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Performance Audit

Management of the National Medical Stockpile

Department of Health

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Canberra ACT
26 June 2014

Dear Mr President
Dear Madam Speaker

The Australian National Audit Office has undertaken an independent performance audit in the Department of Health titled *Management of the National Medical Stockpile*. The audit was conducted in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit to the Parliament.

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's website—<http://www.anao.gov.au>.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ian McPhee', is positioned above the printed name of the Auditor-General.

Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits, financial statement audits and assurance reviews of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

For further information contact:

**The Publications Manager
Australian National Audit Office
GPO Box 707
Canberra ACT 2601**

Phone: (02) 6203 7505

Fax: (02) 6203 7519

Email: publications@anao.gov.au

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Audit Team

Marian Allen
Brett Goyne
Clifford Lloyd
William Na
Michael Masters
Fiona Knight

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Abbreviations

AHMPPI	Australian Health Management Plan for Pandemic Influenza
AHPPC	Australian Health Protection Principal Committee
ANAO	Australian National Audit Office
ASIO	Australian Security Intelligence Organisation
CHO	Chief Health Officer
CMO	Chief Medical Officer
CBRN	Chemical, Biological, Radiological and Nuclear
CPRs	Commonwealth Procurement Rules
FIFO	First-In, First Out
IDSC	Interdepartmental Steering Committee
KPI	Key Performance Indicator
MoU	Memorandum of Understanding
NIR	National Incident Room
PPE	Personal Protective Equipment
SARS	Severe Acute Respiratory Syndrome
Stockpile	National Medical Stockpile
TGA	Therapeutic Goods Administration
WHO	World Health Organization
WMS	Warehouse Management System

Glossary

Antivirals	A type of medication used for treating viral infections, such as influenza.
H1N1	Swine flu influenza.
H5N1	Avian influenza.
Neuraminidase inhibitor	A type of antiviral drug that stops the function of the neuraminidase protein, which is required to replicate the influenza virus.
Personal Protective Equipment	Refers to protective clothing, gloves, goggles, masks and respirators designed to protect the wearer from infection, including viruses such as influenza.
Tamiflu	The trade name for oseltamivir, a neuraminidase inhibitor (see above) used in the treatment of Influenza A.
Relenza	The trade name for zanamivir, a neuraminidase inhibitor (see above) used in the treatment and prevention of influenza caused by influenza A and B viruses.
Vaccine	A formulation that stimulates an immune response to prevent infection or disease when administered.

Summary and Recommendations

Summary

Introduction

1. The National Medical Stockpile (the Stockpile) is a strategic reserve of medicines, vaccines, antidotes and protective equipment available for use as part of the national response to a public health emergency. It is intended to augment state and territory government reserves of key medical items in a health emergency, which could arise from terrorist activities or natural causes such as the 2009 influenza pandemic.
2. The Stockpile is intended to increase Australia's level of preparedness and self-sufficiency during a health emergency, by storing items that may not otherwise be available in Australia in the quantities required, and which may not be accessible from overseas suppliers in the event of an international health emergency.¹
3. The Stockpile was originally established in 2002 as part of the Australian Government's response to the threat of international terrorist attacks. Since 2002 the Stockpile has expanded from a relatively small reserve valued at approximately \$11 million intended to deal with chemical, biological, radiological and nuclear (CBRN) threats, to a resource with a reported value of almost \$196 million in 2012–13.² The Stockpile, comprising 42 products and over 110 million items³, is now dominated by products associated with human influenza pandemic preparedness.
4. The Department of Health is responsible for the planning and management of the Stockpile, while state and territory governments are responsible for deploying Stockpile items within their jurisdictions in the event of a national health emergency.⁴ The Stockpile is warehoused at facilities

1 The Stockpile is comprised of specialised pharmaceuticals and personal protective equipment from overseas suppliers. Securing an adequate supply of relevant items in the timeframes required can be a challenge if there is a global surge in demand, as would be the case in a pandemic.

2 Department of Health and Ageing, *Annual Report 2012–13*, Audited Financial Statements, p. 349. The Department of Health advised in June 2014 that the value of the Stockpile in 2013–14 is approximately \$192 million.

3 Ernst & Young, 'Department of Health and Ageing: National Medical Stockpile Stocktake 2012–13', 30 June 2013.

4 The Department of Health has entered into Memoranda of Understanding with each state and territory for the receipt, storage and use of pharmaceuticals and equipment from the Stockpile.

operated by logistics firms, under contracts administered by the Department of Health.

5. Key challenges in planning for and administering the Stockpile include effective: stock selection and procurement; warehousing to maintain the efficacy of items⁵; stock-control to account for and locate items; and dealing with items as they reach their expiry dates.⁶ Unlike other inventories which are continually being recycled, an emergency stockpile is infrequently deployed and significant volumes of unused goods need to be disposed of on expiry.⁷

6. The limited shelf life of medicines and equipment and the long-term maintenance of emergency stockpiles constitute a significant cost for government, with over \$750 million allocated for the Stockpile in the past ten years.⁸ In 2011, the Department of Finance completed a strategic review⁹ which recommended a number of significant changes to Stockpile management, including a more commercially focussed 'prime vendor' arrangement for outsourcing some management functions under a single contract. In September 2011, the Department of Health also finalised a review of the Australian health sector's response to the 2009 pandemic. The key finding relating to the Stockpile was that while it met the relatively limited demands of the 2009 pandemic, which was considered to be of moderate intensity, it may not meet the more intense demands of a severe pandemic. The review made 25 recommendations including two related to the Stockpile's deployment. Implementation of the Department of Finance and Health reviews remains ongoing.

Audit objective, criteria and scope

7. The audit objective was to assess the effectiveness of the Department of Health's management of the National Medical Stockpile.

5 Certain items must be stored in a controlled environment.

6 The notes to the department's financial statements for 2012–13 indicated that \$4.36 million in Stockpile inventory would pass its expiry date during the period July to September 2013. See Department of Health and Ageing, *Annual Report 2012–13*, p. 349.

7 \$145 million worth of stock had expired in 2010–2011. The expired stock comprised some 2,352 pallets in storage, the bulk of which were PPE, influenza antiviral and antibiotic. The department advised that the cost of storing expired stock in 2010–11 was \$160 000.

8 Department of Finance advice to the ANAO, dated 8 August 2013, based on analysis of Commonwealth Budget Paper 2: 2003–04 to 2013–14.

9 Department of Finance, 'Review of the National Medical Stockpile', 2011.

8. To assist in evaluating the department's performance in terms of the audit objective, the ANAO developed the following high level criteria:

- the Department of Health has sound governance arrangements in place for the management of the Stockpile, including an integrated and systematic approach to risk management and performance reporting;
- the Department of Health's procurement and contract management arrangements for the Stockpile demonstrate a focus on getting the right outcomes and achieving value for money;
- the Stockpile's inventory management system reflects value for money—it provides an assurance that the right items in the correct amount are being purchased, and stored appropriately, until they are either deployed, or they are disposed of on expiry; and
- the deployment plans and processes provide a high level of assurance that the Stockpile can be reliably deployed within agreed timeframes to agreed locations.

9. The ANAO did not assess processes for the disposal or destruction of expired stock.¹⁰ While the audit examined aspects of the deployment strategy for the Stockpile, it did not seek to assess Australia's general preparedness to respond to a national health emergency. Nor did the audit assess the clinical efficacy of stockpiled items.

10. An ANAO performance audit in 2007–08 on Australia's pandemic preparedness concluded that the Stockpile was established without high level planning, assessment of risks and an appropriate management framework.¹¹ The ANAO recommended a shift from a short term 'supply and store' strategy for the Stockpile to a longer term management strategy. The current audit was not intended to assess implementation of all the earlier audit recommendations. However, in the course of the audit the ANAO considered the extent to which the Department of Health has implemented recommendations relating to the Stockpile.

10 For example, the ANAO did not undertake control testing of the disposal or destruction of expired stock. The disposal of expired stock was the subject of a 2012 internal audit by the department.

11 ANAO Performance Audit Report No.6 2007–08 *Australia's Preparedness for a Human Influenza Pandemic*, pp.20-21, p.99.

Overall conclusion

11. The maintenance of the National Medical Stockpile (the Stockpile) since 2002 represents a significant government investment in the nation's preparedness for public health emergencies resulting from terrorist activities or natural causes such as pandemics; with over \$750 million allocated for the Stockpile in the past decade. In 2012–13 the Stockpile comprised 42 products and over 110 million items, with a reported value of almost \$196 million. The effective management of this large strategic reserve, comprising pharmaceuticals and personal protective equipment with a limited shelf life, relies on planning and administrative arrangements geared to: select and procure appropriate items; warehouse and control the stock; and deal with expiring items. Effective deployment arrangements are also required to augment state and territory reserves of items from the Stockpile in a timely manner.

12. Overall, the Department of Health's management of the National Medical Stockpile has been generally effective in recent years, benefiting from improvements introduced since 2010. There remains scope, however, for improving the department's strategic framework, operational management and deployment arrangements for the Stockpile.

13. Since 2007, when the ANAO concluded that the department had not developed an appropriate framework for managing the Stockpile¹², the Department of Health has implemented a more structured management approach, including: the development of strategic and operational risk management plans in 2010; the rationalisation of previously fragmented storage contracts in 2010; the application of an evidence-based approach for the selection of appropriate stockpile items; and the maintenance of formal deployment arrangements with states and territories. Strategies have also been adopted or examined for the cost-effective replenishment and disposal of expired stockpile items. However, there remains scope for improving key elements of the department's management arrangements, including: updating the strategic and operational risk management plans; clarifying aspects of the storage contracts to strengthen reporting and performance monitoring; improving the integrity of data used to manage the stockpile; and planning to

12 ANAO Performance Audit Report No.6 2007–08 *Australia's Preparedness for a Human Influenza Pandemic*, pp. 20–21, pp. 95–99.

test Stockpile deployment arrangements. Key issues relating to the Stockpile's strategic framework, operational management and deployment are discussed in the following paragraphs.

14. The department adopted a more strategic approach to the Stockpile's management with the introduction of a strategic plan in 2010, albeit some eight years after the Stockpile was established. While the plan broadly describes the governance, funding and administrative arrangements for the Stockpile, it should be updated to identify objectives, priorities and strategies for the Stockpile's management—key elements of a strategic plan. High level outcomes for the Stockpile agreed to in 2011 by the then Government should also be reflected in an updated plan.

15. Operational management of the Stockpile benefited from the introduction of an operational risk management plan in 2010, which should be updated to reflect risks identified in the Department of Finance's 2011 Strategic Review of the Stockpile.¹³ Operational management was further improved with the consolidation of warehousing arrangements into two longer-term contracts with logistics firms, relating to pharmaceutical items and personal protective equipment. However, management reports have not been regularly provided, as required under the contracts, and the department should clarify reporting obligations. Further, there is scope to address weaknesses in some system controls and shortcomings in manual processing, which have contributed to the emergence of data integrity issues such as discrepancies between information held in the Stockpile database and warehouse system records.

16. The department has developed a deployment framework with states and territories, although these arrangements have not been recently tested. To provide assurance that deployment arrangements will be effective in a national health emergency, the department should undertake planning to test deployment arrangements, in consultation with other jurisdictions.

17. While there remains scope for further improvement as indicated above, the department's work in recent years demonstrates a more active approach to management of the Stockpile, as does the recent focus on the findings of the 2011 Strategic Review. The ANAO has made four recommendations aimed at

13 These included a lack of logistics and inventory management expertise within the Department of Health and shortcomings in the Stockpile's information management systems.

improving the effectiveness of the department's management of the Stockpile, by: improving strategic planning and risk management; enhancing performance reporting by contractors; reviewing information management arrangements; and planning to test deployment arrangements.

Key findings by chapter

Strategic Framework (Chapter 2)

18. The ANAO's 2007–08 audit observed that the establishment of the Stockpile in 2002 occurred without the high-level planning, assessment of risks and management processes that would usually be put into place by an agency to manage policy initiatives. This was partly due to the immediacy of the Stockpile's formation in an environment of rapidly changing and unexpected international events.

19. The department developed a Strategic Management Plan for the Stockpile in 2010, eight years after the Stockpile was first established. The plan broadly describes the governance, funding and administrative arrangements for the Stockpile. However, it does not identify objectives, strategies and priorities to be implemented in the short term and over the longer term—key elements of a strategic plan. Moreover, the plan does not incorporate the high level outcomes for the Stockpile which were agreed to by the then Government in March 2011, an important step towards developing a more strategic approach to managing the Stockpile. The department should update the 2010 Strategic Management Plan to reflect this development and to include objectives, priorities and strategies.

20. In its 2007–08 performance audit, the ANAO also recommended that the department develop a risk management plan for the Stockpile that is reviewed regularly. The department's enterprise-level risk management plan identifies one strategic risk for the Stockpile; inadequate government funding to maintain stock holdings.¹⁴ The department also developed an operational risk management plan for the Stockpile in July 2010, which documents risks, risk ratings and treatment strategies. The operational risk management plan ranks the most significant risks as: security of information on the location and contents of the Stockpile; stored stock being misplaced or destroyed; and stock incorrectly dispatched during deployment. There would be merit in updating

14 This was rated as a 'high' risk for the department.

the risk management plan to reflect more fully the additional risks identified in the Department of Finance's 2011 Strategic Review of the Stockpile.¹⁵

21. The ANAO further recommended, in its 2007–08 audit report, the development of a performance management and reporting framework for the Stockpile, to provide ongoing assurance about the content, storage, security and management of the Stockpile. While quarterly reports were subsequently prepared for senior management, the department advised the ANAO in the course of the current audit that quarterly reporting on the status of the Stockpile was discontinued from April 2011 in favour of issue specific updates. The department will need to exercise judgement that the revised approach provides an adequate basis for senior management to assess performance.

Procurement and Contract Management (Chapter 3)

22. The department currently manages 31 contracts relating to the supply of items and services for the Stockpile. The ANAO examined the department's procurement processes for the supply and storage of stockpile items, as well as contract management arrangements for the two national storage contracts.

23. The department employed a limited tender process for 18 procurements relating to the purchase of pharmaceuticals, on the basis that there was only one organisation that manufactured or was licensed to supply the particular product in Australia. While a limited tender approach in such circumstances is provided for in the Commonwealth Procurement Rules (CPRs)¹⁶, advice to the delegate on the key issue of value for money¹⁷ was generally limited; focusing on concerns that existing stocks of the relevant pharmaceuticals were reaching their expiry date and required replacement to maintain the Commonwealth's capacity to respond to health threats.

24. Thirteen procurements relating to the purchase of pharmaceuticals and personal protective equipment (PPE) were conducted through open tender

15 The Strategic Review identified a range of issues in the management of the Stockpile such as the: inadequacy of the information management system for accurate recording and reporting on the Stockpile's inventory; lack of logistical and inventory expertise within the department to manage the Stockpile; and lack of documented plans and policies including a long-term strategic plan.

16 The CPRs provide that an agency may approach a single entity through a limited tender process where 'the goods and services can be supplied only by a particular business and there is no reasonable alternative or substitute ... due to an absence of competition for technical reasons'. See CPRs, paragraph 10.3(d) (iii).

17 Achieving value for money is the 'core rule' of the CPRs, and financial approvers must be satisfied, after reasonable enquiries, that the procurement achieves a value for money outcome. See CPRs, paragraph 4.4.

processes advertised on *AusTender*.¹⁸ The tenders were subject to evaluation and ranking by a departmental panel according to previously approved criteria, and advice regarding value for money was based on, and consistent with, the panel's recommendations for the preferred tender.

