

Department of Health: Avoiding, acknowledging and fixing mistakes

INVESTIGATION OF A COMPLAINT ABOUT THE AUSTRALIAN COMMUNITY PHARMACY AUTHORITY

December 2014

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Report by the Commonwealth Ombudsman, Mr Colin Neave, under the *Ombudsman Act 1976*

REPORT NO. **04 2014**

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FOREWORD

This is a report on the Ombudsman's investigation of a complaint from a pharmacist about the Department of Health (DoH) and the Department of Human Services (DHS). The complainant contacted our office because he believed that a neighbouring pharmacy had been incorrectly approved to dispense medications under the Pharmaceutical Benefits Scheme (PBS). He told us the neighbouring pharmacy had relocated from its original site to one closer to his pharmacy than the rules allowed and this affected the viability of his business. He had unsuccessfully attempted to find out from DoH and DHS how this had happened, and was frustrated in his attempts to obtain a resolution.

The approval process, jointly administered by DoH and DHS, relies upon the pharmacist applying for approval to provide evidence of the distances between their new location, old location and any other nearby pharmacies. There was an error in the measurement of the distances between the pharmacies. This error had come to the attention of the DoH before the approval was finalised, but the information was not relayed to DHS, which granted the approval without knowing that the application did not meet the location requirements.

We found problems in the design of the pharmacy approval program, which focussed primarily on the interests of the applicant pharmacist without considering how to protect the interests of other pharmacies in the area. The program was delivered by two separate agencies, without sufficient regard to the need to share information in a timely way to ensure the integrity of the scheme. When it became apparent to DoH that DHS had made a decision based on wrong information, it initially failed to consult with DHS about how to put things right. In our view, DoH responded to the mistake in an inappropriately defensive way. Finally, when someone affected by the error complained about it, they were met by an unwillingness to explain or admit fault, and told their only option was to go to court.

We were unable to obtain a remedy for the complainant. However, DoH agreed that, if the complainant makes a claim for compensation including evidence of loss, it will refer that claim to its Minister for consideration.

We note that DoH has already implemented changes to its administrative procedures to address some of the problems that this complaint revealed. At the conclusion of this report we make four recommendations that we believe will further strengthen those arrangements, and provide a more open and responsive complaint process.

While this complaint is about a very particular set of factual circumstances, we believe it holds broader lessons for Commonwealth agencies about the importance of proper program design, sharing information necessary to ensure proper outcomes and about service recovery arrangements when things go wrong.

EXECUTIVE SUMMARY

This is a report on our investigation of a complaint about the administrative program for the approval of pharmacists to dispense medications which are subsidised by the government under the Pharmaceutical Benefits Scheme (PBS), from pharmacies in particular locations.

In December 2012 the Ombudsman's office received a complaint from a pharmacist about an approval to dispense PBS medications from a pharmacy which had recently relocated to a site about 23 metres closer to the complainant's pharmacy than the minimum 500 metres that the pharmacy location rules allowed. He said the proximity of the two pharmacies affected the viability of his business.

The pharmacy location rules were determined by the Minister for Health under the *National Health Act 1953* and reflected the five yearly Community Pharmacy Agreements between the Commonwealth and the Pharmacy Guild of Australia.

Under the program, applications were received by the Department of Human Services-Medicare (DHS) and were sent to the Secretariat of the Australian Community Pharmacy Authority (ACPA) in the Department of Health (DoH) for the ACPA to make a recommendation under the rules. The ACPA's recommendation was then sent back to DHS, where the delegate of the Secretary of DoH made the final decision.

Our investigation concluded:

- The complainant did not have an opportunity to comment on the proposed decision before
 it was made. Although this was not a legal precondition for the making of the decision, it
 would have been good administrative practice to have provided such an opportunity.
- The ACPA made a recommendation on the basis of a survey provided by the applicant
 which, although prepared by a surveyor with a diploma, was not prepared by a registered
 surveyor and which contained a material error regarding the distances. Had an accurate
 survey been before the ACPA, the application would not have satisfied the rules.
- The ACPA Secretariat became aware of the possibility of an error, by way of a conflicting survey related to another application, after the recommendation had been sent to the delegate of the Secretary of DoH, located in DHS, but before the final decision was made.
- The ACPA Secretariat sought legal advice and considered whether it should act on the
 information, but failed to do so before the decision was made by the delegate. While the
 Ombudsman accepts that there was only a short period of time in which to act on the
 information, we have concluded that the ACPA Secretariat should have at least advised
 the delegate in DoH that there was a material concern with the recommendation within
 that short period of time.
- The ACPA Secretariat failed to take any further service recovery action after it was
 advised that the delegate's decision had been made until the complainant raised the
 matter with it. This was the case, even though the ACPA Secretariat did not know whether
 or not the relocating pharmacist had acted in reliance upon the decision at that time.
- The ACPA Secretariat sought external legal advice and advised the complainant that he
 was not entitled to a statement of reasons under the Administrative Decisions (Judicial
 Review) Act 1977. In the Ombudsman's view, that advice was incorrect.

- DHS considered the complainant's complaint and sought legal advice about what could be
 done. However, by the time it did so more than 6 months had elapsed since the decision
 had been communicated to the relocating pharmacist. The Ombudsman's office has not
 received any evidence indicating that DHS was told that the ACPA Secretariat was aware
 of the error before the decision was made, until more than 6 months after the decision had
 been made.
- Neither the ACPA Secretariat in DoH nor DHS advised the complainant of the fact that the ACPA had been aware of the error independently of survey evidence that the complainant himself had later provided. Nor did either agency admit or explain the error or apologise to the complainant. [The agencies sought legal advice and advised the complainant ...] that the decision was lawful, regardless of after acquired evidence showing its factual basis to be incorrect, and referred him to the Federal Court.

The Ombudsman has made four recommendations.

The first recommendation recognises that the relevant legislation gave very little scope for the correction of an erroneous decision by administrative means, once the decision had been communicated to the applicant and acted on. In such contexts the administrative processes leading up to a decision should include steps to minimise error, such as consultation processes, regardless of whether these are legal preconditions to the making of the decision. We note DoH has already taken steps in relation to the quality of survey evidence it will now accept.

The second recommendation concerns the contribution of the cross agency design of the decision making process to the resulting decision which did not meet the objectives of the rules. The process unnecessarily fragmented access to information which was relevant to the decision. In the case at hand, officers hesitated to inform other officers involved in the decision making process that there was a significant matter regarding the recommendation because, while operating under the same Act and program, those other officers were located in a different agency and they were cautious about the possible application of the secrecy provisions of the *National Health Act 1953* and the *Privacy Act 1988*.

Few programs are amenable to perfect delivery. Good administration recognises this fact and each program should have a service recovery plan encompassing the handling of complaints. The third recommendation concerns the need for a joint service recovery process should the program continue to be delivered across more than one agency. If, in future, the program is delivered by a single agency, then a service recovery process should be devised in relation to the program.

