in a recall action situation from another health professional?

Yes. There are a number of justifications for this in the Health Act 1956 and the Health Information Privacy Code 1994.

Under section 22F of the Health Act, a person who is providing health or disability services to an individual may request the disclosure of health information from any person holding that information. A consumer's contact details or details about medication they are on are considered to be health information under the Health Information Privacy Code.

Another reason for justifying disclosure of health information in a recall action situation is rule 11(2)(a) of the Health Information Privacy Code. Clearly, providing ongoing medical care to a consumer is a closely related purpose and under rule 11(2)(a), disclosure is permitted in this case even where obtaining individual authorisation is not practicable.

Finally, rule 11(2)(d) allows for disclosure of details when the recall of a medicine could cause a serious and imminent threat to the health of a person, such as in a Class I recall.

Refusal to provide information requested

Under section 22F, a valid request may only be refused where the holder believes the individual does not want the information disclosed, where:

- the refusal is authorised by the Health Privacy Information Code
- the person holding the information has a lawful excuse (such as a statutory obligation of confidentiality or one of the grounds in sections 27-29 of the Privacy Act) to refuse the request.

Nothing in the Health Information Privacy Code prevents a health professional from disclosing such details, nor is there a statutory obligation to refuse. The only valid reason for refusal would be if the health professional involved believed the consumer did not want their details disclosed, in which case they should contact the consumer themselves to notify them of a recall action.

For further advice, the Privacy Commissioner can be contacted at:

Privacy Commissioner
PO Box 10-494
The Terrace, Wellington 6143

Telephone 0800 803 909
Fax (04) 474 7595
Email enquiries@privacy.org.nz

Web https://www.privacy.org.nz/

What is open disclosure and how does it apply to the recall procedure?

Open Disclosure refers to open communication when things go wrong in health care.

The elements include:

- providing an expression of regret
- giving a factual explanation of what happened
- explaining the consequences of the event
- describing the steps being taken to manage the event and prevent a recurrence.

Health and disability service provider organisations have a legal duty to ensure that open disclosure is practised by staff and that this is supported by management. It is obvious that a consumer receiving health care should be fully informed in a timely manner about a product recall action involving a medicine or medical device that may adversely affect the consumer. This could either be done by a pharmacist or doctor during a consumer-level recall action, or by a doctor during a consultation where the doctor is aware that a trade-level recall action has taken place.

4. Code of Health and Disability Services Consumers' Rights

There are a number of rights under the Code of Health and Disability Services Consumers' Rights that are relevant to open disclosure.

Right 6(1)(e) provides that health and disability service providers have a duty of open disclosure according to legal, professional, ethical and other relevant standards. This duty is not transferable to third parties who are not health and disability service providers.

Open disclosure standards are included in the revised Health and Disability Services Standards that must be followed by all health and disability services providers certified under the Health and Disability Services (Safety) Act 2001.