25. The ANAO's 2007–08 audit identified a number of issues with the department's storage contract arrangements for the Stockpile. Subcontracting arrangements had resulted in inconsistent standards and practices that were poorly controlled through the contract arrangements. The department responded through a process which consolidated short-term storage contracts into two longer term contracts relating to pharmaceutical items and to non-pharmaceutical items. An open tender process was conducted for the storage of pharmaceutical items, with three submissions received and one submission assessed as fully compliant. While the successful tenderer was offered a contract in December 2007, the contract was not executed until October 2010, some three years later, due to differences over indemnity issues. A second tender, to consolidate the storage of non-pharmaceutical items, attracted two submissions but issues identified by the tender evaluation committee¹⁹ prompted the department to cease the procurement process and directly procure the services of an existing warehouse provider on the basis that an approach to the market had failed. The department cited the provider's positive performance history with the department as the reason for directly approaching this provider.

26. The ANAO also noted in its 2007–08 report that the department's contracts for warehousing in place at that time did not provide a clear statement of contract requirements. In the current audit the ANAO assessed the 2010–14 contract for the pharmaceutical warehouse provider to assess the clarity of contract deliverables. While the contract requires six-monthly performance reports, these are not always submitted to the department, and the weekly stock-on-hand reports received by the department do not provide routine management information.²⁰ Further, the bi-annual stock cycle counts and annual visual inspections of the stock, also required under the contract, are

18 One supplier of PPE was identified as the preferred provider following an open tender process. The Department of Health established a Deed of Standing Offer allowing for the purchase of this PPE item as necessary and in accordance with an approved fee schedule.

19 An independent financial check of one of the organisations identified viability concerns, while the proposal from the other organisation quoted relatively high fees.

20 For instance, on new stock, damaged and expired stock and stock movements.

not currently being carried out and the outcomes are not reported. The department should review and clarify contract reporting arrangements as a basis for more effectively monitoring performance under the contract.

27. The contract for warehousing personal protective equipment has a measurable set of contract deliverables, and the monthly inventory report provided for in the contract provides a reasonable basis for the department to manage the contract and monitor the status of stockpile items. However, some performance information is not being provided monthly as required, and over time, the monthly inventory management report has also become a weekly stock-on-hand report.²¹ This arrangement has evolved without a formal contract variation—an ad hoc approach which can give rise to inconsistency with contract requirements.

28. The department's annual stocktake of warehoused items has two purposes: to check the accuracy of its information on the Stockpile; and to identify any contract management issues. The stocktake involves physically checking stock against departmental records, identifying any variation and accounting for those variations. Significant contract management issues were identified during the 2011–12 and 2012–13 stocktakes, concerning the management of Stockpile inventory in two warehouses. The department advised the ANAO that it has recently approved alternative sites for these warehouses and the relevant contracts have been varied to reflect the new arrangements.

Inventory Management (Chapter 4)

29. The department has completed two reviews of the CBRN components of the Stockpile, in 2004 and 2008. The 2008 review made nine recommendations, including obtaining government agreement on the purpose of the Stockpile. The then Government agreed to high level outcomes for the Stockpile in March 2011, while a number of other recommendations are still being progressed; such as the development of criteria for item selection and pre-deployment of CBRN items with state governments.

30. The initial stockpiling of antivirals in Australia was carried out in 2003–04 as a response to increasing concerns about avian influenza and the potential for an influenza pandemic. In its 2007–08 audit report, the ANAO

21 The report provides information on the number of pallets stored, as a basis for weekly payments to the contractor.

concluded that Australia had addressed the minimal and desirable elements of the WHO planning framework for a pandemic including stockpiling of antivirals. In the current audit, the ANAO examined the Department of Health's recent evidence gathering to support decisions for inventory selection and the quantity of antivirals and PPE purchased in preparation for an influenza pandemic. The department has commissioned two modelling projects—one on antivirals and one on PPE—to inform its consideration of the evidence base for the pandemic component of the Stockpile. The department's approach is intended to provide assurance that the items and quantities purchased to maintain the currency and capability of the Stockpile are informed by appropriate evidence.

31. The 2011 Strategic Review identified significant costs associated with expiring stock and the lack of cost-effectiveness analysis in the selection of the Stockpile's inventory and quantities.²² The main focus of the department's activities since the Strategic Review has been on replenishing expiring stock and responding to the review's recommendations. The department has commenced development of a more systematic approach to selecting items for the Stockpile, including a draft inventory selection framework. The Department of Health and stakeholder agencies have also explored a range of strategies to reduce Stockpile management costs, including: shelf life extension; stock cycling and rotation; returning expired pharmaceuticals to manufacturers in return for fresh stock; and purchasing generic antivirals as they become available. The department has also conducted progressively larger destruction programs to reduce the costs of storing expired items.

32. The ANAO assessed the effectiveness of selected controls for the management of the Stockpile, including processes for monitoring, reconciling and reporting on stock levels. The ANAO did not assess processes for the disposal or destruction of expired stock as this was the subject of an internal audit by the department in 2012.²³ The internal audit report identified weaknesses in some of the controls associated with the department's processes for disposing of expired stock, such as disposal guidelines, disposal planning,

22 The expiry of stock and the need to replenish items to maintain operational capability has emerged as a key issue in the management of stockpile inventory in Australia and around the world. The pharmaceuticals and nearly all other stockpile items have a finite shelf life which means that they may need to be disposed of at the end of that life without being used. Further, the storage of expired stock incurs a cost.

23 Department of Health, 'Audit of the Management of the Disposal of National Medical Stockpile Expired Stock', Audit Report No.19 of 2011–12, Audit and Fraud Control Branch, January 2012.

stock reconciliation and management reporting. The department advised the ANAO that the recommended process improvements for disposing of expired stock had been implemented.

33. The ANAO reviewed controls for the identification, recording and deployment of stock, with weaknesses in some controls resulting in data integrity issues. The department relies on a number of information management systems and processes to administer the Stockpile.²⁴ In the absence of system interfaces to support automatic data transmission between the information management systems, the department employs emails and attachments (including manual forms and spreadsheets) to transmit key information. This has affected the completeness and accuracy of data stored for individual items in the department's Stockpile database resulting in information discrepancies between the Stockpile database and the contractors' warehouse system records.

Deployment (Chapter 5)

34. The department has developed a deployment framework that includes: memoranda of understanding (MoUs) with the states and territories; a departmental deployment plan, policy and procedures; and relevant provisions in contracts with the Stockpile warehouse providers. The states and territories have also developed stockpile distribution plans, a specific requirement of the MoUs. All MoUs were current, having been updated in 2010, with the requirement for a review every five years. However, the department held current distribution plans for only four of the eight jurisdictions, and there would be benefit in the department liaising with jurisdictions which have not updated their plans, to address this deficiency.

35. The department advises its warehouse providers to select stock for deployment which has not exceeded its expiry date, and has adequate stock life for at least a month before its expiry date. The PPE warehouse provider's warehouse management system is capable of selecting unexpired stock on a First-In, First-Out (FIFO) basis; an approach which can provide an effective basis for selecting unexpired stock for deployment. However, the efficacy of this approach can be affected by factors such as: not all PPE stock having a recorded expiry date; the PPE warehouse provider's FIFO date resetting when

24 Including a standalone Stockpile database which records stockpile items and quantities; a range of supporting spreadsheets; and the external warehouse contractors' inventory management systems.

stock is moved from one warehouse to another; data integrity issues arising from inconsistencies between the department's information management systems and warehouse provider data; and warehouse providers not consistently attaching to pallets labels that record expiry details.

36. The 2011 Strategic Review of the Stockpile observed that there was 'no recording mechanism that can accurately determine how returned stock was treated after deployment, thereby guaranteeing its condition prior to its receipt'. The relevant Australian code requires that medicines which have left the care of warehouse providers should only be returned if they are examined and assessed by a person authorised to do so, and 'there is no reason to believe that they have been subject to adverse environmental conditions'. The ANAO's analysis of a deployment of a CBRN poison antidote, which was subsequently returned to the national Stockpile, indicated weaknesses in a number of controls. There was no consideration of the conditions under which the item had been transported and stored after deployment. Further, the item was returned to the Stockpile a month later without examination and assessment by an authorised person as required by the Australian code.

37. In its 2007–08 audit, the ANAO recommended that the Department of Health adequately test its deployment plans in conjunction with states and territories. In September 2012, the department's audit committee considered progress in implementing the ANAO's recommendation, noting that while there had been no testing between 2009 and 2012, testing would occur in late 2012 or early 2013. In the course of the current audit, the department advised the ANAO that it had not conducted any operational testing of the deployment of pandemic items since the last pandemic in 2009. The department also informed the ANAO that no testing of the deployment of CBRN items had been conducted in the last five years. To provide assurance that deployment arrangements will be effective in a national health emergency, the department should undertake planning to test the Stockpile's deployment arrangements, in consultation with other jurisdictions.

Summary of agency response

38. The Department of Health provided the following summary response to the proposed audit report:

The Department of Health notes the audit report and agrees with the recommendations. To date, the Department of Health has invested significant resources, including approximately \$4 million and a dedicated taskforce, to the development of reforms to enhance the efficiency and effectiveness of the management and operation of the National Medical Stockpile. Reform activities, that will address all of the recommendations in the audit report, will now be implemented under the 2014–15 Budget Measure ‘Reinforcing Australia’s Health Protection’ that provides funding of \$15.4 million over four years.

39. The department’s full response is included at Appendix 1.

Recommendations

Recommendation No.1
Paragraph 2.35 To strengthen the management of the National Medical Stockpile, the ANAO recommends that the Department of Health:

(a) update the strategic management plan to identify objectives, priorities and strategies to be implemented in the short term and over the longer term; and

(b) review the operational risk management plan to incorporate emerging risks.

Department of Health's response: *Agreed*

Recommendation No.2
Paragraph 3.45 To gain additional assurance that contract requirements are being met, the ANAO recommends that the Department of Health review and clarify reporting arrangements for its warehousing contracts with external service providers.

Department of Health's response: *Agreed*

Recommendation No.3
Paragraph 4.63 To improve the management and integrity of data relating to the National Medical Stockpile, the ANAO recommends that the Department of Health review its information management arrangements for the transfer of Stockpile data.

Department of Health's response: *Agreed*

Recommendation No.4
Paragraph 5.41 To provide assurance that deployment arrangements will be effective in a national health emergency, the ANAO recommends that the Department of Health undertake planning to test the current Stockpile deployment arrangements, in consultation with state and territory health authorities.

Department of Health's response: *Agreed.*

Audit Findings

1. Introduction

This chapter provides an overview of the National Medical Stockpile. It also sets out the audit objective, scope and approach.

Introduction

1.1 The National Medical Stockpile (the Stockpile) is a strategic reserve of medicines, vaccines, antidotes and protective equipment available for use as part of the national response to a public health emergency. It is intended to augment state and territory government reserves of key medical items in a health emergency, which could arise from terrorist activities or natural causes such as the 2009 influenza pandemic.²⁵

1.2 The Stockpile is intended to increase Australia's level of preparedness and self-sufficiency during a health emergency, by storing items that may not otherwise be available in Australia in the quantities required, and which may not be accessible from overseas suppliers in the event of an international health emergency.²⁶

1.3 The Stockpile was originally established in 2002 as part of the Australian Government's response to the threat of international terrorist attacks. Since 2002 the Stockpile has expanded from a relatively small reserve valued at approximately \$11 million intended to deal with chemical, biological, radiological and nuclear (CBRN) threats, to a resource with a reported value of almost \$196 million in 2012–13.²⁷ The Stockpile, comprising 42 products and over 110 million items, is now dominated by products associated with human influenza pandemic preparedness.²⁸

1.4 The Department of Health is responsible for the planning and management of the Stockpile, while state and territory governments are responsible for deploying Stockpile items within their jurisdictions in the event

25 Many products would be used to support the Australian community in the event of an emergency but many are stockpiled for more strategic use for example, for health care workers or at risk groups.

26 The Stockpile is comprised of specialised pharmaceuticals and personal protective equipment from overseas suppliers. Securing an adequate supply of relevant items in the timeframes required can be a challenge if there is a global surge in demand, as would be the case in a pandemic.

27 Department of Health and Ageing, *Annual Report, Audited Financial Statements*, 2013, p. 349. The Department of Health advised in June 2014 that the value of the Stockpile in 2013–14 is approximately \$192 million.

28 Ernst & Young, 'National Medical Stockpile Stocktake, 2012–13', Commonwealth of Australia, 2013.

of a national health emergency. The Stockpile is warehoused at facilities operated by logistics firms, under contracts administered by the department.

1.5 Key challenges in planning for and administering the Stockpile include effective: stock selection and procurement; warehousing to maintain the efficacy of items; stock-control to account for and locate items; and dealing with items as they reach their expiry dates. Unlike other inventories which are continually being recycled, an emergency stockpile is infrequently deployed and significant volumes of unused goods need to be disposed of on expiry.

Development of the Stockpile

1.6 The Stockpile was established by the Australian Government in 2002 following a number of international events, notably: the terrorist attacks in the United States on 11 September 2001; fears stemming from bioterrorism threats such as the international anthrax and white powder incidents of 2001; and the Bali bombing in October 2002.

1.7 In 2002 the Department of Health established the CBRN Committee to assess the likely threats to public health posed by terrorism and to devise mitigation strategies to deal with the impact of any such events.²⁹ The deliberations of the CBRN Committee informed the department's thinking on the essential items for initial inclusion in the Stockpile. While the CBRN Committee focused on CBRN threats such as anthrax, the department extended its consideration of risks to public health to include human influenza pandemics³⁰ and an additional national committee was established in 2003—the Australian Health Disaster Management Policy Committee. This committee is now known as the Australian Health Protection Principal Committee (AHPPC).³¹

1.8 In 2003–04 the Government allocated nearly \$124 million to purchase antiviral medicines for the Stockpile in response to an outbreak of Severe Acute Respiratory Syndrome (SARS) overseas in November 2002.³² Following

29 The department no longer convenes a CBRN Committee. Instead the Chief Medical Officer receives security briefings from the intelligence community (that is, ASIO, Defence and the Australian Federal Police) on a six-monthly basis.

30 Pandemic influenza is one of a small number of infectious diseases that pose a significant global threat. The two relatively mild pandemics of the twentieth century, in 1957 and 1968, each resulted in two million deaths worldwide while the most severe, in 1918, caused more than 20 million deaths globally.

31 AHPPC was previously known as the Australian Health Protection Committee (AHPC).

32 Australian Government, *Budget Measures: Budget Paper No. 2: 2004–05*, Commonwealth of Australia, 2004, p. 296.

the SARS outbreak, in 2004, there were also signs of avian influenza (H5N1) in Asia which prompted the purchase of additional antiviral medicines for the Stockpile.

1.9 In 2005–06, the government allocated an additional \$135 million to purchase medicines and equipment for the Stockpile and \$32 million to enhance the department’s capacity to respond to an influenza pandemic. Specific initiatives included:

- establishing the Office of Health Protection within the Department of Health to build national capacity and capability to detect, prevent and respond to threats to public health and safety;
- establishing contracts with influenza vaccine manufacturers for the guaranteed supply of vaccines during a pandemic;
- providing funding to accelerate research on influenza and pandemics;
- strengthening health surveillance and laboratory diagnosis capacity; and
- developing a Stockpile deployment plan in consultation with state governments.³³

2009 Influenza Pandemic

1.10 The 2009 (H1N1) pandemic led to a major deployment of the Stockpile in Australia. Some 900 000 courses of antivirals (valued at \$28.8 million) were deployed during the pandemic and almost 2.1 million items of personal protective equipment (PPE—for example, masks) were deployed to health workers to guard against the spread of H1N1. An additional 170 000 items of PPE were provided to Australian Government border agencies to protect workers and 2700 basic health packs were provided to individuals subject to quarantine.