The fourth recommendation concerns the agency culture that we believe underscored DoH's overly cautious and defensive approach to the problem, which undermined the overall objective of the program. The best service recovery arrangements will not be effective if the staff in an agency are not encouraged and supported to identify and take responsibility for fixing errors. Even where the agency believes it is unable to remedy a mistake, it should be prepared to provide an explanation and an apology. We have recommended that steps be taken to support a robust service recovery culture within DoH.

PART 1—THE OMBUDSMAN'S INVESTIGATION

1.1 The information below sets out the Ombudsman's opinion as to the facts of the complaint as a result of our investigation.

Background

The PBS and pharmacy location rules

- 1.2 The Pharmaceutical Benefits Scheme (PBS) provides for the dispensing of medications, as listed in an instrument made under the *National Health Act 1953* (the Act), at a government subsidised cost. The Act defines these medicines as 'pharmaceutical benefits'. A pharmacist who has not been approved to supply pharmaceutical benefits from a particular pharmacy cannot supply the listed medicines from that location and claim the subsidy.
- 1.3 The First Community Pharmacy Agreement (1990-95) between the Commonwealth and the Pharmacy Guild of Australia included rules about the location of pharmacies in response to the emergence of uneven concentrations of pharmacies across Australia during the 1980s which impacted on the cost of the PBS program, access for consumers and viability of businesses. The Fourth Community Pharmacy Agreement (2005-10) included the terms of agreement on new pharmacy location rules which were determined by the Minister in 2006 and are referred to below.
- 1.4 The objectives of the new pharmacy location rules were set out at item 25.1 of the Fourth Agreement as follows:

...to ensure:

a. All Australians have access to PBS medications;

- b. A commercially viable and sustainable network of community pharmacies dispensing PBS medicines;
- c. Improved efficiency through increased competition between pharmacies:
- d. Improved flexibility to respond to the community need for pharmacy services;
- e. Increased local access to community pharmacies for persons in rural and remote regions of Australia; and
- f. Continued development of an effective, efficient and well-distributed community pharmacy network in Australia.
- 1.5 The Fifth Community Pharmacy Agreement (2010-2015), in place at the time of the events in this report, did not alter arrangements regarding the pharmacy location rules made under the Fourth Agreement.
- 1.6 At the time of the events giving rise to this report, s90 of the Act provided that the Secretary of the Department of Health may, upon application by a pharmacist, approve that pharmacist for the purpose of supplying pharmaceutical benefits at particular premises. Before doing so, the Secretary was required to refer specified applications to the Australian Community Pharmacy Authority (the ACPA) for recommendation. The Secretary could decline to approve an application recommended for approval by the ACPA, but the Secretary could not approve an application where the ACPA had not also recommended approval.
- 1.7 Section 99L of the Act required the Minister to determine rules under which the ACPA was to make its recommendations. The rules determined in the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* (the Rules) reflected the Fourth

Regulation Impact Statement, *National Health Amendment Bill (No.1) 2000* Explanatory Memorandum, pp 4-6.

Community Pharmacy Agreement and made provisions about the location of the premises at which pharmaceutical benefits could be supplied.

1.8 Where a pharmacist sought to relocate their existing approved pharmacy location, rule 105 specified the permissible distances from the new site of the pharmacy to both its original location and the location of other approved pharmacies, for approval to be recommended by the ACPA.

Pharmacy C and Mr C's complaint

- 1.9 From June 2011 Mr C was the proprietor of a pharmacy (pharmacy C) approved to dispense medications under the PBS at a commercial and residential precinct in NSW (the precinct).
- 1.10 In December 2012 Mr C complained to the Ombudsman about the approval of another pharmacy (pharmacy X), which had relocated within the precinct, to provide PBS medications under rule 105. He believed that pharmacy X did not comply with the relocation distances set out in the Rules and was neither the required distance from its original location nor from pharmacy C. Mr C complained that relocated pharmacy X's proximity to pharmacy C impacted on his business.

Approval process

1.11 The approval process required submission of an application, accompanied by survey evidence, to the Pharmacy Program area of the Department of Human Services Medicare program (DHS), which then provided the application to the ACPA Secretariat in DoH. The Secretariat listed the application for recommendation by the ACPA, the members of which are appointed by the Minister for Health. The ACPA's recommendatory powers required it not to make a recommendation to approve the application unless the distance requirements were met. The ACPA would then send its recommendation, along with the application, back to the Secretary of DoH's delegate under the Act who was located in DHS. The Secretary of DoH's delegate then made the final decision whether or not to approve the application.

Pharmacy X

1.12 On 18 July 2011, Mr X (the proprietor of pharmacy X) lodged an application under rule 105 to dispense PBS medications from his relocated pharmacy. Mr X's application was accompanied by a survey report setting out the distances between the original location of his pharmacy and its new location and also between the new location and Mr C's pharmacy. The survey report indicated the surveyor held a relevant diploma but the survey was not, and did not purport to be, prepared by registered surveyor. This was not a requirement at that time, according to the Pharmacy Location Rules Applicant's Handbook (the Applicant's Handbook). We note that the Applicant's Handbook does require that the information provided with an application is accurate and up-to-date, and also advises that provision of false or misleading information is an offence under the *Criminal Code 1995*.

Making a decision on Mr X's application

1.13 While consultation with other surrounding pharmacies was not required by law, we understand that the ACPA often does so, except where the identity of the applicant would be obvious. The Applicant's Handbook explained the consultation process as 'standard practice' (though noting that 'the Authority is not required or obliged to seek comments from nearby pharmacists') and that, once it has made a recommendation about an application, the ACPA will write to any pharmacist who provided comments on the application to advise the outcome.² However, the ACPA did not afford any surrounding pharmacies an opportunity to

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P.8. See Appendix.

comment on Mr X's application. DoH advised that this was because the applicant's identity would be obvious in short distance relocations, potentially breaching s135A of the *National Health Act 1953*.

1.14 On 30 September 2011 the ACPA recommended approval of the application to supply PBS medicines from the relocated pharmacy X on the basis that it met rule 105. This recommendation was sent to the Secretary's delegate in DHS.

