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HCCA Submission on the Draft Management of Medicine and Medical Device Recalls and Shortages

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Background

The **Health Care Consumers' Association (HCCA) of the ACT** was formed over 30 years ago to provide a voice for consumers on local health issues and now provides opportunities for health care consumers in the ACT to participate in all levels of health service planning, policy development and decision making.

HCCA involves consumers through:

- consumer representation
- consultations
- training in health rights and navigating the health system
- community forums
- information sessions about health services
- advocating for issues of concern to consumers

The HCCA is dedicated to the promotion of consumer-centred health care, which we believe can be successfully achieved through the application of five key principles:

1. **Respect**
2. **Choice and empowerment**
3. **Consumer involvement in health policy**
4. **Access and support**
5. **Information**

It is with reference to these principles that this submission has been developed. We have also consulted with our membership in order to identify important issues for consumers.

Introduction

HCCA welcomes the opportunity to provide input to the Policy for Management of Medicine and Medical Device Recalls and Shortages. It is excellent to see that the policy has acknowledged the lack of clear guidelines for processes related to medication shortages and attempted to address this deficit. In the context of increasing global medication shortages, it is essential that the ACT Health Directorate has effective strategies in place to ensure that consumers have access to the medication and care that they need at all times.

HCCA understands that the current policy has been aimed at better defining roles and responsibilities of members within the Health Directorate, particularly at the executive level, and commends the Health Directorate on this initiative. We strongly support the additional goal of providing for urgent communications that occur outside of business hours, as this is an essential aspect of meeting consumer needs. As inconvenient as it is, our health care needs often occur outside business hours.

There are a number of issues with the current draft that HCCA urges the Health Protection Service (HPS) to consider when developing the final version. In particular, HCCA is concerned that the policy does not adequately address the need to communicate relevant information about shortages and recalls to consumers, in accordance with the ACT Health 2010-2015 Quality and Safety Framework. Page 5 of the draft refers to situations where “significant adverse public health outcomes are anticipated”, but does not mention any procedure for communicating these risks to consumers or providing advice regarding how to seek help, apart from a vague reference to engaging the media. The Quality and Safety Framework states that the Health Directorate is committed to consumer-centred care, including communication with consumers and inclusion in care planning. As such, the Health Directorate needs to be responsible for ensuring that consumers have access to all necessary information about shortages and recalls so that they can be included in the management process. HCCA urges the HPS to ensure that this is reflected in the policy, while avoiding duplicating the role of the TGA in this regard.

Similarly, the diagrams included in the appendix have the Minister and/or Media as the last point of contact following a notification or recall. If medication recalls and shortages are to be managed effectively, the focus needs to be on the individual consumer, who will be most affected by these events. Is there another SOP that will outline how this aspect of the process will be managed? If this is the case, HCCA suggests that the two documents should be integrated to ensure that consumers are fully involved in the process and are able to become aware of issues that are likely to affect their health in a timely and appropriate manner.

1. Policy Statement

Will the term ‘product sponsors’ be understandable to all staff needing to access this document, considering that front line health staff will be using this information? It may be worth adding this to 7. Definition of Terms.

3. Scope

While this section refers to the development of local SOPs in order to apply this policy, it might also be practical to have an overarching SOP to ensure consistency and act as an additional guide for local SOPs.

4. Roles & Responsibilities

(The subheadings in this section are numbered 3.1 and 3.2, it is assumed that these will be corrected to read 4.1 and 4.2 in the final version)

4.1 TGA/sponsor notifications for medicines and medical devices

This section says that the media is to be contacted 'as required', it would be good to clarify the specific conditions under which the media should be contacted, and how media communication would be used to help manage recalls (and shortages). For instance, the policy could explicitly mention that the purposes of engaging the media will be to communicate with consumers. The use of the media to distribute urgent health and safety information to consumers will be integral to the effectiveness of this policy, considering that there are few cases where individual consumers would be able to be contacted directly. As part of this process, it would be good to direct consumers to the TGA website for more detailed information and updates. While it is essential that consumers are provided with as much information as possible, it is also important to consider how this can be achieved without resorting to scare-tactics and causing unnecessary panic. The policy could do well to address this issue by providing guidelines for appropriate language use and media engagement.

It would also be good to outline how the Chief Health Officer is to go about distributing 'urgent product safety information', as this is another essential component of the policy that deserves going into greater detail. In the list of responsibilities of the Director General, the phrase 'ensure that appropriate action is taken' is quite vague. This section could do well to clarify how the 'appropriate' action will be identified in the first place or whether there are existing guidelines to assist with this process. For example, this could be part of the ACT Health Directorate's Communication Strategy.

4.2 Information relating to medicine shortages

In cases where alternative supply sources for medications are unavailable, it is essential that consumers are informed as to the circumstances and are advised what their options are. This would be particularly relevant to consumers living with chronic conditions, who rely on regular medication to manage their conditions. If there is an anticipated shortage of medications commonly used to treat a specific chronic condition, information needs to be provided as soon as possible to these consumers and their GPs so that they are able to make alternative plans.

It is also worth noting that local pharmacies may often have trouble locating or organising alternatives to medications and medical devices for their consumers, particularly as it is difficult for them to communicate with the prescribing doctor to seek further advice. While this issue may be beyond the scope of this particular policy, it highlights the importance of ensuring that health care providers are empowered by the Health Directorate to adequately cater to consumer needs during medicine shortages.

HCCA is pleased to see that managers are being told to ensure that all staff are able to interpret and apply this policy document. This a rare quality in policy documents, but an essential aspect of developing policies and applying them effectively. As this is such an important component, it would be worth considering explaining or providing examples of how this could be achieved.

5. Evaluation

HCCA is concerned that the outcome measures in this section are highly limited. Moreover, they provide no indication of the actual effect that this policy will have on the management of population health and avoiding unnecessary harm. In the very least, there needs to be some measure of the extent to which notifications are acted on effectively. It is also important to consider the minimisation of or reduction in the number of consumers suffering adverse reactions to medication AFTER a recall notice has been issued. In terms of medication shortages, another outcome measure could be the adequate provision of alternatives or the efficient sourcing of alternative supplies as well as the reduction in adverse health outcomes as a result of medication shortages.

The existing outcome measure 'timeliness of advice' is ambiguous, there needs to be a specific timeframe set as a goal so that timeliness can be effectively assessed against a clear standard. It may also be useful to divide the outcome measures so that the management of recalls and shortages can be separately assessed.

In addition to the assessment of HPS data, outcome measures could be assessed based on consumer feedback in accordance with the principles of consumer centred care. Another option to consider would be conducting a case study to evaluate the Health Directorate's handling of a particular medicine/medical device shortage or recall in the ACT following the implementation of the new policy.

6. Related Legislation and Policies

HCCA would like to see this policy being linked with the ACT Health 2010-2015 Quality and Safety Framework, as it is highly relevant to the issues being addressed in this policy.

We would be more than willing to further discuss any of the issues raised in this submission with the HPS.

Author

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