1.11 In September 2011, the department finalised a review of the Australian health sector’s response to the 2009 pandemic, which made 25 recommendations. The key finding relating to the Stockpile was that while it met the relatively limited demands of the 2009 pandemic, which was considered to be of moderate intensity, it may not meet the more intense demands of a

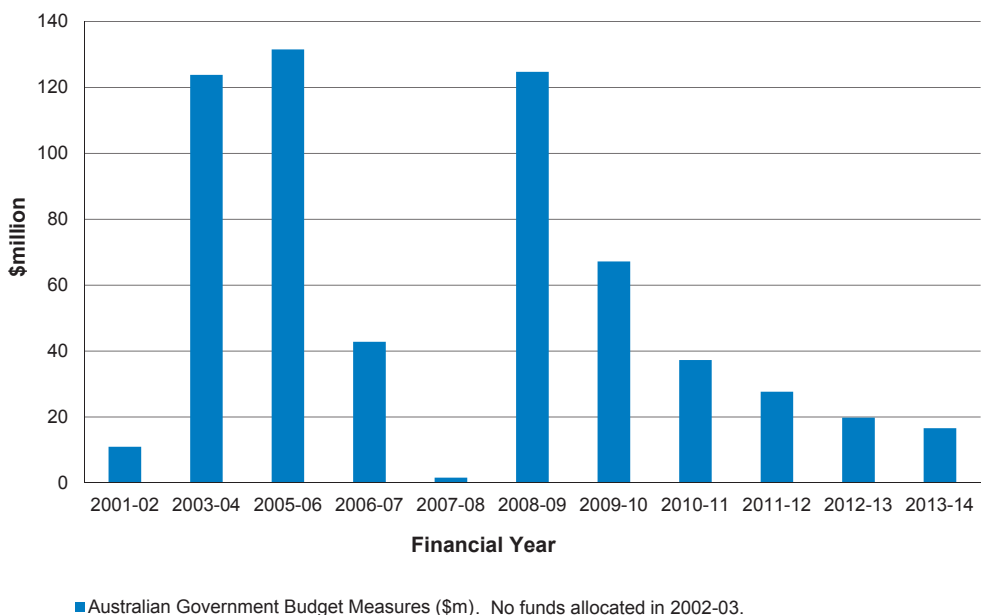
33 Department of Health and Ageing, *Annual Report 2006-07*, Canberra, 2007, p.165.

severe pandemic.³⁴ The Pandemic Review Implementation Advisory Committee was established in November 2011 to oversee implementation of the review’s recommendations, and implementation remains ongoing.³⁵

The Stockpile today

1.12 Figure 1.1 shows funds allocated to the Stockpile over the past 12 years.

Figure 1.1: Funding of the National Medical Stockpile (2002 to 2014)



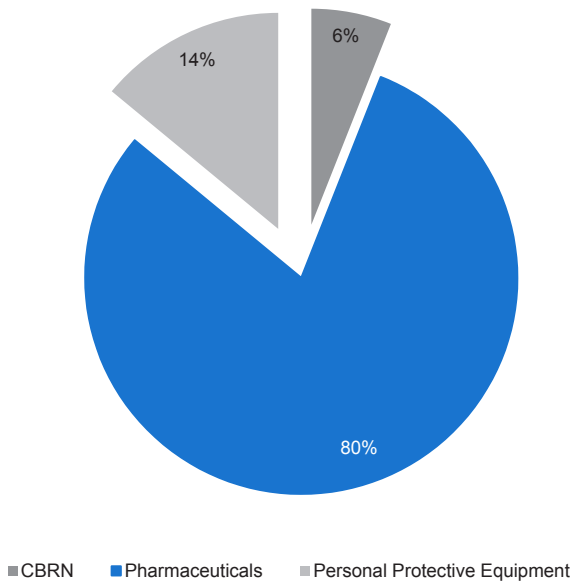
Source: ANAO.³⁶

1.13 As discussed, the Stockpile has expanded substantially from its origins in primarily combating CBRN threats to now being dominated by products associated with human influenza pandemic preparedness. Figure 1.2 shows that the CBRN component of the Stockpile is now \$12 million (six per cent) while preparedness for pandemic influenza accounts for the rest—pharmaceuticals worth \$157 million (80 per cent) and PPE valued at \$27 million (14 per cent).

34 Department of Health, *Review of Australia’s Health Sector Response to Pandemic (H1N1) 2009: Lessons Identified*, [internet], 2011, <<http://www.health.gov.au>> [accessed 29 October 2013], p. xi.

35 The Committee, now disbanded, was chaired by the Commonwealth Chief Medical Officer, and included relevant government and medical representatives.

36 Data sourced from Department of Finance advice to the ANAO, dated 8 August 2013, drawing on Commonwealth Budget Paper 2: 2003–04 to 2013–14.

Figure 1.2: Value of each component of the National Medical Stockpile

Source: Department of Health expenditure figures as at 30 June 2013.

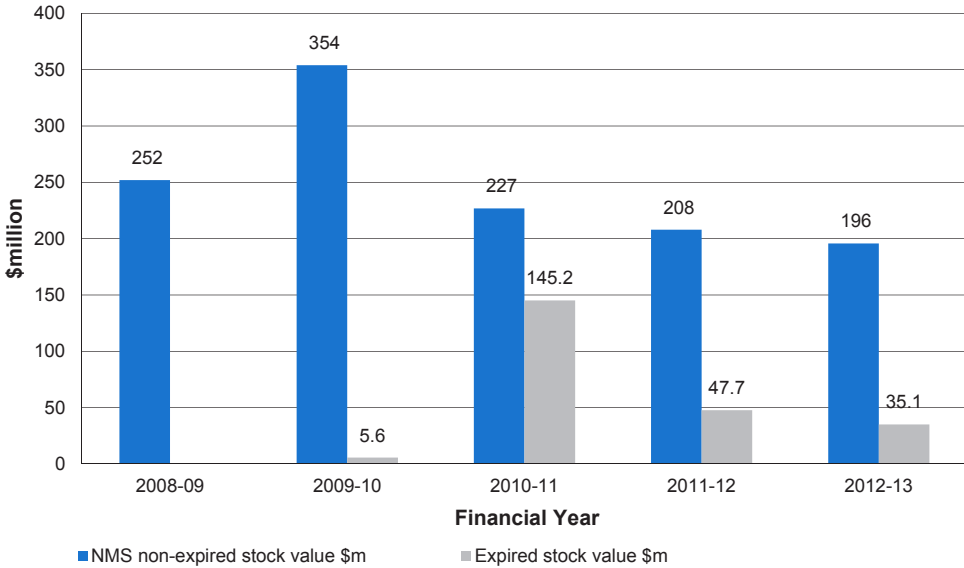
1.14 The main components of the Stockpile are antivirals (Tamiflu and Relenza) which are used to treat patients with influenza like symptoms and to prevent the spread of the disease by targeting vulnerable groups with underlying health conditions and health care workers in exposure prone areas.

1.15 A key challenge for the Department of Health in managing the Stockpile is the limited shelf life of stockpiled goods. Antivirals, for example, typically have a seven to 10 year shelf life.³⁷ Unlike other inventories which are continually being recycled, an emergency stockpile is infrequently deployed, and significant volumes of unused goods need to be disposed of on expiry.

1.16 Figure 1.3 shows a comparison of expired stock and non-expired stock in storage from 2008–09 through to 2012–13.

³⁷ Shelf life is specific to a product. The Department of Health secured an extension to shelf life for antivirals from the manufacturers, Roche (Tamiflu) and GlaxoSmithKline (Relenza). Tamiflu currently has a shelf life of 10 years, while Relenza has a seven year shelf life.

Figure 1.3: Value of expired stock and non-expired stock



Source: Department of Health, Annual Reports.

2011 Strategic review

1.17 The limited shelf life of medicines and equipment and the long term maintenance of emergency stockpiles constitute a significant cost for government. In 2011, the Department of Finance completed a strategic review³⁸ which recommended a number of significant changes to the management of the Stockpile, including:

- improving the existing inventory management arrangements;
- improving the strategic planning, information management/reporting systems and stock deployment arrangements;
- adopting a more proactive approach to stock management, to avoid having to store expired items; and
- transferring to a more commercially focussed model, such as a 'prime vendor' arrangement where some of the stockpile management functions could be outsourced under a single contract.

³⁸ Department of Finance, 'Review of the National Medical Stockpile', 2011.

1.18 In response to the 2011 Strategic Review, the Australian Government committed \$6.8 million in 2011–12 and an additional \$15.4 million over four years in the 2014–15 Budget to improve the management of the Stockpile.³⁹ The 2014–15 Budget measure is for the implementation of management reforms intended to reduce waste, decrease risk, increase the surety of supply and strengthen deployment arrangements.

Previous ANAO audit reports

1.19 The Australian National Audit Office (ANAO) examined Australia's preparedness to respond to a human influenza pandemic in 2007–08.⁴⁰ The audit concluded that the department had not developed an appropriate framework for managing the Stockpile. Key issues relating to the administration of the National Medical Stockpile included:

- the lack of an implementation strategy for the establishment and ongoing management of the Stockpile;
- operational management shortcomings relating to monitoring contracts, approving subcontracting arrangements and inventory management; and
- poor understanding of state governments' deployment arrangements which could impede effective deployment of the Stockpile.

1.20 The audit observed that while the Department of Health's focus had been on procuring and storing the Stockpile, its focus should shift from short term 'supply and store' to a longer-term management strategy, underpinned by a proper assessment of the risks involved in managing and deploying the Stockpile.⁴¹ The audit made three recommendations in relation to the Stockpile which were agreed by the department. The relevant recommendations are reproduced at Appendix 2.

39 Australian Government, *Budget Measures: Budget Paper No. 2: 2014–15*, Commonwealth of Australia, Canberra, 2014, p. 12.

40 ANAO Performance Audit Report No.6 2007-08 *Australia's Preparedness for a Human Influenza Pandemic*, Commonwealth of Australia, 2007.

41 *ibid.*, pp. 20–21, pp. 95–99.

1.21 Whilst the current audit was not intended to assess implementation of all recommendations in the ANAO's 2007–08 audit, the ANAO considered the extent to which the Department of Health has implemented recommendations relating to the Stockpile.

Audit objective, criteria, scope and methodology

1.22 The audit objective was to assess the effectiveness of the Department of Health's management of the National Medical Stockpile.

1.23 To assist in evaluating the department's performance in terms of the audit objective, the ANAO developed the following high level criteria:

- the Department of Health has sound governance arrangements in place for the management of the Stockpile, including an integrated and systematic approach to risk management and performance reporting;
- the Department of Health's procurement and contract management arrangements for the Stockpile demonstrate a focus on getting the right outcomes and achieving value for money;
- the Stockpile's inventory management system reflects value for money—it provides an assurance that the right items in the correct amount are being purchased, and stored appropriately, until they are either deployed, or they are disposed of on expiry; and
- the deployment plans and processes provide a high level of assurance that the Stockpile can be reliably deployed within agreed timeframes to agreed locations.

1.24 The ANAO did not assess processes for the disposal or destruction of expired stock.⁴² While the audit examined aspects of the deployment strategy for the Stockpile, it did not seek to assess Australia's general preparedness to respond to a national health emergency. Nor did the audit assess the clinical efficacy of stockpiled items.

⁴² For example, the ANAO did not undertake control testing of the disposal or destruction of expired stock. The disposal of expired stock was the subject of a 2012 internal audit by the department.

1.25 The audit was conducted by:

- a review of departmental records;
- site visits to examine processes and procedures in place for the storage and deployment of the Stockpile;
- review of the information management arrangements used by the department and its external service providers, which included conducting an assessment of selected controls; and
- interviews with relevant departmental staff and key stakeholders, including officials from state government departments and relevant experts.

1.26 The audit fieldwork was mainly conducted between June 2013 and December 2013. The audit was conducted in accordance with ANAO Auditing Standards at a cost of approximately \$597 000.

Structure of chapters

1.27 The remaining chapters are:

- Strategic Framework (Chapter 2);
- Procurement and Contract Management (Chapter 3);
- Inventory Management (Chapter 4); and
- Deployment (Chapter 5).

2. Strategic Framework

This chapter examines the Department of Health's framework for managing the Stockpile, including governance arrangements, strategic planning, risk management and performance reporting.

Introduction

2.1 Strategic planning, risk management and performance monitoring are essential tools for ensuring that outcomes are achieved and that potential risks are identified and addressed. An effective strategic framework will identify objectives, strategies, priorities and timeframes, which should be reviewed regularly and updated to reflect changing circumstances. The ANAO's 2007–08 performance audit report *Australia's Preparedness for a Human Influenza Pandemic*, concluded that the department had not developed an appropriate framework for managing the Stockpile.⁴³

2.2 To consider whether the department has established an effective strategic framework for managing the Stockpile, the ANAO examined:

- governance and administrative arrangements;
- strategic planning;
- risk management; and
- performance monitoring and reporting.

Governance and administrative arrangements

2.3 The Stockpile was established in 2002 by the Australian Government without a specific legislative framework, although elements of the *Quarantine Act 1908*, *National Health Security Act 2007* and *Therapeutic Goods Act 1989* govern aspects of the Stockpile's management and deployment processes.⁴⁴

43 ANAO Performance Audit Report No.6 2007–08 *Australia's Preparedness for a Human Influenza Pandemic*, Commonwealth of Australia, 2007, p. 90.

44 The *Therapeutic Goods Act 1989*, for instance, allows the responsible Minister to exempt therapeutic goods from some of the regulatory requirements of the legislation if the Minister is satisfied that these goods need to be stockpiled to prepare for a potential threat to public health or to respond urgently to an actual threat. These provisions have been used to import many of the CBRN items that are not registered or listed through the *Therapeutic Goods Act 1989*.

2.4 The Department of Health is responsible for coordinating a response to a national health emergency which may include deployment of the Stockpile. The Health Emergency Management Branch within the Office of Health Protection⁴⁵ is responsible for the day-to-day management of the Stockpile within the broader context of national health emergency planning and response. The Branch includes the Health Emergency Countermeasures Section with responsibilities for the management of the Stockpile including: procurement, storage, inventory management, disposal and reporting.⁴⁶

2.5 The Health Emergency Management Branch also provides secretariat support for the Australian Health Protection Principal Committee (AHPPC) which is chaired by the Australian Government's Chief Medical Officer (CMO). The CMO provides operational oversight of the Stockpile and has authority to approve deployment of the Stockpile to assist in responding to a health emergency.⁴⁷

2.6 The AHPPC was established by Australian Health Ministers in 2006 to coordinate a national response to a health emergency. Figure 2.1 outlines the AHPPC and its current committee structure. Under the National Health Security Agreement 2008⁴⁸, AHPPC is to coordinate the national response under the guidance of relevant standing committees and in a manner consistent with national plans and protocols.⁴⁹ The Stockpile is available to support a national emergency response consistent with these plans and protocols.⁵⁰

45 The Office of Health Protection is responsible for building capability to detect, prevent and respond to threats to public health and safety. As part of a 2004–05 Budget initiative, the Office of Health Protection was established to enhance the department's capacity to respond to an influenza pandemic.

46 The Health Emergency Management Branch is part of the OHP and is responsible for surveillance of current and emerging communicable disease threats to the Australian population, in partnership with other jurisdictions and stakeholders. The Branch also monitors and implements effective and sustained responses to national health emergencies and risks. These national health emergencies and risks include mass casualty events, communicable disease outbreaks, terrorism and natural disasters.