Pharmacy Y

- 1.15 Meanwhile, a third pharmacist (Mr Y) moved to the original premises of pharmacy X and sought approval to dispense medicines under the PBS from that location (new pharmacy Y). The ACPA decided not to recommend approval for pharmacy Y on the basis of the location rules. Mr Y sought review of this decision by the Administrative Appeals Tribunal (AAT). In the course of those proceedings, Mr Y lodged a survey which contradicted the distance between pharmacy Y (the original premises of the relocated pharmacy X) and pharmacy X's new site as shown by the survey that accompanied Mr X's application.
- 1.16 For the purposes of the AAT proceedings, on 8 November 2011 DoH Legal Services sought instructions from the Pharmacy Location Rules section within DoH, which also operates as the ACPA Secretariat.³ An officer in that section noted the contradiction between the survey that Mr Y submitted in his AAT proceedings and the survey Mr X submitted in support of his application for the approval of pharmacy X.
- 1.17 On 9 November 2011, in comments in response to DoH Legal Services, the officer noted:

If the straight line distance measurement between the proposed premises and approved premises at [pharmacy X's new location], is correct at 1.56km, then the recommended (approved) applicant for [pharmacy X's new location] would have failed under Rule 105.

1.18 That is, the survey provided by Mr Y showed that the relocated pharmacy X was too far from its original site (1.56 km rather than 1.5 km), and it later transpired too close to pharmacy C (477m rather than 500m), to qualify for approval under Rule 105.

Dealing with the contradictory surveys

- 1.19 On 9 November 2011 the Pharmacy Location Rules section/ACPA Secretariat requested that an independent survey be obtained through the Australian Government Solicitor (AGS).
- 1.20 The independent survey was consistent with Mr Y's survey and was provided by the AGS to the ACPA Secretariat at 11.32 am on 23 December 2011 with the [comment...] that it 'must cast doubt on the earlier (unrelated) application to relocate from [Mr X's original premises]'.
- 1.21 The ACPA Secretariat and DoH Legal Branch consulted AGS by telephone the same day (23 December 2011). This was the last working day before Christmas in 2011. Owing to a Public Service holiday observed by DoH on 28 December 2011, the next working day for DoH was 3 January 2012.
- 1.22 No records of the advice AGS gave DoH on 23 December 2011 that were made on that date have been uncovered by our investigation. DoH reports that it was advised that it

The same DoH officer (Officer Q) signs correspondence on behalf of the Secretariat and also on behalf of the Pharmacy Location Rules section of DoH.

could not provide the results of the independent survey to the Secretary's delegate in DHS, until AGS had the opportunity to consider the matter further and that written advice would be provided on 4 January 2012.

Approving Mr X's application in respect of pharmacy X

- 1.23 DHS did not observe the Public Service holiday on 28 December 2011. On 28 December 2011, the delegate in DHS accepted the ACPA's recommendation in respect of pharmacy X and granted the approval to dispense medications under the PBS from that site.
- 1.24 On 3 January 2012 AGS sent an email to DoH [reflecting ...] its understanding that the Secretary's delegate in DHS had not yet approved the application.

A missed opportunity

- 1.25 On 4 January 2012 AGS advised DoH that it would be prudent for the ACPA Secretariat to advise the relevant delegate in DHS that the ACPA had new evidence relevant to the applicant's application for the relocated pharmacy and was considering how to proceed. AGS advised that the DHS delegate may wish to hold off making any decision until the beginning of the following week.
- 1.26 On 5 January 2012, the Secretariat contacted DHS and discovered the decision to approve the application had already been made by the delegate and advised AGS accordingly.
- 1.27 In an email of 5 January 2012 AGS advised DoH that it would cease preparation of the requested advice [but made relevant passing comments]
- 1.28 [Subsequently DoH concluded that ...] the Secretary's approval in this case was [...] valid.
- 1.29 Our investigation found no further evidence of any discussion between DoH and AGS about whether at that point in time the erroneous approval might be recalled or corrected, even though the successful applicant may not have acted on it in the few days that had elapsed since 28 December 2011. Nor was there evidence of consideration of any impact the incorrect approval decision might have on other pharmacies located in the precinct.⁴

Mr C's efforts to resolve his complaint with DOH and DHS

- 1.30 In February 2012, Mr C discovered from conversations with his customers that pharmacy X had begun dispensing PBS medications from its new location. Mr C's lawyer wrote to the Secretariat on 13 February 2012 and requested a statement of reasons under the *Administrative Decisions (Judicial Review) Act 1977.*
- 1.31 The Secretariat sought legal advice and, on 20 February 2012, declined to provide a statement of reasons to Mr C's lawyer by letter signed by Officer Q, advising that Mr C was not a person aggrieved by the decision and as such was not entitled to receive a statement of reasons for it. [...] We consider that advice was incorrect.⁵
- 1.32 The Secretariat did not provide any information to Mr C about either the application for approval of pharmacy X or Mr Y's application for approval for pharmacy Y, or the surveys in

Pharmacy Guild of Australia v ACPA, [FCA Branson, J 1996]. The decision in respect of the 'person aggrieved' point had not been superseded.

Our investigation found [evidence that options for undoing a recommendation had been considered possible on a previous occasion, where, among other preconditions, the decision has not been notified....]

support of those applications. DoH says the Secretariat [sought legal advice and] considered that the information was confidential under s135A of the Act [...].

- 1.33 Mr C obtained information about the distance between pharmacies C, X and Y from independent observation. He then commissioned his own survey, which he provided to the Secretariat on 28 March 2012 and to DHS on 2 April 2012.
- 1.34 On 19 April 2012, Mr C also wrote to the Minister for Health about his belief that the application concerning pharmacy X should not have been approved.
- 1.35 On 5 April 2012 the Secretariat responded by email advising that the ACPA was satisfied, on the evidence available to it on the date it made its recommendation, that the pharmacy X application met the requirements of rule 105 of the Rules and that the ACPA was unable to reconsider its decision regardless of any new information. The Secretariat's response noted that decisions of the ACPA are reviewable by the Federal Court on a point of law and recommended Mr C seek his own independent legal advice before proceeding.
- 1.36 Thereafter Mr C contacted DHS at regular intervals to follow up his complaint to that agency.
- 1.37 DHS conducted a site visit to the precinct on 24 May 2012. DHS wrote to Mr X [or his representatives on four occasions in 2012 from 28 May 2012 ...]
- 1.38 Following a request from Mr X's representatives that an amicable resolution be achieved, DHS wrote to them again on 27 September 2013 and 17 October 2013. DHS suggested in the latter correspondence that Mr X approach the Pharmacy Guild of Australia for the purposes of mediating between himself and Mr C.
- 1.39 We understand that Mr X responded to DHS' letter, [...and] he raised concerns that Mr C had not objected during the approval process. We consider this demonstrates that Mr X had assumed that Mr C, as the proprietor of pharmacy C in the precinct, would have been advised of his application to dispense PBS medications from pharmacy X before the decision was made.
- 1.40 On 4 June 2012, Officer Q responded to Mr C on behalf of the Minister for Health. The response noted that the ACPA can only consider evidence before it at the time it considers an application, regardless of any new information that subsequently becomes available. The letter advised that under the Rules the ACPA must satisfy itself that, on the day it considers an application, the requirements of the particular Rule under which the application was made are met; that there is no provision for the ACPA to remake its recommendation; that DHS has the responsibility of ensuring compliance with the PBS program including the granting and cancelling of approval and that Mr C's correspondence has been referred to DHS. The letter does not contain any information about the independent survey commissioned by the Secretariat and does not admit any error had been made.
- 1.41 On 4 June 2012, Officer Q of DoH also wrote to DHS about the referral of Mr C's complaint, enclosing a copy of the independent survey that AGS commissioned at DoH's request. The survey included photographs dated 14 December 2011. Representatives of DHS and DoH also discussed the matter at monthly meetings about Pharmacy Location Rules Issues.
- 1.42 On 18 June 2012 DHS sought legal advice [... on the facts known to it, which did not include the date of receipt of the independent survey] concerning the lawfulness of the approval decision and whether it might be reconsidered. [...abridged...] [DHS concluded] the incorrectly made decision could not now be remedied [...].

- 1.43 On 13 July 2012, DHS asked DoH to clarify whether the usual consultation processes had been undertaken in the approval process for pharmacy X. DHS referred to Mr X's question about why Mr C had not raised his concern about the distances between pharmacy C and the pharmacy X at an earlier time.
- 1.44 Officer Q responded on 16 July 2012 that DoH had not, and was not obliged to, consult the surrounding pharmacists. In a separate email the same day Officer Q confirmed that DoH had received the independent survey report on 23 December 2011.
- 1.45 On 17 July 2012 DHS sought further legal advice [and concluded it would not be appropriate to take any action unless the complainant...] or some other person, challenged the decision in a court. [...].
- 1.46 On 31 July 2012 the Acting National Manager, Ministerial Coordination and Parliamentary, in DHS advised Mr C that DHS was looking into his complaint about the approval of pharmacy X.
- 1.47 On 17 August 2012 DHS wrote to Officer Q regarding its proposed response to Mr C's complaint, advising:
 - [Mr C] will also be advised that at the time the delegate assessed the application there was no indication that any information was incorrect, and therefore the Secretary's decision was correctly made and is valid and it will be suggested that he seek further legal advice through his legal representative.
- 1.48 In our view, it was incorrect to say that there was 'no indication that any information was incorrect' on 28 December 2011. While the incorrect information may not have been apparent to the delegate in DHS, it was known to the DoH Secretariat on that date. However, DHS has advised us that it was responding on its own behalf and not on behalf of DoH.
- 1.49 On 28 August 2012 the National Manager, DHS, replied to Mr C that '[a]t the time of approval, the information before the delegate of the Chief Executive Medicare on behalf of the Secretary of the Department of Health and Ageing met all of the legislative requirements under section 90 of the *National Health Act 1953*' and that Mr C may wish to seek further advice through his legal representative.
- 1.50 In September 2012 Mr C met Mr Y, the proprietor of pharmacy Y. Mr Y informed Mr C of matters relating to Mr Y's approval application. Mr Y told Mr C that Mr Y's survey had contradicted Mr X's survey and had been provided to the ACPA in 2011.
- 1.51 On 24 October 2012, after meeting Mr Y, Mr C lodged an application with the AAT for review of DHS' decision to approve Mr X's application. However, the AAT informed Mr C that it could only review decisions that declined approvals and his complaint concerned the giving of an approval. The AAT told Mr C he would need to apply to the Federal Court, which he advised [would be costly].

Ombudsman's consideration of Mr C's complaint

1.52 While we were considering Mr C's complaint, in October 2013, the Federal Court decided *Kastrinakis v ACPA & Ors* [2013] FCA 995, concerning the ACPA's recommendation in respect of an unrelated pharmacy. The court accepted an argument on the application of jurisdictional error to a recommendation for approval by the ACPA based upon incorrect distance information. In particular, Davies J distinguished the *Australian Pharmacy Guild* case [see footnote 5] on the basis of the High Court [decision in *Enfield City Corporation v Development Assessment Commission*⁶] and the new Rules, and concluded that meeting the

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⁶ [2000] HCA 5.

distance requirement was a jurisdictional fact. This meant the approval in that case was not valid because the distance requirement was not met. It follows that the decision to approve pharmacy X, about which Mr C has complained, might have been open to a similar challenge. It is acknowledged however that neither DoH nor DHS would have had the benefit of this judgement at the relevant time and that the agencies relied on legal advice [...].

Proposing a remedy for Mr C

- 1.53 In December 2013, the Ombudsman wrote to DoH to communicate his preliminary view about Mr C's complaint. DoH did not dispute our outline of the facts, but does not agree that its actions were unreasonable, that defective administration had been established or that any error made by it caused loss for Mr C.
- 1.54 On 3 March 2014, after considering the DoH's response to his preliminary view, the Ombudsman wrote again to the DoH. The Ombudsman made a recommendation under paragraph 92 of the *Finance Circular 2009/09* that DoH consider paying Mr C compensation for detriment caused by defective administration.
- 1.55 DoH's response to the Ombudsman indicated that it remained of the view that its actions were not unreasonable, did not amount to defective administration and that it did not agree that any error made by it caused loss to Mr C. However, DoH advised it would put any application with evidence of loss made by Mr C to its Minister for consideration. We conveyed this information to Mr C.

PART 2—SYSTEMIC WEAKNESSES

- 2.1 In our view, the design of the approval process for pharmacies to dispense PBS medications made it vulnerable to errors of the type that occurred in this case. The weaknesses included:
 - cross agency decision-making combined with uncertainty about whether s135A of the National Health Act permitted relevant information to be transferred between different participants in the same process
 - the apparent inability to correct errors combined with a low evidentiary threshold (an unregistered surveyor's report prepared for the applicant)
 - the absence of consultation with nearby pharmacies or other informed stakeholders.
- 2.2 Taken together, these deficiencies left little opportunity for checks and balances to prevent errors and no scope for service recovery. Moreover, timely action was not taken when the error was discovered. Subsequently, when a person affected by the error (Mr C) complained about it, the agencies responded in a defensive manner which, in turn, prolonged the complaint experience and impeded Mr C's capacity to resolve the matter.

Consultation with nearby pharmacies

- 2.3 On 13 April 2012 the Pharmacy Guild of Australia wrote to the Pharmacy Location Rules Section of DoH regarding 'the process of notifying nearby approved pharmacies when an application for approval to supply pharmaceutical benefits is lodged'. The Guild raised concerns that there was no guarantee that the ACPA would write to all nearby pharmacists who might be affected. The result was that these pharmacists did not have the opportunity to supply evidence which may have assisted the ACPA, leaving some to take costly legal proceedings which might have been avoided by an opportunity to comment on the application. The Guild also suggested that where an application concerned the measurement of a distance, which was close to the allowable distance, the ACPA should seek advice from a second independent surveyor at the cost of the applicant.
- 2.4 DoH responded on 1 May 2012. It stated that it could not guarantee to write to all surrounding pharmacists first, because its database was not able to identify all of the contact addresses of all pharmacies in a location; and, secondly, the ACPA secretariat does not have real time data to capture surrounding pharmacies that have recently been approved. However, it advised:

Where the ACPA considers that a distance requirement for a particular application is close or questionable (whether raised by a surrounding pharmacist or not), the decision on the application is usually deferred and an independent survey is obtained at the Department's expense.