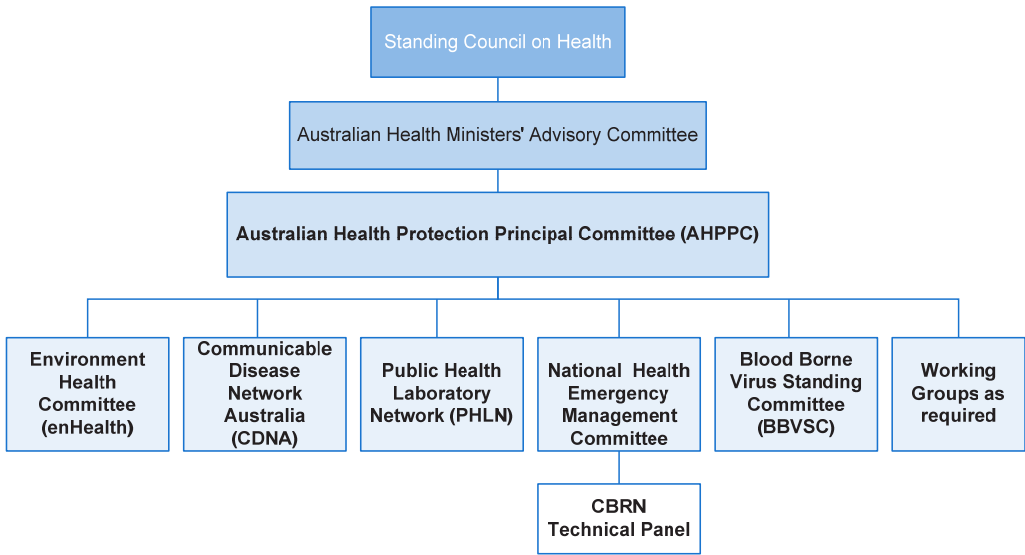
47 The CMO is able to approve the release of stockpiled items apart from those that have been exempted from the regulatory requirements of the *Therapeutic Goods Act 1989*. The Secretary of the Department of Health has the legislative authority for the release and use of pharmaceuticals exempted under the *Therapeutic Goods Act 1989*. Once the Secretary of Health has approved the release and use of these pharmaceuticals, then the CMO has administrative authority to deploy them from the Stockpile to the relevant jurisdictions.

48 The role of the AHPPC is outlined in Part 6 of the National Health Security Agreement.

49 Emergency response plans and protocols include the Australian Health Management Plan for Pandemic Influenza (AHMPPI); the domestic response plan for mass casualty incidents of national consequence (AUSTRALMAPLAN) and the Chemical, Biological, Radiological and Nuclear counter-terrorism plan (CBRNPLAN).

50 Department of Health, National Health Emergency Response Arrangements, [internet], <<http://www.health.gov.au>>, [accessed 29 October 2013], Canberra, 2011, p.10–11.

Figure 2.1: AHPPC and its standing committees



Source: ANAO.

2.7 Membership of the AHPPC includes the Commonwealth CMO, Chief Health Officers (CHOs) from state and territory governments, the Chair of each AHPPC standing committee, representatives from the Australian Defence Force and Emergency Management Australia, health disaster officials and clinical experts. The AHPPC meets three times a year with a group of AHPPC members sometimes meeting the day after to discuss issues specific to the procurement, operation and deployment of the Stockpile. Members of the AHPPC Stockpile specific group include the CMO, CHOs from state health departments and representatives from the Department of Defence. Significant stockpile management issues or deployment issues are discussed with the full membership of the AHPPC. For example, the November 2013 AHPPC meeting was provided with an update by the department on current developments to improve the efficiency and effectiveness of the management of the Stockpile.

2.8 State governments are responsible for responding to public health events within their jurisdictions, and can request a national health sector response to a health incident in the event that it is likely to overwhelm their resources or cross state boundaries. The AHPPC is responsible for coordinating a national health sector response in accordance with relevant legislation and

established plans and protocols.⁵¹ States are responsible for ensuring that items released from the Stockpile reach the right recipients within their jurisdiction. Memoranda of Understanding (MoUs) have been developed with each state government for the receipt, storage and use of pharmaceuticals and equipment from the Stockpile. To provide expert advice on improving collaborative arrangements between Commonwealth and state health authorities, the department established the National Medical Stockpile Advisory Group in 2012.

Other Advisory Groups

2.9 The department also engages with a number of advisory groups in relation to the management of the Stockpile.

Clinical and security advice

2.10 The department's Medical and Scientific Advisory Unit is available to provide clinical, scientific and public health advice and support for the Stockpile. This unit has reviewed the planning assumptions that underpin the Australian Health Management Plan for Pandemic Influenza (AHMPPI), which should help inform consideration of appropriate quantities of stockpile items for an effective pandemic response. The department also established the CBRN Technical Panel in 2010 to review clinical guidelines for specific conditions and events which may, over time, also inform appropriate levels of CBRN stockpile items. In 2012, a Specialist Medical Advisor was appointed to provide expert clinical advice to the Health Emergency Management Branch. The CMO also receives security briefings from the intelligence community (that is, ASIO, Defence and the Australian Federal Police) on a six-monthly basis on potential security threats.

Interdepartmental Steering Committee

2.11 An Interdepartmental Steering Committee (IDSC) was established in August 2011 to provide high level advice and strategic direction to the department on the significant issues identified in the Department of Finance's 2011 Strategic Review of the Stockpile. The IDSC was established with representatives from the Department of Health (chair), including the Therapeutic Goods Administration; the Department of the Prime Minister and Cabinet; the Treasury; Department of Finance; and Department of Defence.

51 Under the *National Health Security Act 2007* and National Health Security Agreement signed by Australian Health Ministers on 18 April 2008.

2.12 The IDSC had its first meeting in November 2011 and continues to meet regularly to provide strategic advice to the department. The minutes of the IDSC reflect the progress made by the department over the last two years in examining the issues raised in the Strategic Review. These include: assessing the outsourcing of Stockpile management functions to a third party; identifying supply chain procurement risks; examining a range of cost effectiveness measures to minimise stock loss through expiry; and improving coordination arrangements with state health departments.⁵²

Strategic planning

2.13 A strategic plan should provide a high level view of the objectives, priorities and strategies to be undertaken in the short and longer-term.

2.14 The ANAO's 2007–08 audit observed that the establishment of the Stockpile in 2002 occurred without the high level planning, assessment of risks and management processes that would usually be put into place by an agency to manage policy initiatives.⁵³ This was partly due to the immediacy of the Stockpile's formation in an environment of rapidly changing and unexpected international events.⁵⁴

2.15 The department developed a strategic plan for the Stockpile in 2010, some eight years after the Stockpile was first established. The plan broadly describes the governance, funding and administrative arrangements for the Stockpile. However, the plan does not identify objectives, priorities and strategies to be implemented in the short term and over the longer term—key elements of an effective strategic plan. Moreover, the plan does not reflect the high level outcomes for the Stockpile which were agreed by Ministers in March 2011—following completion of the 2011 Strategic Review.

2.16 The high level outcomes of the Stockpile agreed by the then Government are to:

- (a) provide a strategic reserve of medicines, vaccines, antidotes and personal protective equipment for use in a national response to a public

52 The IDSC was supported by a National Medical Stockpile Taskforce resourced by staff from the Department of Health. The Taskforce was established to scope new arrangements for the Stockpile stemming from the 2011 Strategic Review. It operated from October 2011 to December 2012.

53 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p.87.

54 *ibid.* p. 87.

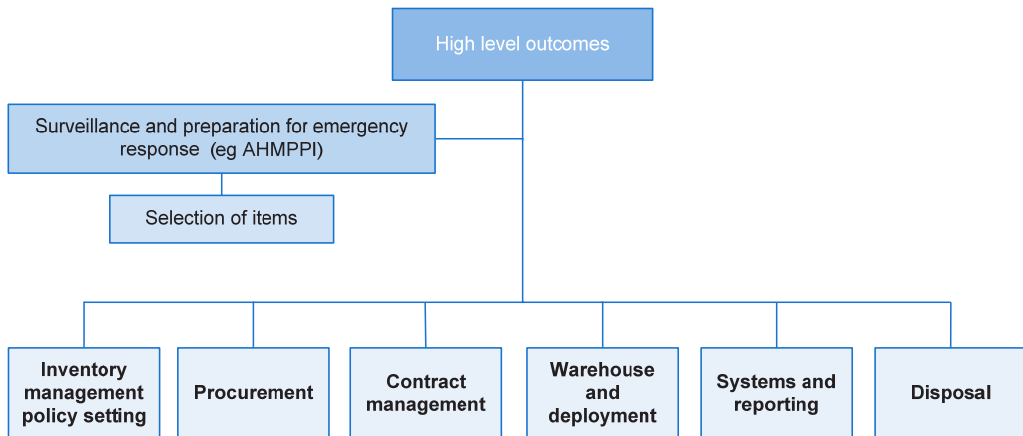
health emergency which could arise from natural causes or terrorist activities; and

- (b) supplement holdings of medicines and personal protective equipment held by state health authorities to ensure continuity of service provision and to provide an immediate source of supply of highly specialised medicines in an emergency that may not be held elsewhere in the Australian pharmaceutical supply system.

2.17 Defining the high level outcomes for the Stockpile in 2011 was an important step towards developing a more strategic approach to managing the Stockpile, and the department should update the 2010 strategic plan to reflect this development.⁵⁵

2.18 Figure 2.2 illustrates the scope of activities undertaken by the department in managing the Stockpile. A strategic plan should link objectives, priorities and strategies across this range of activities to deliver the high level outcomes for the Stockpile.

Figure 2.2: Scope of activities for managing the Stockpile



Source: ANAO.

Note: AHMPPI is the Australian Health Management Plan for Pandemic Influenza.

2.19 The ANAO's assessment of the 2010 National Medical Stockpile Strategic Management Plan (strategic plan) indicates that there is scope for the department to update and refine its strategic plan so that it clearly identifies

⁵⁵ The department advised the ANAO that it had attempted to draft a revised strategic plan in 2012–13 but was unsuccessful as stakeholders were not keen to pursue this activity until an outcome from the reform process was achieved.

objectives, priorities and strategies across the Stockpile's operational activities to deliver its high level outcomes.⁵⁶

Risk management

2.20 A well structured risk management framework will facilitate the identification of risks and possible treatments, and strengthen planning and decision-making processes. The ANAO's 2007–08 audit of *Australia's Preparedness for a Human Influenza Pandemic* recommended that the department develop a risk management plan for the Stockpile that is regularly reviewed.⁵⁷

2.21 The current audit examined the two risk management plans that support the department's management of the Stockpile—the Enterprise Risk Management Plan and the National Medical Stockpile Operational Risk Management Plan. The ANAO examined whether the department had:

- identified and treated the key risks; and
- reviewed and updated the risk management plans in the context of the changing operating environment.

Enterprise Risk Management Plan

2.22 The department maintains an Enterprise Risk Management Plan for the department's strategic level risks. Operational risks are managed at a division, branch, program and project level. Under the department's reporting arrangements, risks are reported to both divisional and departmental executives.

2.23 The ANAO reviewed the Enterprise Risk Management Plan for 2012–13 and found that one strategic risk had been identified for the Stockpile; relating to the adequacy of government funding to maintain stock holdings. This had been rated as a 'high' risk to the department.

Operational Risk Management Plan

2.24 The department developed an operational risk management plan for the Stockpile in July 2010, some time after the Stockpile was established in

⁵⁶ This is the subject of a recommendation later in this chapter.

⁵⁷ ANAO Audit Report No.6 2007–08 *Australia's Preparedness for a Human Influenza Pandemic*, p. 32.

2002. The risk management plan identifies emerging risks, risk ratings and treatment strategies; ranking the most significant risks as:

- information on the location and contents of the Stockpile;
- stored stock being misplaced or destroyed; and
- stock incorrectly dispatched during deployment.

2.25 While security of information has been identified in the 2010 risk management plan as one of the three most significant risks for the administration of the Stockpile, the risk management plan has not been updated to reflect the department's decision to revise the security classification of the Stockpile in August 2012.

2.26 Further, the risk management plan has not been updated to adequately reflect the significant risks identified in the 2011 Strategic Review. That review identified some key issues in the management of the Stockpile, such as the: inadequacy of the information management system for accurate recording and reporting on the Stockpile's inventory; lack of logistical and inventory expertise within the department to manage the Stockpile; and lack of documented plans and policies including a long term strategic plan. The 2010 risk management plan should be updated to reflect these risks.

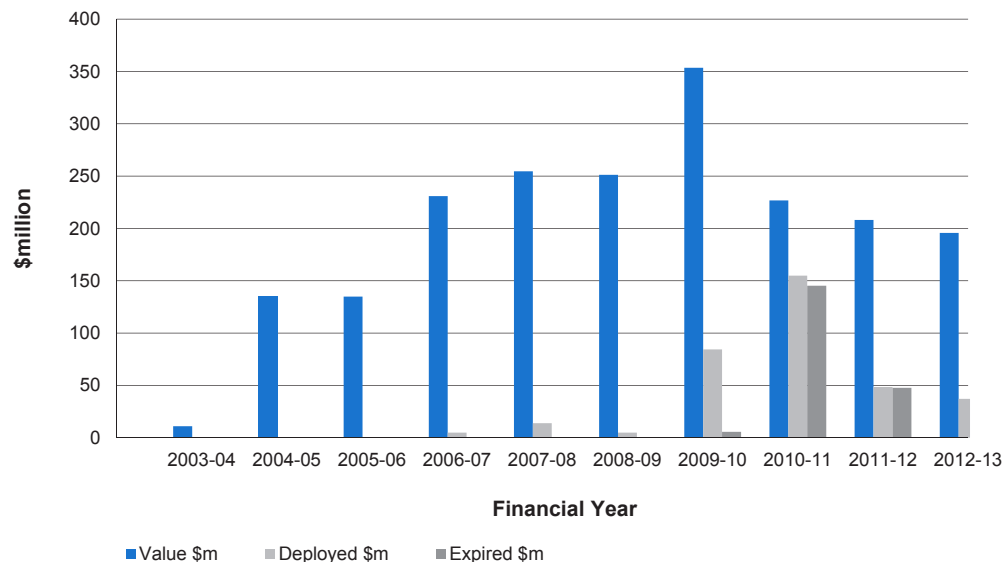
2.27 The department's Audit and Fraud Control Branch conducted follow up audits on the implementation of recommendations from the 2007–08 ANAO report in December 2008 and, again, in July 2011. The 2011 Internal Audit report recommended that the risk management plan could be enhanced by including additional risks identified in the 2011 Strategic Review.

2.28 The department did, however, identify two risks in its 2010 risk management plan that were also identified by the 2011 Strategic Review relating to the disposal of expiring stock and insufficient government funding for replenishing expiring stock. These risks have been rated as 'moderate' and are considered an 'acceptable risk' after treatment strategies are applied.

2.29 As shown in Figure 2.3, stock expiry was an emerging issue by 2010 and by June 2011 \$145 million worth of stock had expired. The department has advised that storage costs for expired items for the 2010–11 financial year were approximately \$160 000. The expired stock comprised some 2352 pallets in storage, the bulk of which were PPE, influenza antivirals and antibiotics. Storage costs for expired items for the 2009–10 financial year were almost

\$500 000. The expired stock comprised some 3000 pallets in storage, the bulk of which were personal protective items (including 98 million latex gloves).⁵⁸

Figure 2.3: National Medical Stockpile; expired and deployed stock



Source: Department of Health, Annual Reports from 2003–04 to 2012–13.

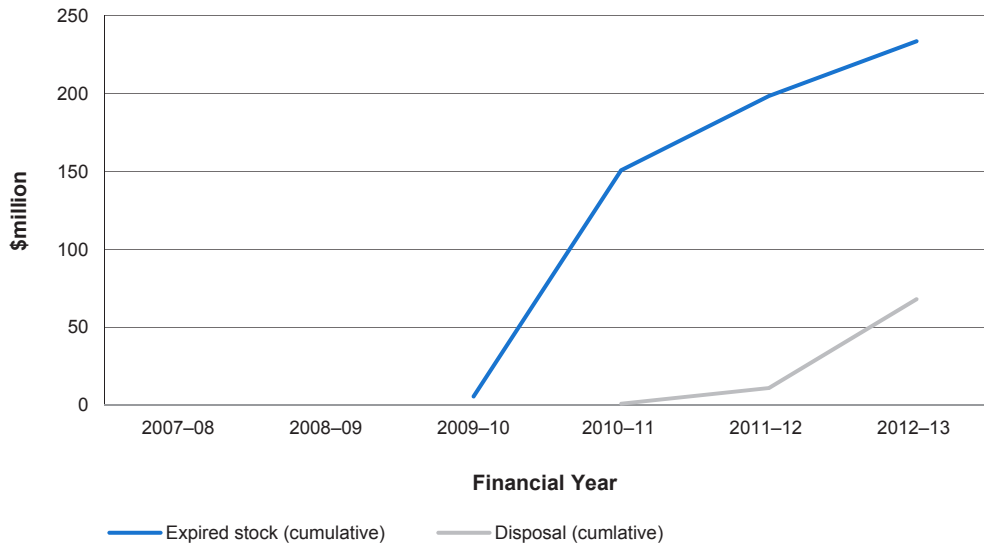
2.30 The department’s approach has been to dispose of expired stock only when government funds are available to replenish expired stock. The department has received Budget funding to replenish expiring stock in recent years (\$37 million in 2010–11, \$48 million in 2012–13, \$17 million in 2013–14)⁵⁹, but advised the ANAO that this has not enabled it to fully replenish expiring stock. As a result there has been a decline in the overall value of the Stockpile (refer to Figure 2.3). While the overall funding for the Stockpile is a matter for government decision, the department must also assess the safety and efficacy of the stock as it approaches its expiry date, to ensure that any stock that is retained past its expiry date does not pose a risk. The department has monitored the level of expiring stock and has made annual submissions to government since 2010–11 for additional funding.