. . .

While the majority of comments from surrounding pharmacist (sic) do not provide relevant information for the ACPA and the worth of the process has been questioned, there are cases where surrounding pharmacists do provide the ACPA with significant information which informs the decision-making process.

. . .

In addition ... for Rule 125⁷ - short distance relocation (more than 1 km), to enable a surrounding pharmacist to comment would require the identification of the existing premises and therefore potentially the identification of the owner. This would provide specific information about the commercial plans / activities of the applicant to the surrounding pharmacies. To provide such information may be in breach of the secrecy provisions of the *National Health Act 1953*.

- 2.5 DoH also advised that it would 'continue its efforts to ensure, but cannot guarantee⁸, that comments are sought from surrounding pharmacies, where relevant.' In doing so, DoH advised that it is required to have regard to the secrecy provisions under s135A of the *National Health Act* when considering seeking views from nearby pharmacies.
- 2.6 In the case of the approval of pharmacy X, consultation with the surrounding pharmacists would have notified Mr C who could then have raised his concerns prior to the decision being made. Moreover, it is apparent that the applicant and the Secretary's delegate in DHS expected that any objections would be made in this way.
- 2.7 In relation to the DoH concerns that it did not have the data to guarantee that every potentially affected pharmacist would be consulted and that it might breach the Act by so doing, we do not consider these concerns are necessarily impediments. To demonstrate compliance with rule 105, Mr X had identified pharmacy C in his application. Moreover, most approved pharmacies, including pharmacy C, would appear to be on the Pharmacy Approval database and there are other reasonable searches that might be made to enable their identification. An applicant pharmacist could be required to identify surrounding pharmacies in their application for approval. In our view an administrative process, to obtain the consent of applicants to the release of such information as is necessary for consultation with potentially affected pharmacists and that does not conflict with the Act, could be devised notwithstanding the secrecy provisions in the legislation.

Recommendation 1

A consultation process with potentially impacted pharmacies is developed to enable the receipt of comments on an application prior to the making of a recommendation or decision on that application.

Inability to correct errors combined with low evidentiary threshold

It was critical to the ACPA's recommendation to approve the dispensing of PBS 2.8 medications from pharmacy X, that the distances between the locations of the pharmacies were accurately measured. Yet, in this case the ACPA accepted evidence of the distances prepared by a person instructed by the applicant and who was not a registered surveyor. DoH has pointed out that the survey letter head indicated the surveyor held a diploma in surveying. However, it is registration rather than qualification that provides access to the profession's complaints body. DoH also said that it relied on a statement in its application materials to the effect that the provision of false or misleading information is an offence under the Criminal Code 1995. However this is no protection against ordinary mistakes which, in the Ombudsman's experience, are more common than an intention to mislead. The applicant had a right of appeal to the AAT in the event that an error was made resulting in a decision not to recommend approval of his application. However, if an error was made in the applicant's favour, which might impact on surrounding businesses, there was no right of appeal to the AAT and the legal options for correcting an error after approval was given were limited and costly.

The 2006 Rules had been revoked by this time and replaced with rules affecting applications made from 18 October 2011.

- 2.9 In this case, the survey submitted by Mr X showed the relocated premises to be 1386m from the original site by straight line and 515m from pharmacy C by straight line. The requirements to meet rule 105 were that the premises be between 1000m and 1500m from the original site and over 500m from another approved pharmacy. We note the 15m, by which Mr X's survey represented that the new location complied, did not trigger the ACPA Secretariat to request its own survey or seek further evidence.
- 2.10 In our view, the decision-maker's level of satisfaction as to the facts on which an administrative decision is based should increase in proportion to the consequences of that decision, in particular where the decision cannot be readily corrected. In this regard we acknowledge DoH's advice to us on 25 February 2013 in response to our investigation, that the ACPA is now more cautious when considering survey reports:
 - "...whilst there is no requirement for the Authority to gather its own evidence, where there is any doubt, the Authority will continue to commission its own independent survey report. In addition, the Authority will now only consider a survey report that has been prepared by a registered surveyor. This allows for any significant discrepancies in survey reports to be referred to the Survey Board in the relevant state."
- 2.11 DoH also advised that it would consider whether 'an amendment to the (National Health) Act could allow corrective or other action to be taken where there appears to have been a gross error of fact in the evidence provided with an application'.

Cross agency decision-making process

- 2.12 While applications were received and registered by DHS, they were sent to the Secretariat in DoH for handling before and after consideration by the ACPA. Thereafter the same applications accompanied by the ACPA recommendations were returned to DHS for consideration by the delegate of the Secretary of DoH. Yet the Secretariat hesitated in informing the delegate of the existence of the independent survey that suggested an earlier ACPA recommendation was based upon incorrect evidence. The Secretariat also delayed suggesting to DHS that it postpone considering the ACPA's recommendation until a material issue which had come to the Secretariat's attention was clarified.
- 2.13 Despite the Secretariat's officers' awareness, based on two surveys, that Mr X's survey (on which the ACPA's recommendation was based) was more likely than not incorrect, they exercised a misplaced level of risk adversity regarding the provision of information about the independent survey to the delegate in DHS. Instead the officers sought legal advice and, while no record was made on that day, DoH reports the officers [understood ...] they could not inform the delegate in DHS until further advice was provided.
- 2.14 In our view it is difficult to see how s135A of the Act could prohibit the Secretariat officers providing information received in the course of their duties to the Secretary's delegate under the same Act for the purpose of the exercise of functions under that Act, even though that delegate is located in a different government agency provided the information is relevant to the function.
- 2.15 The independent survey information was not personal information; it was not obtained from any 'third person' on the basis of it being for a particular purpose and the information concerned the distance between two locations, which were accessible to the public in any event. The only information the survey may have contained which could be described as 'information with respect to the affairs of a third person' would be the implied existence of an application from a proprietor of a pharmacy in one of the locations it referenced. While this information could not be released to the public at large without consent, it does not seem impermissible to release it to the Secretary's delegate for the purpose of completing the decision making process. DHS already had an awareness of the applications from its role in the receipt of applications. DoH advised its officers were also concerned that the independent

survey might 'infect' the decision-making process in respect of pharmacy X, because it had been obtained to resolve a question arising in a different application. In our view this would only arise if the independent survey were irrelevant to the issues to be decided in respect of pharmacy X, which it was not. The independent survey measured the actual distance between the locations of pharmacies X and Y and was relevant to both applications. Should the delegate have decided to have regard to the information, which was adverse to the interests of an applicant, it would have been necessary to afford that applicant an opportunity to comment on the information. However, this was a not an impediment to DoH advising the delegate of the independent survey.