58 Department of Finance, ‘Review of the National Medical Stockpile’, 2011, pp 73-74.

59 The 2014–15 Budget also made provision for the purchase of antivenoms and vaccines, but the expenditure for this measure was not published in the Budget papers due to commercial sensitivity. See Budget Paper No.2: Expense Measure-Health, p.129.

2.31 Figure 2.4 shows the value of expired and disposed stock between 2007–12; illustrating the substantial costs associated with stockpiling items with an inherently limited shelf-life.

Figure 2.4: Value of expired stock and disposed stock, 2007–2012



Source: ANAO.

2.32 To mitigate against some of the current risks associated with managing the Stockpile, a key recommendation from the 2011 Strategic Review was to outsource some functions to a third party or prime vendor. The Strategic Review noted that one of the advantages of contracting a prime vendor is that it would allow the department access to inventory management and logistical expertise from the private sector. The 2011 Strategic Review suggested a prime vendor could be responsible for some or all of the following functions:

- inventory policy planning and setting;
- procurement, strategic sourcing and category planning;
- contract negotiation and management;
- maintenance management;
- systems and reporting; and
- disposal and replacement.

2.33 The department commissioned consultants to identify and assess the risks of outsourcing some or all of the Stockpile's inventory management

functions to a third party. The analysis undertaken is also of value in respect to the department's current management of the Stockpile, and could usefully be considered in the context of assessing and managing risks relating to the Stockpile.

2.34 In summary, the Stockpile's 2010 risk management plan has not been reviewed or amended to reflect key risks and challenges identified by subsequent reviews of the Stockpile. The department should review the Stockpile's operational risk management plan to assess risks in light of those reviews and, as necessary, identify risk treatments. A review would be consistent with the department's agreement to regularly review its risk management plan for the Stockpile, in response to a recommendation made in the ANAO's 2007–08 audit of Australia's preparedness for a human influenza pandemic.

Recommendation No.1

2.35 To strengthen the management of the National Medical Stockpile, the ANAO recommends that the Department of Health:

- (a) update the strategic management plan to identify objectives, priorities and strategies to be implemented in the short term and over the longer term; and
- (b) review the operational risk management plan to incorporate emerging risks.

Department of Health response:

2.36 *The department agrees with this recommendation.*

2.37 *A procurement was initiated in May 2014 to engage a consultant to assist the Department with development of a new strategic plan and operational risk framework.*

Performance monitoring and reporting

2.38 The ANAO examined the extent to which key information is captured by the Department of Health to support internal and external reporting on the management of the Stockpile.

Internal reporting

2.39 The ANAO's 2007–08 audit recommended the development of a performance management and reporting framework for the Stockpile that provides ongoing assurance about the content, storage, security and

management of the Stockpile. The ANAO observed that it was important to report on whether the Stockpile is being efficiently and effectively managed and provided examples of key performance indicators that could be included in a performance report, specifically: progress with procurement action, delivery and storage action, stock due to expire, status of stocktakes, movement of stockpile goods, relocation of storage sites and issues with storage providers. The department agreed to the relevant recommendations.⁶⁰

2.40 A follow-up internal audit conducted by the department's Audit and Fraud Control Branch in 2009 concluded that quarterly reports had been introduced and provided to departmental executives.⁶¹ The scope of these reports included data on expiring stock, new purchases, current procurements, deployment activity, finances and a summary of current holdings. From April 2011, quarterly reports on the status of the Stockpile were discontinued in favour of issue specific updates to the departmental executive. For instance, an update was provided to the CMO in April 2013 which outlined current procurement action.

2.41 Current internal reporting on the Stockpile is ad hoc and limited to inventory reporting with little capacity to report on how well the program is performing against key objectives and a range of performance measures. The department will need to exercise judgement that the revised approach, focusing on issue specific updates, provides an adequate basis for senior management to assess performance.

External reporting

2.42 At present there is no specific performance indicator regarding the Stockpile in the department's Portfolio Budget Statements. The department last reported against specific indicators for the Stockpile in its 2010–11 Annual Report. The 2010–11 performance indicators were:

- material in the National Medical Stockpile is replaced as it expires (replacement times as close to the item's expiry date as possible); and

60 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p.90.

61 Department of Health, 'Follow-up Audit of the National Medical Stockpile', Final Report No.12 of 2009-10, Audit and Fraud Control Branch, December 2009, p. 11.

- capacity for the timely deployment of the National Medical Stockpile (measured by the deployment of the Stockpile either through exercise or live deployment, meeting the six hour response benchmark).

2.43 The department advised the ANAO that it has shifted its focus to more high-level, strategic reporting in the Portfolio Budget Statements and annual reports. This has been part of a department-wide shift to align with broader reforms in agency performance reporting. While specific performance information is not provided through the department's annual reports or Portfolio Budget Statements, the department has advised that it has publicly released information on the Stockpile, including a report on the 2009 H1N1 Pandemic response which documented Stockpile activities and capabilities.

Conclusion

2.44 The ANAO's 2007–08 audit observed that the establishment of the Stockpile in 2002 occurred without the high-level planning, assessment of risks and management processes that would usually be put into place by an agency to manage policy initiatives. This was partly due to the immediacy of the Stockpile's formation in an environment of rapidly changing and unexpected international events.

2.45 The department developed a Strategic Management Plan for the Stockpile in 2010, eight years after the Stockpile was first established. The plan broadly describes the governance, funding and administrative arrangements for the Stockpile. However, it does not identify objectives, strategies and priorities to be implemented in the short term and over the longer term—key elements of a strategic plan. Moreover, the plan does not incorporate the high level outcomes for the Stockpile which were agreed to by the then Government in March 2011, an important step towards developing a more strategic approach to managing the Stockpile. The department should update the 2010 Strategic Management Plan to reflect this development and to include objectives, priorities and strategies.

2.46 In its 2007–08 performance audit, the ANAO also recommended that the department develop a risk management plan for the Stockpile that is reviewed regularly. The department's enterprise-level risk management plan identifies one strategic risk for the Stockpile; inadequate government funding to maintain stock holdings. The department also developed an operational risk management plan for the Stockpile in July 2010, which documents risks, risk ratings and treatment strategies. The operational risk management plan ranks

the most significant risks as: security of information on the location and contents of the Stockpile; stored stock being misplaced or destroyed; and stock incorrectly dispatched during deployment. There would be merit in updating the risk management plan to reflect more fully the additional risks identified in the Department of Finance's 2011 Strategic Review of the Stockpile.

2.47 The ANAO further recommended, in its 2007–08 audit report, the development of a performance management and reporting framework for the Stockpile, to provide ongoing assurance about the content, storage, security and management of the Stockpile. While quarterly reports were subsequently prepared for senior management, the department advised the ANAO in the course of the current audit that quarterly reporting on the status of the Stockpile was discontinued from April 2011 in favour of issue specific updates. The department will need to exercise judgement that the revised approach provides an adequate basis for senior management to assess performance.

3. Procurement and Contract Management

This chapter examines the process for procuring stock, warehousing the Stockpile and related contracts.

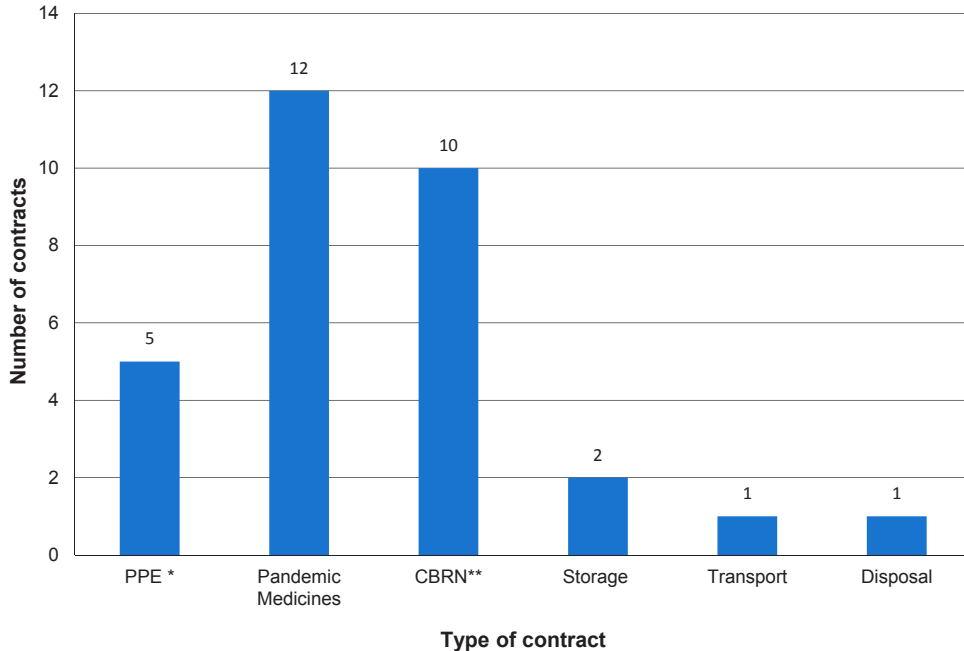
Introduction

3.1 Items for the Stockpile are sourced and directly procured by the Department of Health, stored in contracted warehouses and either deployed in the event of a health emergency or disposed of on expiry. The department is responsible for the management of contracts for the supply of pharmaceutical items and equipment, warehousing of stockpile items, transport of goods to deployment or disposal sites and the disposal of expired items.

3.2 The ANAO examined the department's procurement processes for the supply and storage of Stockpile items, as well as the effectiveness of contract management arrangements for the national storage contracts.

Sourcing items for the Stockpile

3.3 The department has a total of 31 current contracts relating to the supply of items and services for the Stockpile. Figure 3.1 identifies the number and types of contracts, with most of the contracts (27 contracts) relating to the supply of pharmaceutical items and personal protective equipment.

Figure 3.1: Types of contracts for the Stockpile at 30 June 2013

Source: ANAO.

Note: * PPE is personal protective equipment which includes masks and respirators.

** CBRN refers to stockpile items for responding to chemical, biological, radiological and nuclear threats.

3.4 The current contracts for the supply of pharmaceuticals and personal protective equipment (PPE) for the Stockpile have been negotiated with overseas suppliers.⁶² The pharmaceutical items have either been manufactured and/or supplied by pharmaceutical companies within Europe and the United States; while PPE items have been sourced mainly from Asian companies. Access to overseas pharmaceutical products not registered for use in Australia has been facilitated by an exemption available under the *Therapeutic Goods Act 1989*. This exemption provides authority, because of emergency, for the Health Minister to approve an exemption of goods from the operation of the Act.⁶³ This authority has been delegated to the Secretary of the Department of Health.

62 The markets for many of the key pharmaceuticals held within the Stockpile are reliant on one supplier globally and none of these suppliers are based in Australia, although they may have an Australian arm.

63 Section 18A of the *Therapeutic Goods Act 1989* provides for an exemption from some of the regulatory requirements of Division 2 of part 3–2 of the Act in order to stockpile pharmaceutical items in preparation for a public health emergency. The 18A approval is provided to the Australian Quarantine and Inspection Service (AQIS) so that a Permit to Import Quarantine Material can be issued to the Department of Health.

The procurement of stockpile items

3.5 The procurement of appropriate items for the Stockpile involves a range of considerations, including the (sometimes limited) availability of stock in an international market, the availability of funding, the clinical evidence base, and the expiry dates of stockpile items.

3.6 The ANAO examined departmental procurement processes for the Stockpile items under current contract arrangements, to establish whether value for money had been considered in the purchasing decisions. Specifically, departmental approvals for the commitment of public money provided under Regulation 9 of the Financial Management and Accountability Regulations 1997 and tender evaluation documents, where applicable, were reviewed.⁶⁴

3.7 Australian Government policy on procurement is set out in the Commonwealth Procurement Rules (CPRs).⁶⁵ Achieving value for money is the 'core rule' of the CPRs⁶⁶, and its application in the procurement process contributes to the proper use of Commonwealth resources.⁶⁷ The CPRs allow for a so-called 'limited tender' process in certain circumstances, and this process was adopted by the Department of Health in 18 cases mainly on the basis that there was only one organisation that manufactured or was licensed to supply that particular product in Australia.⁶⁸ In the remainder of the cases, procurement was through open tender processes advertised on the *AusTender* website. Table 3.1 shows the value and number of current Stockpile contracts.

64 Regulation 9 requires an approver to be satisfied, after making reasonable inquiries, that giving effect to a spending proposal would be a proper use of Commonwealth resources. 'Proper use' in this context means 'efficient, effective, economical and ethical use that is not inconsistent with the policies of the Commonwealth', as specified in section 44 of the FMA Act and FMA Regulation 9. This is often referred to as the 'value for money' test.

65 The CPRs came into force on 1 July 2012, replacing the Commonwealth Procurement Guidelines (CPGs). There is no significant difference between the two in respect of the limited tender process discussed in this section.

66 CPRs, paragraph 4.4.

67 CPGs, paragraph 4.4(b).

68 The ANAO examined the Regulation 9 advices and approvals to establish the basis on which a limited tender process was agreed. The department justified a limited tender approach for most cases on the basis that there was only one provider of the product. The CPRs at paragraph 10.3(d) (iii) provide that a Commonwealth agency may approach a single entity through a limited tender process 'where the goods and services can be supplied only by a particular business and there is no reasonable alternative or substitute...due to an absence of competition for technical reasons'.

Table 3.1: Procurement processes for current Stockpile contracts

	Open Tender	Limited Tender
Number of contracts	13	18
Total value on contracts	Approx \$25.7 million	Approx \$62.9 million

Source: Department of Health.

Note: The current contracts examined by the ANAO as part of this audit were generally for a period of three years.

3.8 The ANAO reviewed the Regulation 9 approvals for the purchase of items for the Stockpile apart from one—ACAM 200 smallpox vaccine. The department advised the ANAO that it was unable to locate the Regulation 9 approval for the smallpox vaccine which was purchased in 2004.

3.9 The Regulation 9 documentation for pharmaceutical items indicates that more than half of the entities approached did not submit tenders, citing difficulties in supplying specified volumes or meeting the required submission deadlines. For PPE, the department's Regulation 9 documentation indicated that in two of the five open tenders, the successful tenderer was not able to supply the items and the department entered into 'without prejudice negotiations' with alternative tenderers.

3.10 For the limited tender procurements, advice on value for money was generally limited, with departmental documentation explaining that the proposal represented value for money because existing stocks of the relevant pharmaceuticals in the Stockpile were reaching their expiry date and needed to be replaced in order to maintain the Commonwealth's capacity to respond to any health threat.