2.16 In establishing administrative procedures for the shared delivery of a program across more than one agency, consideration should be given in advance to any impediments to dividing the responsibilities for delivery of the program, such as any limitations that might prevent sharing of information. In this case the staff in DoH were uncertain whether they could advise the delegate in DHS about relevant information. Unfortunately, the time taken to obtain formal advice about sharing information meant that it was too late to prevent an incorrect decision being made and critically delayed service recovery action.

Recommendation 2

Where more than one agency is engaged in the delivery of a program, administrative processes should ensure that decision-making is not fragmented, that all decision-makers are able to receive all information relevant to a decision, and that staff training material refers to the provision of information to participants engaged in program decision-making located in other agencies.

Service recovery

- 2.17 Service recovery is one way of managing the risk of error in the delivery of government programs. In this report 'service recovery' refers to an agency's response to risks that materialise and systemic and individual problems that arise in the delivery of services to the public. In the experience of the Ombudsman's office, few programs are amenable to perfect administration and it follows that good administration of a program includes the recognition that service recovery is a central part of program delivery. Consequently, in implementing any program, regard should be had to potential service recovery issues, such as:
 - what issues are likely to arise?
 - who might be affected by the program or complain?
 - who is best placed to remediate any problems or handle complaints?
 - do those officers have the appropriate authorisations?
 - what contact arrangements, tools, training or other materials are required?
 - how to ensure that people (staff and the public) know or can easily find out about a service recovery process?
 - how to ensure that information obtained from service recovery experiences are drawn on for future service improvements?

- 2.18 A number of service recovery issues were identified in the investigation of this complaint, including:
 - the Secretariat identified the error, but did not take timely action to prevent the error having consequential effects, while it was deciding how to respond;
 - the Secretariat did not identify all parties potentially affected by the error;
 - when Mr C identified himself as a person affected by the error, the agencies acted defensively and did not acknowledge or take responsibility for the error or its resolution.

Immediate service recovery action to prevent consequential effects of error

- 2.19 The Secretariat suspected that Mr X's survey might have been incorrect on 9 November 2011, when it requested the independent survey. However, there is no evidence that action was taken at that time to check whether or not the ACPA's recommendation to approve Mr X's application (which had been returned to DHS), had been actioned and, if not, of advice to the delegate that they may wish to delay deciding the matter.
- 2.20 Similarly, there is no evidence to suggest that action was taken to check the progress of the approval process with DHS or advise of the need for clarification when, on 23 December 2011, the independent survey confirmed the error.
- 2.21 Ordinarily, once a decision-maker is ready to make a decision, it should be made without further delay, unless there is a good reason not to do so. In this case the Secretariat had a reasonable basis by 23 December 2011 (two surveys by registered surveyors) on which to suspect that a material piece of information before the decision-maker was incorrect and could result in an incorrect decision. That is, there was a good reason to request that the delegate delay making the decision while the Secretariat, acting in a timely manner, clarified the options. As explained at paragraph 2.14, it would not have been unlawful for DoH to request that the DHS delegate delay their decision or, indeed in our view, to advise them of the independent survey.
- 2.22 However, the Secretariat did not balance the risk of the consequences of advising the delegate to delay the decision against the risk of the delegate making an incorrect decision in the absence of such advice. Instead, the Secretariat allowed the risk of an incorrect approval decision being made to continue while it sought the independent survey and, later, while it sought legal advice.
- 2.23 The risk for DoH in advising the delegate in DHS to delay its decision was that, if this proved ultimately unnecessary, the applicant might complain about the delay and, if that delay were of an unreasonable duration, claim that the new business had lost profits. On the other hand the risk for DoH of failing to advise was that an incorrect decision would be made which, while favouring the applicant, could affect surrounding pharmacies and the reputation of the program.

Identifying who was potentially affected by the error

2.24 Balancing the risks of whether or not to advise the delegate immediately would have included consideration of who was likely to be affected by each option and how. In this case, it was likely to have led to the identification of Mr C as a potentially affected person. This is because the distance between pharmacy C and pharmacy X was included in the (incorrect) survey that Mr X provided in support of his application.

2.25 While, we do not know exactly why the Secretariat or other DoH staff did not suggest the delay of the delegate's decision on 23 December 2011, we note that this is consistent with the subsequent defensive approach that DoH took in response to Mr C's complaint.

Taking responsibility for errors

- 2.26 Once the Secretariat became aware that the delegate in DHS had sent the approval to the applicant, the Secretariat would appear to have done nothing further to minimise any consequences of the error for the public. When Mr C identified himself as a person adversely affected by the approval and queried the basis for it, six weeks after the decision had been made, the Secretariat provided him with inadequate advice and declined to provide him with the reasons for its decision.
- 2.27 It was not until June 2012 that one of the agencies (DHS) sought legal advice about what could be done to remedy the matter. By this time it was too late for an administrative revocation of the decision, as Mr X had relied upon the decision for some 6 months and could potentially himself have been aggrieved by any revocation of the decision. In July 2012, after receiving advice from Officer Q confirming the date of receipt of the independent survey, DHS sought advice [and concluded it would be appropriate to take no action ...] unless another party took proceedings in court.
- 2.28 While both DoH and DHS advised Mr C to seek legal advice, neither agency admitted, explained nor apologised for the error. We do not believe that this was an appropriate response, particularly when Mr C provided a further survey at his own expense, as evidence in support of his complaint that the decision to approve pharmacy X was based on incorrect information.
- 2.29 Indeed DHS' response to Mr C, written after consultation with DoH, appears to have been carefully worded to advise only that the information before the delegate in DHS on the date of the decision supported that decision, with no mention that elsewhere in the decision-making chain (at the Secretariat) there had existed information to the contrary. While DHS advises that it considered this was a matter for DoH, these actions prolonged and exacerbated Mr C's frustration. On the one hand, it was left to him to bear the risk of court proceedings to remedy the error. On the other hand, the agencies declined to give him all of the necessary information to seek advice on his prospects of success.
- 2.30 In our view, the complaint handling aspect of service recovery in this matter was made more difficult by the cross agency nature of the program. DoH did not identify Mr C's request for a statement of reasons as a complaint. While Mr C's complaint was entertained by DHS, that agency did not possess all of the information to fully respond to the complaint.

Recommendation 3

A joint service recovery process should be developed for the pharmacy location program if it continues to be delivered across more than one agency.

If the program is delivered by a single agency, that agency should have a service recovery process that applies to the pharmacy location program.

Staff should be made aware of the service recovery process.

Information about how to complain about the program, consistent with the service recovery process, should be available to the public.

2.31 This investigation also raised concerns about the prominence that service recovery is given in DoH. In our view, the DoH's approach to service recovery and complaint handling veered between cautious and defensive and led to missed opportunities for resolution.

2.32 With the benefit of hindsight, and as an outside observer, it is apparent that DoH could have prevented or delayed the approval by promptly contacting the delegate in DHS. However, the Secretariat officers appear to have lacked the confidence to take any action without legal advice, even where this may have led to a wrong decision affecting others being made in the meantime. While we acknowledge that DoH was concerned about what it describes as 'the litigious nature of the sector', the lesson from this case study is the importance of a culture that supports staff to take preventative action, and to try to mitigate errors, even where they may do so imperfectly.

Recommendation 4

DoH promote a service recovery culture within the agency and ensure that its officers have appropriate delegation or escalation avenues for timely service recovery and are aware that service recovery activities will be supported.

PART 3—CONCLUSION AND RECOMMENDATIONS

- 3.1 This investigation report provides a case study on the consequences of failure to incorporate service recovery into the framework of program delivery design. The consequences of a lack of support for service recovery culture and the role that complaint handling plays within service recovery is also demonstrated. This was particularly evident in the cautious actions of the officers in the ACPA Secretariat, who initially lacked the authority or confidence to take immediate remedial action in the absence of legal advice, despite the fact that this compromised the objectives of the program in that an incorrect decision prevailed; and later defended the reputation of the agency, rather than responding to the complainant in a fair and open manner. We do not mean this as a comment on any individuals, but rather on the scope of the role they occupied and constraints implied by agency culture.
- 3.2 We accept that to empower officers to take the initiative to respond to service failings where, as in this case, circumstances require timely action and an evaluation has to be made (possibly by someone not used to doing so) between imperfect options, carries a risk that the response will not be the one that a fully informed more senior officer may have made. However, as this report shows, to do nothing also carries risk.
- 3.3 Moreover, an approach to complainants that is less than fair and open does not enhance an agency's reputation. In the Ombudsman's experience, a complainant and those to whom his story is conveyed, is likely to complete the missing parts of the story with assumptions which may be less favourable than the explanation which could have been provided by the agency itself. Further the person's unsatisfactory experience with the agency will be aggravated and prolonged if they believe that they have been 'brushed off'.
- 3.4 To address the shortcomings we have identified in our investigation of Mr C's complaint, we make the following four recommendations:

Recommendation 1

A consultation process with potentially impacted pharmacies is developed to enable the receipt of comments on an application prior to the making of a recommendation or decision on that application.

3.5 This recommendation recognises that the relevant legislation gave very little scope for the correction of an erroneous decision by administrative means. In such contexts the administrative processes leading up to a decision should include steps to minimise error, such as consultation processes, regardless of whether these are legal preconditions to the making of the decision. We note DoH has already taken steps in relation to the quality of survey evidence it will now accept.

Recommendation 2

Where more than one agency is engaged in the delivery of a program, administrative processes should ensure that decision-making is not fragmented, that all decision-makers are able to receive all information relevant to a decision, and that staff training material refers to the provision of information to participants engaged in program decision-making located in other agencies.

3.6 This recommendation concerns the contribution of the cross agency design of the decision making process to the resulting decision which did not meet the objectives of the rules. The process unnecessarily fragmented access to information which was relevant to the decision. In the case at hand, officers hesitated to inform other officers involved in the decision making process that there was a significant matter regarding the recommendation

because, while operating under the same Act and program, those other officers were located in a different agency.

Recommendation 3

A joint service recovery process should be developed for the pharmacy location program if it continues to be delivered across more than one agency;

If the program is delivered by a single agency, that agency should have a service recovery process that applies to the pharmacy location program;

Staff should be made aware of the service recovery process.

Information about how to complain about the program, consistent with the service recovery process, should be available to the public.

3.7 Few programs are amenable to perfect delivery and good administration includes the recognition of this fact and a service recovery plan encompassing the handling of complaints. The third recommendation concerns the need for a joint service recovery process should the program continue to be delivered across more than one agency. If, in future, the program is delivered by a single agency, then a service recovery process should be devised in relation to the program.

Recommendation 4

DoH promote a service recovery culture within the agency and ensure that its officers have appropriate delegation or escalation avenues for timely service recovery and are aware that service recovery activities will be supported.

3.8 The fourth recommendation concerns the need for a service recovery culture that we believe underscored the failure by the ACPA Secretariat within DoH to take responsibility for the error, take pro-active action to minimise any consequential effects and to consider and respond to the complainant's reasonable concerns. Even where the agency may have been unable to correct the decision, we think it is appropriate to provide the complainant with an explanation and an apology. Consequently, we have recommended that steps be taken to support a service recovery culture within DoH.

PART 4—AGENCY RESPONSES

4.1 A copy of this report was provided to the Secretaries of DoH and DHS for comment by those agencies. A copy was also provided to the Australian Government Solicitor to ensure that references to that body were correct.

Comments and responses to recommendations provided by DoH

A copy of the draft report was provided to the Department of Health on 14 November 2014 for comment. The Department's comments on matters set out in the report have been taken into account in the body of the report.

The Department provided comments on the recommendations in its letter reproduced below:

I refer to your letter of 14 November 2014 and thank you for the opportunity to review and provide comments on the draft report *Department of Health: Avoiding, acknowledging and fixing mistakes* (the report).

The Department is committed to accurate and effective decision-making. Further, it works to ensure processes, particularly those that are outward-facing, evolve to maintain pace with changing provider practice and public governance. For these reasons the Department welcomes the report as an opportunity to further review the processes of the Australian Community Pharmacy Authority (ACPA).

May I acknowledge from the outset the professional and constructive way in which your officers have worked with the Department to progress this report.

It may be useful to make some preliminary observations on the context in which the Australian Community Pharmacy Authority operates. The Authority administers the pharmacy location rules determined by the Minister under the National Health Act 1953 in light of the five yearly agreements reached with the Pharmacy Guild of Australia. Decisions must be made by the Authority in areas of great commercial sensitivity to pharmacists who compete against each other on a local geographic basis. The Authority permits on the one hand access to the operation of pharmacies within a geographical area, whilst at the same time permitting new competition to existing pharmacies in the same areas. The distances selected under the location rules are necessarily arbitrary. Decisions of the Authority are frequently contentious. and often lead to challenges to decisions in the AAT. During the period of the Fifth Community Pharmacy Agreement the Department has dealt with 70 matters in the AAT and 15 in the Federal Court, and provided 168 statements of reasons. Accordingly, the Authority needs to deal with competing stakeholders in an even-handed manner, whilst at the same time conducting itself in a way which does not prejudice the interests of the Commonwealth and others should decisions lead to litigation. The appropriate management of complaints need on the one hand to deal fairly and reasonably with stakeholders, whilst managing legal risk appropriately in a contentious and often litigious environment. At the same time, staff need to ensure that information which is frequently commercially sensitive is managed in a way which does not infringe privacy constraints or the prohibitions contained in s.135A of the National Health Act. This raises challenges for a complaints handling system which do not arise where a single party (with interests which do not conflict with the interests of any other individual) is concerned. The Department is happy to review its complaints handling processes and procedures, but notes that this will need to be done against an often contentious and sensitive context, in a way which ensures the information of all parties concerned is treated in line with legislative constraints, and in a way which does not prejudice the position of the Commonwealth or individuals in any litigation which may result.