3.11 The difficulty faced by the department in regard to the limited tenders involving a single supplier was that it could not establish value for money through a comparative analysis of the price and quality of each proposal. In these cases value for money needs to be established by documenting the local and overseas market environment and assessing the merits of the procurement in terms of product quality, price and the ability to secure items required for the Stockpile.⁶⁹ In the sample⁷⁰ of limited tender (sole provider) procurements examined by the ANAO:

69 ANAO Better Practice Guide—*Fairness and Transparency in Purchasing Decisions*, August 2007, Canberra, p. 5.

70 The ANAO examined a sample of nine FMA Regulation 9 approvals from limited tender processes involving sole providers.

- only two procurement approvals explained clearly the basis on which pharmaceutical items had been selected;
- no explanation was provided, in any of the approvals, as to the appropriateness of the quantities purchased; and
- only two approvals provided a more detailed consideration of costs and this involved securing discounts from suppliers; and none of the other approvals considered costs in establishing a case for ‘value for money’.

3.12 In the case of the 13 open tender processes, tenders were subject to evaluation and ranking by a departmental panel according to previously approved criteria, and advice regarding value for money was based on, and consistent with, the panel’s recommendations for the preferred tender.

3.13 The procurement process for H5N1 vaccine involved a complex combination of open and limited tender procurement processes. The procurement process resulted in three separate suppliers signing contracts following an open tender process run by the department in 2010–11. The intention was to have the vaccine delivered by 30 June 2013. However, when two out of the three suppliers were unable to meet the department’s requirements, a limited tender process was initiated by the department with the companies registered on the Australian Register of Therapeutic Goods to supply the influenza pandemic vaccine. The department eventually sourced 1.7 million doses of vaccine from three companies through three separate limited tender processes—including one company involved in the 2010-11 tender process.

3.14 Three separate FMA Regulation 9 financial approvals were given for the H5N1 vaccine, with the anticipated ‘cost per dose’ varying between the three suppliers. While the relevant Regulation 9 documentation contained advice on value for money considerations, including the various discounts offered by the recommended suppliers, there was no explanation of why the cost per dose varied or whether a higher cost was offset by some other benefit to the department. Including this information in the approval documentation would have documented why the financial approver was satisfied that contracting with the most expensive supplier was considered value for money and a proper use of Commonwealth resources. In the course of the audit, the department advised the ANAO that pricing differences were due to the different product presentations—some vaccine was purchased in a multi-dose vial form which was cheaper than vaccine packaged as a single dose vial.

3.15 The development of an inventory selection framework by the department should assist with identifying the full range of evidence to be considered in procurement decisions for the Stockpile.⁷¹ This evidence includes: the risk that the stockpiled item will address, as identified through emergency response plans; the clinical evidence base for the item; and market factors including supply risks and cost effectiveness considerations. As well as encouraging a more systematic approach to procurement decisions, the inventory selection framework would also provide a framework for making and documenting procurement decisions.

Risk assessment for procurement

3.16 The department developed procurement strategies and risk assessments for the current contracts, which were reviewed by the department's Procurement Advisory Services Unit.⁷² Signed contracts were registered on the National Medical Stockpile's contract register which is stored on a secure laptop.⁷³ The contract register is used to monitor contract end dates and prepare for new procurements.

Storage of pharmaceutical items

3.17 The ANAO's 2007–08 audit identified a number of issues with the department's supply and store contract arrangements for the Stockpile. Essentially, the department's previous arrangements required the suppliers of medical items and equipment to also arrange for their storage. By 2007, four of the nine suppliers of medicines and equipment had subcontracted their storage arrangements to a third-party provider. These subcontracting arrangements resulted in inconsistent standards and practices that were poorly controlled through the contract arrangements.⁷⁴

3.18 In February 2007, the department commenced a process of consolidating its short-term storage contracts into longer term contracts. The department developed a procurement strategy drawing on expertise from a warehousing advisory service, which outlined a number of advantages for the department in procuring a single storage provider, including: tighter control

71 As discussed in paragraph 4.19.

72 Department of Health, 'Rules and Guidance for Procurement', p. 3 and p. 40.

73 Each contract is registered with information on the contractor's name, product, file number, start and finish dates for contract, reporting requirements and contract manager.

74 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p. 92.

over the conditions under which stock is stored and deployed; access to improved logistics advice; economies of scale; and more streamlined administration.

3.19 The ANAO examined the department's processes for procuring pharmaceutical warehousing services for the Stockpile to establish whether value for money and risk had been considered in the purchasing decision. The ANAO also examined the department's management of the contracts.

National storage provider for pharmaceutical goods

3.20 In developing its procurement strategy for a national storage provider of pharmaceutical goods, the Department of Health identified the benefits of a single national provider. In March 2007, the department commenced an open tender procurement process by seeking an expression of interest from the market to provide storage services for the Stockpile's pharmaceutical items. In September 2007, a Request for Tender was released by the department and three tender submissions were received in October 2007. A comparative assessment of price and quality was undertaken by the Tender Evaluation Committee which was outlined in the tender evaluation report. As funding for this proposal crossed three financial years, an FMA Regulation 10 approval was obtained.⁷⁵

3.21 Of the three submissions received, only one was assessed by the department as being fully compliant with the tender specifications and the successful tenderer was subsequently offered a contract on 17 December 2007. The contract was executed on 21 October 2010. It took the department almost three years to negotiate the contract, with indemnity issues being the main point of difference.⁷⁶

3.22 The Australian Government's 2003 indemnity guidelines⁷⁷ provide that government policy is only to accept the risks relating to an indemnity 'when the expected benefits, financial or otherwise, are sufficient to outweigh the

75 FMA Regulation 10 provides for the Finance Minister or a delegate to agree to expenditure for which there is insufficient available appropriation. Agreement is typically required for spending proposals which cross financial years.

76 The successful tenderer sought to remove standard indemnity and liability clauses and replace them with clauses that limited its liability for damage or loss of goods, including losses arising from its own negligence.

77 Financial Management Guidance No.6, *Guidelines for Issuing and Managing Indemnities, Guarantees, Warranties and Letters of Comfort*, outline the Australian Government's policy applicable to FMA Act agencies on managing contingent liabilities including approval, recording and reporting obligations.

level and cost of the risk'. Further, the 'specific rationale behind entering into such an agreement should be adequately documented' to ensure: transparency in the decision-making process; the indemnity is entered into for sound reasons; and the original justification for the decision is available for review.

3.23 The department sought legal and actuarial advice on the proposed changes to the standard contract indemnity clauses sought by the successful tenderer. Advice provided by the department's external legal advisers and the Australian Government Actuary was that the changes sought by the storage provider to the contract were unlikely to be supported by the Department of Finance. The contract was amended to provide additional protection for the Commonwealth and incorporate risk mitigation measures, which the department was advised would be acceptable to the Department of Finance.⁷⁸

Management of the contract

3.24 When developing a contract it is important to establish a clear and appropriate statement of contract deliverables and an effective performance management regime.⁷⁹ The ANAO examined the department's contract with the storage provider for pharmaceutical goods to establish whether it provided: clear and well defined contract deliverables that identify standards and timeframes; and a basis for monitoring contract outcomes.

Contract deliverables

3.25 Clear and transparent contract deliverables underpin effective contract management. The ANAO noted in its 2007–08 performance audit report that the Department of Health's contracts for warehousing in place at the time did not provide a clear statement of contract requirements.⁸⁰

3.26 In the current audit the ANAO assessed the 2010–14 contract for the storage of pharmaceutical goods to assess the clarity of the deliverables, which include:

- providing storage in accordance with the manufacturer's storage instructions for the goods;

78 Comcover approved these changes, which were reflected in the final contract. Regulation 10 agreement was obtained for expenditure under the contract.

79 ANAO Better Practice Guide—*Developing and Managing Contracts*, 2012, Canberra, p. 16.

80 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, Canberra, 2007, p. 93.

- holding all appropriate licences and certificates that are required for the storage and handling of prescription material including compliance with the Australian Code of Good Manufacturing Practice for Medicinal Products, the Australian Medical Device Requirements (ISO 13485) and the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 (the code)⁸¹;
- accurately tracking stock with an effective inventory management system;
- following specific protocols when receiving, transferring or deploying items from the warehouse; and
- minimum storage, security, pest control and cleaning requirements for the premises.

3.27 In summary, the contract deliverables identified in the contract for the storage of pharmaceutical goods were generally clear and well defined. However, there were no associated performance standards and timeframes for these contract deliverables—the basis of an effective performance reporting regime.

Performance reporting requirements

3.28 The Stockpile contains a sizeable quantity of costly items with a limited shelf life. While storage for the Stockpile has been outsourced, the department relies on a suite of performance and stock-control reports from its service provider to manage both the Stockpile and the contract.

3.29 The ANAO assessed the current contract to establish whether it provides a basis for the department to assess the extent to which the storage provider for pharmaceutical goods meets contract requirements. The contract requires a six-monthly report detailing the quantity of goods received and stored at each site; the results of bi-annual stock counts; any security breaches; deployment readiness; and any other relevant performance information.

3.30 The storage provider for pharmaceutical goods has not regularly provided the department with the six-monthly performance reports required under the contract. However, a weekly stock-on-hand report has been consistently provided, which details stock currently held and its condition.

⁸¹ National Coordinating Committee on Therapeutic Goods, *Australian Code of Good Wholesaling Practice for Medicines*, Schedules 2, 3, 4 and 8, 1 April 2011.

However, these reports do not provide routine management information on new stock, damaged and expired stock, and stock movements.

3.31 The provision of regular performance reports enables the department to identify performance trends over time and assess the delivery of contracted outcomes. The department should review and clarify contract reporting arrangements as a basis for more effectively monitoring performance under the contract.⁸²

3.32 Given the value of the stock, and the need to store pharmaceuticals in controlled conditions, consideration could also be given to include annual reporting of the storage provider's insurance status and periodic reporting on the currency of licences required for the storage and handling of goods.⁸³

Storage of non-pharmaceutical items

3.33 In April 2008, a second procurement process was initiated to consolidate the storage of non-pharmaceutical items held in the Stockpile. The department sought an expression of interest (EOI) from the market followed by a select (prequalified) tender process.⁸⁴ Four commercial organisations expressed interest and were invited to submit tenders by 22 September 2008, of which two organisations responded. The Tender Evaluation Committee identified issues with both proposals submitted. An independent financial check of one of the organisations identified viability concerns, and the proposal from the other organisation quoted relatively high fees. In March 2009 the department decided to cease the procurement process and directly procure the services of one of the existing warehouse providers for the non-pharmaceutical

82 See paragraph 3.45.

83 The storage provider for pharmaceutical goods is required to maintain a number of licences which comply with the Australian Code of Good Manufacturing Practice for Medicinal Products, the Australian Medical Device Requirements and the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use. The Therapeutic Goods Administration (TGA) is responsible for assessing compliance with a number of these standards. A 2009 Department of Health internal audit report recommended that the department consider whether there is scope to leverage off the audits conducted by TGA for a risk based assessment of site inspections. There was no evidence that the department was using the TGA audit results to develop risk based monitoring schedules.

84 Open, select and direct tenders are now referred to as open tender, prequalified tender and limited tender, respectively, as of 1 July 2012, following release of new Commonwealth Procurement Rules (CPRs) and procurement method descriptions for contract and standing offer notices reported on *AusTender*.

items in the Stockpile, on the basis that an approach to the market had failed.⁸⁵ The department cited the positive performance history of the provider as the reason for directly approaching this particular provider.

3.34 The department assessed the proposal submitted by the provider as meeting the revised specifications. The provider was offered a three year contract at a cost of up to \$7.7 million, which was signed on 6 December 2010 and was subsequently extended to 30 June 2014. The required FMA Regulation 9 and Regulation 10 approvals were obtained.

Contract for storage of non-pharmaceutical items

3.35 The ANAO examined key elements of the contract for the storage of non-pharmaceutical items, such as personal protective equipment, and the department's management of the contract.

Contract deliverables

3.36 The ANAO noted in its 2007–08 report that the department's Stockpile contracts then in place did not provide a clear statement of contract requirements. The report recommended that minimum storage requirements, security requirements and safety requirements should be specified.⁸⁶ The current contract for the storage of non-pharmaceutical items has a measurable set of contract deliverables that identify minimum storage requirements, security and pest control requirements for the premises.⁸⁷

Performance Reporting

3.37 To support the management and assessment of the performance of a contract, the contract deliverables should be accompanied by a performance management regime. The contract should include a balanced set of performance measures against key contract deliverables that will alert the

85 The department decided to directly source the provider under section 8.33 of the Commonwealth Procurement Guidelines 2008, which outlined the specific circumstances under which direct sourcing could be undertaken, such as when an approach to market has failed. The department sought internal probity advice, which proposed that a formal request for tender process be adopted due to the high value of the contract.

86 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, Canberra, 2007, p. 91.

87 The external service provider for storage of non-pharmaceutical items from the Stockpile, is not subject to the same storage conditions that the external service provider for pharmaceutical items must comply with. Specifically, the external service provider for the storage for non-pharmaceutical items is not required to hold appropriate licences and certificates for the storage and handling of prescription pharmaceuticals.

contract manager to potential problems, so that remedial action can be taken if required.⁸⁸

3.38 The contract requires the external service provider to provide the department with a monthly inventory report which is to include:

- item details including product code, batch/serial number;
- item manufacture dates, expiry dates and information on expiring items;
- items received, stored and transported (including date of receipt and quantity of items and pallets, their location and movement during the reporting period);
- lost, damaged or unaccounted for stock;
- results of pest management reports; and
- insurance status.

3.39 The monthly inventory report provides a reasonable basis for the department to manage the contract and monitor the status of the stockpile items. However, some performance information is not being provided monthly, as required. Over time, the monthly inventory management report has become a weekly stock-on-hand report which provides information on the number of pallets stored and is the basis for weekly payments to the external service provider. This arrangement has evolved without a formal contract variation. Further, while the inventory reports detail product description, product code, quantity of items and quantity of pallets—and more recently the expiry date for some items—the reports do not identify the date items are received, item batch/serial numbers (where available), item manufacture dates and stock movement.⁸⁹

3.40 The service provider for non-pharmaceutical items informed the ANAO that it provides pest management reports on a six-monthly basis to the department; however the department was unable to provide these reports to the ANAO. Reports on damaged stock are provided by the service provider on an exception basis, when damage is identified. The service provider has not reported on insurance status or status of expired goods on a monthly basis

88 ANAO Better Practice Guide—*Developing and Managing Contracts*, February 2012, Canberra, p. 30.

89 Not all PPE has a batch or serial number.

although this information is provided when requested. The ANAO was advised by the service provider that notwithstanding the contract requirements, the frequency and scope of the monthly inventory reports is dependent on the Department of Health's contract manager and whether these reports are actually sought.

3.41 The inventory report has a dual purpose—firstly, to provide a list of current stock that the department can use to update its information management system on the Stockpile; and secondly, to provide performance information for monitoring the contract for the storage of non-pharmaceutical items. Rather than relying on ad hoc local arrangements which are potentially inconsistent with contract requirements, there would be merit in the department considering the formal separation of the inventory report provided by the service provider into two reports—a regular inventory stock-on-hand report and a less regular performance report.

Monitoring of contract performance

3.42 The annual stocktake conducted by the department provides a further basis for monitoring contract performance. The stocktake has two purposes: to check the accuracy of the department's information on the Stockpile; and to identify any contract management issues. The stocktake involves physically checking stock against departmental records, identifying any variation and accounting for variations. Each year the department contracts an external contractor to lead the stocktake process. The Department of Health's role is to coordinate site visits, participate in the physical stocktake and general contract management (including assessing deliverables). The role of the contractor is to conduct an assessment of the stock holdings and report on the accuracy of the department's records against these.

3.43 Significant contract management issues were identified during the 2011–12 and 2012–13 stocktakes, concerning the storage of non-pharmaceutical items in warehouses in two states under subcontracted arrangements. The department's contract for non-pharmaceutical items makes provision for subcontracting arrangements with departmental approval. However, there is an ambiguity in the contractor's Business Continuity Plan about the exact nature of subcontracting arrangements and whether it is consistent with the department's contract provisions. In view of these inventory management issues—which have now been identified over two years in two states—there would be merit in the department clarifying the character of the arrangements entered into by the external service provider, and whether departmental

approvals are required under the subcontracting provisions of the contract. The department advised the ANAO that it has recently approved the use of alternative sites to address the issues identified, and the contract has been varied to reflect the new arrangements.

3.44 In summary, the current contract reporting system does not enable the department to confidently assess the extent to which external service providers are satisfying contracted requirements. The department should review reporting processes to gain additional assurance that all contracted performance reporting requirements are being met.

Recommendation No.2

3.45 To gain additional assurance that contract requirements are being met, the ANAO recommends that the Department of Health review and clarify reporting arrangements for its warehousing contracts with external service providers.

Department of Health response:

3.46 *The department agrees with this recommendation.*

3.47 *Procurement activity commenced in May 2014 in relation to outsourcing management of the Stockpile under a 'Prime Vendor' arrangement. The Prime Vendor system will include new arrangements for storage and maintenance of the Stockpile.*

Conclusion

3.48 The department currently manages 31 contracts relating to the supply of items and services for the Stockpile. The ANAO examined the department's procurement processes for the supply and storage of stockpile items, as well as contract management arrangements for the two national storage contracts.

3.49 The department employed a limited tender process for 18 procurements relating to the purchase of pharmaceuticals, on the basis that there was only one organisation that manufactured or was licensed to supply the particular product in Australia. While a limited tender approach in such circumstances is provided for in the Commonwealth Procurement Rules (CPRs), advice to the delegate on the key issue of value for money was generally limited; focusing on concerns that existing stocks of the relevant pharmaceuticals were reaching their expiry date and required replacement to maintain the Commonwealth's capacity to respond to health threats.

3.50 Thirteen procurements relating to the purchase of pharmaceuticals and PPE were conducted through open tender processes advertised on *AusTender*. The tenders were subject to evaluation and ranking by a departmental panel according to previously approved criteria, and advice regarding value for money was based on, and consistent with, the panel's recommendations for the preferred tender.

3.51 The ANAO's 2007–08 audit identified a number of issues with the department's storage contract arrangements for the Stockpile. Subcontracting arrangements had resulted in inconsistent standards and practices that were poorly controlled through the contract arrangements. The department responded through a process which consolidated short-term storage contracts into two longer term contracts relating to pharmaceutical items and to non-pharmaceutical items. An open tender process was conducted for the storage of pharmaceutical items, with three submissions received and one submission assessed as fully compliant. While the successful tenderer was offered a contract in December 2007, the contract was not executed until October 2010, some three years later, due to differences over indemnity issues. A second tender, to consolidate the storage of non-pharmaceutical items, attracted two submissions but issues identified by the tender evaluation committee prompted the department to cease the procurement process and directly procure the services of an existing warehouse provider on the basis that an approach to the market had failed. The department cited the provider's positive performance history with the department as the reason for directly approaching this provider.

3.52 The ANAO also noted in its 2007–08 report that the department's contracts for warehousing in place at that time did not provide a clear statement of contract requirements. In the current audit the ANAO assessed the 2010–14 contract for the pharmaceutical warehouse provider to assess the clarity of contract deliverables. While the contract requires six-monthly performance reports, these are not always submitted to the department, and the weekly stock-on-hand reports received by the department do not provide routine management information. Further, the bi-annual stock cycle counts and annual visual inspections of the stock, also required under the contract, are not currently being carried out and the outcomes are not reported. The department should review and clarify contract reporting arrangements as a basis for more effectively monitoring performance under the contract.

3.53 The contract for warehousing personal protective equipment has a measurable set of contract deliverables, and the monthly inventory report provided for in the contract provides a reasonable basis for the department to manage the contract and monitor the status of stockpile items. However, some performance information is not being provided monthly as required, and over time, the monthly inventory management report has also become a weekly stock-on-hand report. This arrangement has evolved without a formal contract variation—an ad hoc approach which can give rise to inconsistency with contract requirements.

3.54 The department's annual stocktake of warehoused items has two purposes: to check the accuracy of its information on the Stockpile; and to identify any contract management issues. The stocktake involves physically checking stock against departmental records, identifying any variation and accounting for those variations. Significant contract management issues were identified during the 2011–12 and 2012–13 stocktakes, concerning the management of Stockpile inventory in two warehouses. The department advised the ANAO that it has recently approved alternative sites for these warehouses and the relevant contracts have been varied to reflect the new arrangements.

4. Inventory Management

This chapter examines inventory management for the Stockpile, including the selection of items and quantities.

Introduction

4.1 The ANAO observed in its 2007–08 performance audit that effective inventory management requires processes and systems to ensure the content and currency of the Stockpile is maintained. Effective inventory management relies on a planned approach to selecting items for the Stockpile, and systems to track the condition and quantity of stock so as to maintain the efficacy of the Stockpile and inform the planning process.⁹⁰

4.2 This chapter focuses on the level of assurance provided by the department's inventory management of the Stockpile through:

- selecting items for the Stockpile on the basis of a planned approach informed by clinical evidence and appropriate advice; and
- using inventory management and information systems that effectively track stock and accurately record inventory status.

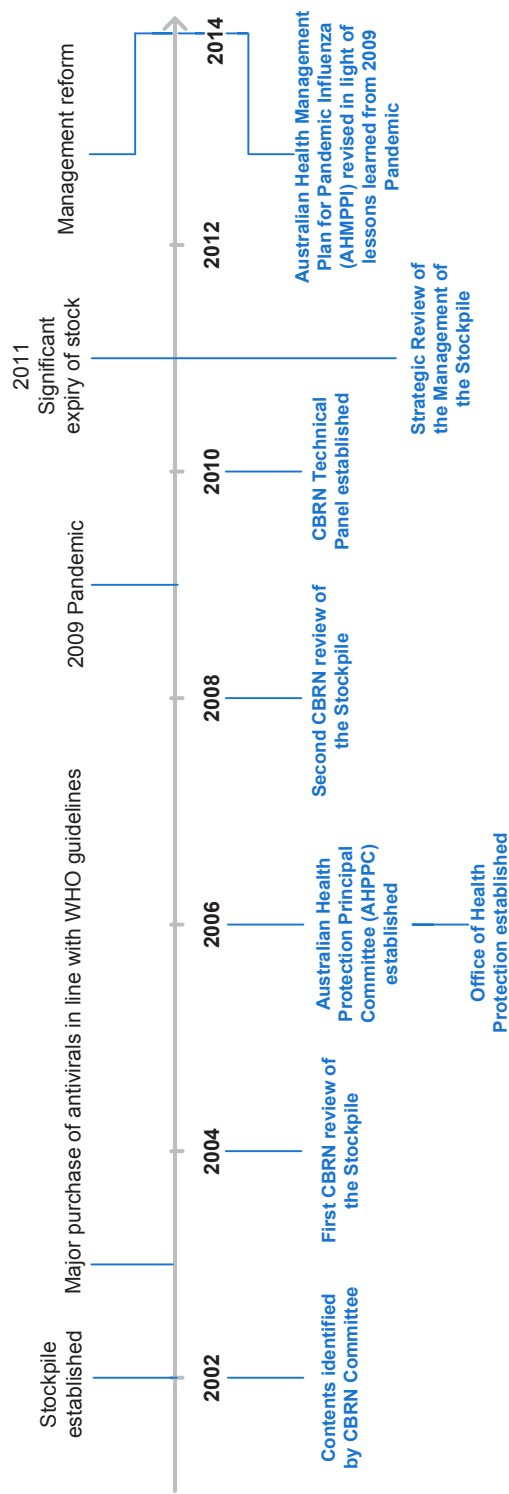
Selecting the Stockpile inventory

Phase 1: Establishing and reviewing the CBRN inventory

4.3 Since it was established in 2002, the Stockpile has grown substantially from a relatively small resource intended to deal with chemical, biological and nuclear threats and terrorist activity. Today, the Stockpile is dominated by products associated with human influenza preparedness. The development of the Stockpile can be separated into three distinct phases: the establishment of the Stockpile in 2002; a pandemic preparedness phase; and a post-2009 pandemic phase, which has required consideration of issues relating to stock expiry, reform and review processes. Figure 4.1 outlines key events and management responses in the development of the Stockpile.

90 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p. 96.

Figure 4.1: Key events and management responses in the development of the Stockpile



Source: ANAO.

4.4 The department established a CBRN committee in 2001—following the 11 September 2001 terrorist attacks in the United States and the 2001 anthrax letter attacks in the United States—to advise on the development and contents of the Stockpile and emerging threats. Since that time the department has periodically reviewed the evidence base for the Stockpile.⁹¹

4.5 The department has completed two reviews of the CBRN components of the Stockpile, in 2004⁹² and 2008.⁹³ The 2008 review⁹⁴ assessed the appropriateness of the CBRN contents and was informed by the interim CBRN review in 2004. The 2008 review made nine recommendations related to:

- obtaining stakeholder agreement on the purpose of the Stockpile and criteria for including items in the Stockpile;
- increasing or maintaining inventory levels on specific items in the Stockpile;
- prospective purchases of items and quantities required; and
- pre-deployment arrangements including holding arrangements for Stockpile items.

4.6 Some recommendations have been implemented. For instance, the then Government agreed to high level outcomes for the Stockpile in March 2011.⁹⁵ A number of recommendations are still being progressed such as the development of criteria for item selection and pre-deployment of CBRN items with state governments.⁹⁶

91 Following the establishment of the Stockpile in 2002, the CBRN committee continued to advise the CMO on Stockpile matters and, in 2004, a Department of Health Infectious Diseases Emergency Response working group conducted the first major review of the biological countermeasures in the Stockpile and reported to the CMO. The department, through the Australian Health Protection Principal Committee, has also produced a Domestic Health Response Plan for CBRN of National Consequence which provides a framework and mechanisms for effective national coordination, response and recovery arrangements.

92 The review was conducted by the Department of Health's Infectious Diseases Emergency Response working group in 2004 and was the first major review of the biological countermeasures in the Stockpile.

93 The department advised that 'the CBRN reviews undertaken were internal, informal review [activity] that was not endorsed, nor recommendations accepted by the Department or key expert advisory bodies. The reviews were processes to guide thinking in the context of stockpile replenishment and response planning.'

94 Department of Health and Ageing, 'Final Review of National Medical Stockpile', November 2008.

95 Refer to paragraph 2.16 for more detail.

96 In April 2011, the Government tasked the Department of Health with considering and implementing, where appropriate, the recommendations of the 2008 review; and to involve the Minister for Health and other Ministers where appropriate.

Phase 2: Pandemic Preparedness

4.7 The initial stockpiling of antivirals in Australia was carried out in 2003–04 as a response to increasing concerns about avian influenza and the potential for an influenza pandemic. The department's actions in stockpiling antivirals drew on World Health Organization (WHO) guidance on pandemic preparedness, which indicated the effectiveness of antivirals for the prevention and early treatment of influenza. In its 2007–08 audit the ANAO concluded that Australia had addressed the minimal and desirable elements of the WHO planning framework for a pandemic including stockpiling of influenza antivirals.⁹⁷ At the time, Australia had one of the highest per capita stockpiles of influenza antivirals in the world at nearly 44 per cent of the population.⁹⁸

4.8 The Australian Health Management Plan for Pandemic Influenza (AHMPPI) is the agreed basis on which the national health sector responds to pandemic influenza.⁹⁹ As part of the planning process associated with the AHMPPI, the department has done relevant work to obtain evidence which informs the selection of appropriate levels of antiviral coverage for the Stockpile.¹⁰⁰ In particular, this work has informed decision-making on the minimum quantity of items in the Stockpile needed to minimise the severity of the assessed risk.

4.9 The ANAO examined the department's recent evidence gathering to support decisions for inventory selection and the quantity of antivirals and personal protective equipment (PPE) purchased in preparation for an influenza pandemic.¹⁰¹ The department has commissioned two modelling projects—one on antivirals and one on PPE—discussed in the following paragraphs.¹⁰²

97 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p. 19.

98 *ibid.*, p. 20.

99 The plan was first developed in 2006 and was revised in 2008 and 2009. It was further revised in 2014 in light of the lessons learned from the 2009 Pandemic.

100 The department's *Review of Australia's Health Sector Response to Pandemic (H1N1) 2009* also recognised the moderate nature of the 2009 pandemic and that the higher demands of a severe pandemic made it prudent to review the range and quality of stockpiled goods for an influenza pandemic.

101 A supply chain analysis prepared by consultants in August 2013 reported that in terms of the department's expenditure on key items, the suppliers of antivirals and P2 respirators together accounted for 85 per cent of the total Stockpile expenditure on purchases. The total cost of PPE for the Stockpile includes the cost to store PPE, which is significant as PPE items represent 59.9 per cent of the total volume of the Stockpile.

102 The department advised the ANAO that several other literature and evidence reviews have been commissioned which have been used as reference material in drafting the revised AHMPPI, in particular Part 3 which relates to decision support and evidence collection.

Antiviral modelling

4.10 The Department of Health contracted the University of Melbourne to undertake antiviral modelling to inform the evidence base for the revised AHMPPI. The purpose of the modelling was to assist in determining the coverage and quantities of antivirals required for the Stockpile. The reports on this modelling were delivered between June 2012 and June 2013.

4.11 These studies identified the number of doses required for an antiviral stockpile to achieve a particular level of coverage¹⁰³ and a range of effective inventory levels of antivirals, depending upon the prevention and treatment strategy selected and modelled.¹⁰⁴

4.12 The focus of this work on antivirals has been for adults. The ANAO examined departmental records on epidemiological modelling and inventory levels and did not observe specific analysis informing paediatric antiviral inventory levels. This issue arose in the context of the 2011 Strategic Review, which recommended that 'the level of paediatric antiviral supplies should be reviewed by the department (using epidemiological modelling) to ensure an appropriate inventory level and cost effectiveness'.¹⁰⁵ The department advised the ANAO that the recommendation has not yet been implemented as the relevant manufacturer has only recently recommenced production. The department further advised that it will commence a review in 2015 of the paediatric inventory.¹⁰⁶

PPE modelling

4.13 The department also commissioned research which estimated PPE usage and inventory levels for the Stockpile, with a final report received in December 2013. The report concluded: 'with full cohorting, a PPE stockpile of

103 The study determined that an antiviral stockpile of approximately eight million doses 'was generally sufficient to enable continuous pre-exposure coverage of frontline workers, along with a targeted post-exposure treatment and prophylaxis strategy'.

104 Murdoch Children's Research Institute and University of Melbourne, 'Interim Report on Simulation Modelling: Mathematical Modelling of Antivirals for a Public Health Response to an Influenza Pandemic', June 2013, pp. 4–6.

105 Department of Finance, 'Review of the National Medical Stockpile', 2011, Canberra, p.16.

106 The department advised that the Stockpile has lower strengths of Tamiflu capsules that could be used for children.

the order presently maintained by the Australian government would likely be sufficient for use in a pandemic of moderate impact'.¹⁰⁷

4.14 Estimates of the amount of PPE required depend on a range of factors such as the model of care adopted, assumptions about how PPE is used in health care settings, and the transmissibility of the influenza strain.¹⁰⁸

4.15 The model of care used in the research was based on a 'cohorted' model involving General Practice clinics and influenza hospitals dedicated to pandemic treatment. The main implication of the selected model of care on estimates of PPE required in a pandemic is that the cost of PPE is significantly reduced if health care is delivered in a cohorted model.¹⁰⁹ The model of care affects the selection and amount of PPE required for the Stockpile, and will have implications for the inventories held in general practice, and for state stockpiles.¹¹⁰

4.16 The department's re-exploration of the evidence base for the pandemic component of the Stockpile was intended to provide assurance that the items and quantities purchased to maintain the currency and capability of the Stockpile are informed by appropriate evidence.¹¹¹

Phase 3: Inventory management since the 2009 Pandemic

4.17 The expiry of stock and the need to replenish items to maintain operational capability has emerged as a key issue in the management of stockpile inventory in Australia and around the world. The pharmaceuticals and nearly all other Stockpile items have a finite shelf life which means that they may need to be disposed of at the end of that life without being used. Further, the storage of expired stock incurs a cost.¹¹²

4.18 The 2011 Strategic Review identified significant costs associated with expiring stock and the lack of cost-effectiveness analysis in the selection of the

107 The Australian National University, University of Adelaide and University of Melbourne, 'Final Report on Estimated PPE Usage and Stockpiling Requirements', Department of Health, December 2013, p. 4.