As I noted previously, the Department welcomes, and is broadly supportive of, the recommendations in the report as an opportunity to improve processes in relation to the ACPA and the Department more generally. I make the following additional observations about the individual recommendations.

Recommendation 1 – Consultation with nearby pharmacies:

The report has identified that where possible, and with appropriate reference to the secrecy provisions of the Act, the ACPA secretariat makes significant efforts to ensure that surrounding pharmacists are provided the opportunity to comment on relevant applications, consistent with the obligations imposed on them under the *Privacy Act* and the confidentiality constraints set out in section 135A of the *National Health Act*. The Department also notes the limitations of the existing pharmacy database and will investigate options for more frequent updates to the database to reflect approvals made by the delegate at DHS, or other means by which up-to-date details of surrounding pharmacies can be obtained in a timely manner.

Recommendation 2 – Cross agency decision-making process

The Department accepts that improved information sharing between administrative and delivery agencies is likely to enhance the consistency of decision-making. The Department will work with DHS to further enhance the connection between the agencies and ensure that documented systems are instituted to ensure information is shared in a timely manner to the extent practically and legally possible.

Recommendation 3 - Service recovery

While I note the report advocates for the ACPA administrative and delivery processes to be operated through a single agency, a decision to move functions between agencies is ultimately a matter for Government. However, and in relation to service recovery processes for the ACPA and pharmacy approval processes generally, I suggest that enhanced communication between the Department and DHS outlined above, in addition to consideration of possible changes to the Act enabling reversal of an ACPA recommendation and subsequent approval where they have been made in error will significantly improve service recovery for this programme.

Recommendation 4 – Departmental service recovery culture

Both this report and the Capability Review of the Department by the Australian Public Service Commission released on 4 December 2014 provide an opportunity to take the Department forward, build the capability for the future and make the Department the best organisation it can be. In particular the Department must address some inadequate governance arrangements and delivery frameworks and also foster a culture that that is open and appropriately embraces and manages risks within defined tolerances. The Department is committed to achieving the necessary reforms, including service recovery, and understands this will require the contributions of all staff at all levels.

Thank you again for providing the department an opportunity to comment on the draft report.

Yours sincerely

Martin Bowles PSM Secretary 22 December 2014

Comments and response to recommendations provided by DHS

A copy of the draft report was provided to the Department of Human Services on 14 November 2014 for comment. The Department's comments on matters set out in the report have been taken into account in the body of the report.

The Department provided the following comments on the recommendations:

Recommendation 1

The first recommendation is that a consultation process be established to enable potentially impacted pharmacies to make comments on an application prior to a recommendation or a decision being made in respect of the application.

The department agrees that having a formal consultation process is likely to mitigate the risk of similar problems arising with respect to pharmacy approval processes going forward. However, the department submits that any consultation should occur only once, and would best occur prior to the ACPA making its recommendation in relation to an application. The department sees little merit in further consultation occurring after the ACPA has made its recommendation, noting that potentially impacted pharmacies could still make submissions to the department or the Department of Health following that recommendation but prior to the departmental delegate's approval of the application

Recommendation 2

The second recommendation is that administrative processes should ensure that decision making is not fragmented, that all decision makers should receive information relevant to the making of decisions, and that training material should refer to relevant information being exchanged between decision makers in different agencies.

The department agrees with this recommendation insofar as it relates to the exchange of relevant information. The department notes that decision making in relation to pharmacy approvals remains fragmented to some extent as a result of the applicable statutory framework, which provides for a two stage process involving different decision makers located in different agencies.

Recommendation 3

The third recommendation is that a joint service recovery process be developed in relation to the pharmacy approval application process.

The department takes the view that service recovery processes should be in place to mitigate any potential risks identified with decision making processes associated with the approval of pharmacies to supply PBS medicines. The department therefore agrees that a service recovery process should be developed to address the particular deficiencies identified by this investigation, which centre on the failure of relevant information being considered by, and made available to, decision makers in the department and the Department of Health.

Recommendation 4

The department has no comment to make on the fourth recommendation, which is directed at the Department of Health.

Thank you for giving the department an opportunity to comment on the draft report.

Yours sincerely

Kathryn Campbell December 2014

APPENDIX

Extract from Pharmacy Location Rules Applicant's Handbook current at 2011

8. Opportunity for nearby pharmacists to provide comment

Once an application has been referred to the ACPA, it is standard practice for the ACPA to seek comments from other pharmacists in the vicinity of the proposed pharmacy. This practice applies to nearly all types of applications.

The ACPA is not required or obliged to seek comments from nearby pharmacists, or to advise pharmacists that an application for approval has been made. However, this practice of seeking comments allows other pharmacists the opportunity to comment on whether, in their opinion, the proposed pharmacy would meet the requirements of the pharmacy location rules. It is also informative for the ACPA to obtain information from persons other than the applicant, who have specialised knowledge of a particular area. Pharmacists will generally be given two weeks to respond.

The ACPA cannot guarantee that it will write to all pharmacists who might be affected by an application for approval. It may be in the interest of any pharmacist that receives

Pharmacy Location Rules - Applicant's Handbook

an invitation for comment to make sure other pharmacists in the area are informed and have the opportunity to comment.

Any comments must be made in writing to the ACPA and should relate to the relevant criteria of the pharmacy location rules. Giving false or misleading information is a serious offence under Division 137 of the *Criminal Code 1995*, the maximum penalty for which is imprisonment for 12 months.

Once the ACPA has made a recommendation in respect of an application, the ACPA will write to any pharmacist that provided comments on that application to advise the outcome. It should be noted that if an ACPA recommendation is subsequently the subject of an appeal to the Administrative Appeals Tribunal (AAT) or a Federal Court, the ACPA will only advise pharmacists, who provided comment on the application, of the appeal.

The details of any comments, including the pharmacist that made the comments, will not be disclosed to the applicant or any other party. However, it is important to note that if the ACPA's recommendation is the subject of a review by the AAT or a Federal Court, then any comments provided on that application will be released to the applicant and the AAT or court. Further, any comments provided on an application may have to be released under the *Freedom of Information Act 1982*.