108 For example, a low-transmissibility pandemic grows slowly and requires a larger volume of PPE as the pandemic persists for longer.

109 Based on the health care model used in the 2009 pandemic, the PPE non-cohorted total cost was estimated at \$63.6 million compared to \$28.2 million for a PPE cohorted total cost.

110 For example, the ANAO observed that one state's stockpile contained predominantly surgical masks and it was therefore reliant upon the national Stockpile for its supplies of P2 respirators.

111 The department advised that the modelling would also be a key input into considering required quantities as part of proposed new stockpiling arrangements between the Commonwealth and the states.

112 See paragraph 2.29.

Stockpile's inventory and quantities. The main focus of the department's activities since the Strategic Review has been on replenishing expiring stock, responding to the review's recommendations and management reform.

4.19 The department has commenced development of a more systematic approach to selecting items for the Stockpile. An inventory selection framework has been drafted by the department that identifies a range of issues that should be considered when determining the items (and quantities) for inclusion in the Stockpile. When finalised, the framework should provide the basis for a more systematic approach to selecting the Stockpile inventory, including CBRN items.

4.20 In order to maintain the operational capability of the Stockpile, the department monitors the expiry dates of Stockpile items and has sought additional funding to replenish expiring stocks through the annual Budget process.

Improving Stockpile management

4.21 In April 2011, following the 2011 Strategic Review, the Australian Government tasked the Department of Health and the National Medical Stockpile Interdepartmental Steering Committee (IDSC) to explore a range of strategies to improve the efficiency of the department's management of Stockpile items. Two key strategies were:

- developing a fully-costed model for shelf life extension; and
- examining options for stock cycling or rotation.

Shelf life extension

4.22 The 2011 Strategic Review found that there were 'considerable savings to be found in adopting shelf life extension where products are stable and risks can be mitigated'.¹¹³ An effective shelf life extension program, involving an acceptable level of risk, has the potential to reduce the capital cost of stockpiling pharmaceuticals, and given the dominance of these items in the capital cost of the Stockpile overall, could deliver significant savings.

4.23 The IDSC's meeting records for 2011 and 2012 indicate that the committee examined the use of expired stock and shelf life extension.

¹¹³ Department of Finance, 'Review of the National Medical Stockpile', February 2011, Canberra, p.10.

However, consideration of these issues ended with the IDSC meeting of 24 August 2012, with the minutes recording that: ‘the Department will not implement the proposed model noting that significant liability issues, potential breaches of state legislation, public perception regarding the use of expired products, and cost related to possible re-labelling outweigh its benefits’.

4.24 The department prudently explored the issue of shelf life extension and use of expired stock, as proposed by the 2011 Strategic Review, and the IDSC came to a view on the matter.

Cycling or rotating Stockpile stock

4.25 The 2011 Strategic Review also considered the possibility of cycling or rotating Stockpile items to: minimise waste; minimise storage and disposal costs; and reduce the need for regular replenishment. There are a range of market factors and sensitivities that determine the cost-effectiveness or viability of rotating stock. For instance, only some stockpile items could be cycled through state hospital supply chains or Defence’s supply chains.

4.26 The department engaged an external consultant to examine the supply chains and operational model for the Stockpile. The consultant’s 2013 report identified potential to rotate some stockpile items through the supplier’s stock; particularly antibiotics and some PPE.¹¹⁴ Currently the department has arrangements for stock rotation through suppliers for some antibiotics and it was considered possible to rotate 10–15 per cent of P2 respirators. However, the savings estimated over a 10 year period for P2 respirator rotation were less than one per cent; and for the antibiotic, amoxicillin, were also less than one per cent. The consultant also reported on the risks associated with stock rotation and cited two ‘extreme’ risks—relating to contractual failure to deliver and deployment delays due to complexities. In addition, the risk that suppliers may not hold the required volumes despite rotation volume agreements, was assigned a ‘high’ risk rating. That said, the report listed a number of risk mitigation strategies including: conducting negotiations with potential suppliers to agree on contractual terms and conditions; having appropriate information systems to track items and destination locations in real-time which are accessible to the department during an emergency; and undertaking

¹¹⁴ CBRN items were not considered to be viable for rotation as they were specialised items that were not in general use.

regular stocktakes at both the department's and supplier premises to ensure appropriate levels of stock are on hand.¹¹⁵

4.27 The report also identified a number of barriers to the effective rotation of some stockpile items. For instance, the stockpile's volumes of Tamiflu were very high compared to overall Australian market demand, thus preventing effective rotation of Tamiflu.¹¹⁶ Similarly, there was no Australian market to enable rotation of Relenza and relabelling requirements prevented product entry into other markets.¹¹⁷

Other strategies to reduce cost

4.28 The department has identified a number of opportunities to reduce costs in respect to specific stockpile items. The department advised that the Australian Government purchased Tamiflu at a government price offered worldwide by the manufacturer, Roche, which was less than the price paid commercially for the product. The department also participated in a program offered by Roche to return some of its expired Tamiflu bulk powder to the manufacturer and received new Tamiflu capsules at approximately half the cost of new product. The department's second and final exchange of Tamiflu bulk powder was completed in 2014. While there may be opportunities to purchase antivirals at a better price into the future (Relenza will come off patent from 2014 and Tamiflu from 2016), the department has advised that there is no guarantee when or if a generic product will come onto the market.¹¹⁸

4.29 The 2011 Strategic Review identified opportunities to reduce storage costs, observing that the Department of Health was paying to store expired stockpile items.¹¹⁹ The department has advised that it has conducted progressively larger destruction programs to assist in reducing the costs of storing expired items.¹²⁰

115 Ernst & Young, 'Supply Chain and Logistical Operating Model Review', August 2013, p.59

116 This was advised by the manufacturer of Tamiflu, (Roche), to Ernst & Young.

117 This was advised by the manufacturer of Relenza, (GlaxoSmithKline), to Ernst & Young.

118 The department also advised that regulatory processes can mean long lead times for new products emerging onto the market. The department has estimated that the market may take two to three years to settle following a patent expiration. There are also a number of new antivirals currently undergoing clinical trials that may in the future prove more efficacious.

119 For example, storage costs for expired items in 2010–11 were \$160 000. It should be noted that expired items are not disposed of until replenishment has occurred. Hence expired stock will incur storage costs.

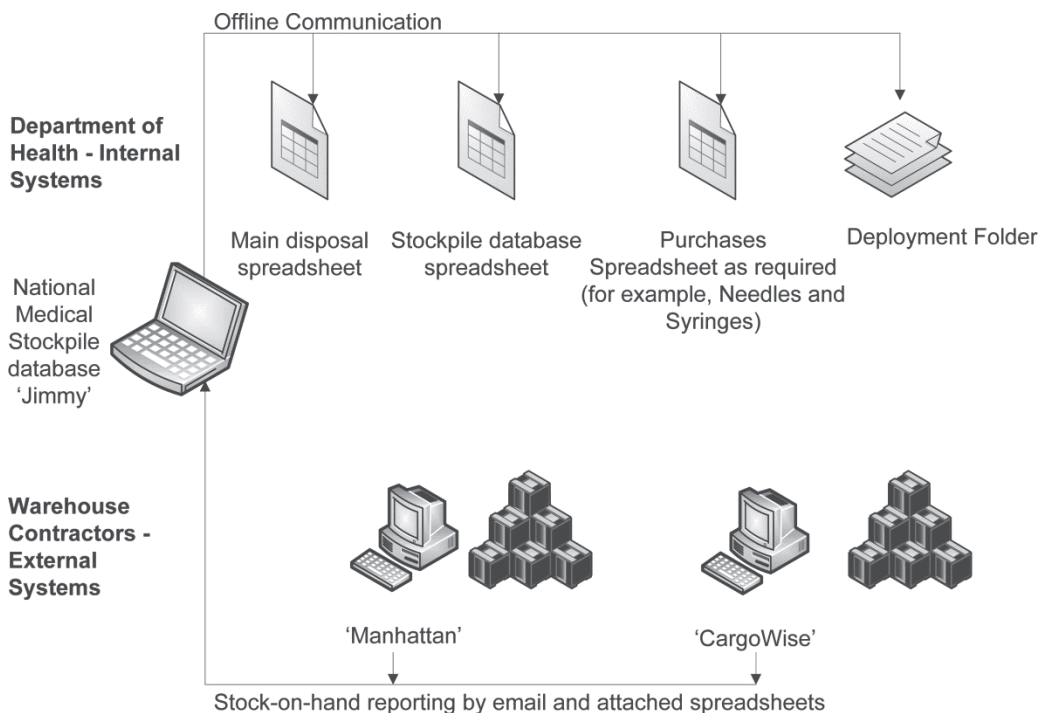
120 In 2012–13 the department disposed of stock valued at \$57 453 224 compared to \$10 111 076 in 2011–12 and \$1 166 396 in 2010–11.

Stockpile inventory management systems

4.30 Information management systems can contribute to the efficient and effective management of the Stockpile by providing accurate and timely information on stock levels, status (condition and expiry information) and location. This information is necessary for an effective response to a health emergency, day-to-day management of the stock and longer term planning for the Stockpile.

4.31 The process for linking together different computing systems and software applications so they operate as a coordinated whole is referred to as system integration. Well integrated systems deliver timely and accurate information. Other benefits include greater efficiency through reduced manual intervention and consistent practices. The main information management systems for the Stockpile are outlined in Figure 4.2.

Figure 4.2: Main Stockpile information management systems



Source: ANAO.

4.32 Figure 4.2 shows that a number of information management systems and processes are used to support the Stockpile's management. These include a standalone stockpile database which records stockpile items and quantities; a

range of supporting spreadsheets; and external warehouse inventory management systems used by contractors.

4.33 Currently, there are no system interfaces to support automatic data transmission between the information management systems shown in Figure 4.2.¹²¹ Instead, the department relies on emails and attachments (including manual forms and spreadsheets) to transmit key information for the operation of the Stockpile.¹²² A report by KPMG in 2012, which included an assessment of the Stockpile's information systems, found that all management of the Stockpile required offline communication with multiple service providers to coordinate inventory movements and operations.

4.34 To assess the adequacy of the inventory management systems that support the operational management and deployment of the Stockpile, the ANAO examined systems integration and data integrity in relation to:

- the Stockpile database, which is the department's in-house stand-alone information system, and supporting information processes¹²³; and
- the Warehouse Management Systems (WMS) used by the two major warehouse providers contracted by the department to hold stock.¹²⁴

4.35 The ANAO also assessed the effectiveness of selected controls for monitoring, reconciling and reporting on stock levels. The ANAO did not assess processes for the disposal or destruction of expired stock as disposal was the subject of an internal audit by the department in 2012. The internal audit report identified weaknesses in some of the controls associated with the department's processes for disposing of expired stock, such as disposal guidelines, disposal planning, stock reconciliation and management reporting.¹²⁵ The program area responsible for managing the Stockpile agreed to address the six recommendations outlined in the internal audit report by February 2012, and the department's internal audit function

121 The department advised that the main reason there has been no system interface is due to lack of capacity for security/confidentiality.

122 The department advised that these emails and attachments are cross-referenced with invoices, information from suppliers, disposal contractors and other jurisdictions, depending on the information being supplied.

123 This includes the Stockpile database spreadsheet, the deployment folder, the disposal spreadsheet, and the purchases spreadsheet.

124 The two warehouse providers each use different warehouse management systems to manage their stockpile inventories.

125 Department of Health, 'Audit of the Management of the Disposal of National Medical Stockpile Expired Stock', Audit Report No.19 of 2011–12, Audit and Fraud Control Branch, January 2012.

advised the ANAO in May 2014 that all recommended process improvements for disposing of expired stock have been fully implemented.

The Stockpile database

4.36 The Stockpile database was custom-built in July 2010 to support inventory management, some eight years after the establishment of the Stockpile. The database was designed as a standalone system and does not interface with the department's internal IT systems or those used by the warehouse providers.¹²⁶

4.37 The ANAO observed that some Stockpile information is also recorded in spreadsheets that are stored outside of the Stockpile database. There would be benefit in reviewing the security and operational risks of this practice to ensure that the spreadsheets are subject to relevant security and IT controls.

4.38 A number of other features of the database's design have limited its functionality and useability, resulting in the need for work-arounds and duplication of effort.¹²⁷ Some of the observed limitations were evidenced by practices that included:

- departmental staff using spreadsheets from the database, to supplement missing functionalities in the database; and
- managing the disposal process through a master spreadsheet which manually combines information from the Stockpile database and information from warehouse contractors' information systems.

4.39 Information stored in the Stockpile database is based on the manual entry of information provided by warehouse contractors. The quality and availability of data therefore depends on the accuracy and timeliness of its entry in the database. There were instances of delays and inaccuracies arising from the manual updating process.

¹²⁶ Both financial information and inventory information were sourced from other systems and then manually consolidated and recorded in the Stockpile database.

¹²⁷ The department advised the ANAO that only essential software upgrades have been undertaken due to limited resources.

4.40 Delays related to:

- the correction of inaccurate stock records which the department identified through the 2012–13 stocktake;
- updates to the database following a high volume disposal process undertaken in the first half of 2013; and
- updates following the receipt of goods as part of a large purchase of syringes and needles in 2013.

4.41 Inaccuracies that were identified included:

- discrepancies between the Stockpile database and the spreadsheet that the department used to coordinate all disposals, which makes it difficult for the department to identify which information is authoritative; and
- inconsistencies and errors from mismatched stock reports for disposal compared with records in the Stockpile database.

4.42 For example, the ‘Main DoH Disposal Spreadsheet 2012–13’ identified stock for destruction which had not been destroyed according to stock-on-hand reports provided by the warehouse contractors. Part of the problem related to the complexity of identifying stock for disposal when assembling the department’s disposal spreadsheet from various sources and then informing the warehouse contractor.

4.43 The department relies on records held in the database to support the Stockpile’s operation and for management and business level reporting. Delays in updating the database and inaccuracies in data holdings can compromise the database’s value as an authoritative source of information for management and planning purposes. A 2012 consultant’s report found that the department’s continued reliance on the current stockpile systems would ‘likely cause ongoing issues due to inefficiencies, functionality gaps and manual processing and rework and the lack of a single source of truth.’¹²⁸

128 KPMG, ‘Department of Health and Ageing: National Medical Stockpile Migration Project Technology Enablers, Final Report’, 2012, p. ix.

Warehouse management systems used by external service providers

4.44 The external storage provider for non-pharmaceutical items predominantly uses CargoWise—a commercially available warehouse management system that supports warehouse and logistics operations—to manage the stockpile inventory for warehouses that it directly manages, as well as for its three subcontractor warehouses.¹²⁹

4.45 CargoWise is capable of identifying and labelling individual pallets of stock, which potentially enables the rapid identification of stockpile items in a warehouse. The system can also: provide online and real time access to information on inventory status; generate reports; and perform business transactions. However, these capabilities are not used by the contractor for the day-to-day management of the department's stockpile items.¹³⁰

4.46 Cargowise can identify and label each pallet of stockpile items by creating and using a unique identification number for each pallet called a Licence Plate Number.¹³¹ The external service provider provides Licence Plate Numbers for other clients but does not use this functionality for the department's stockpile items. Instead, it identifies a group of pallets of like items with the same product, batch number or expiry date.¹³²

4.47 At present, the external service provider can identify a common group of stockpile items but it cannot identify a unique stockpile pallet. While this approach does not necessarily put stock at risk, it makes it more difficult to identify a stockpile pallet if the department required a particular pallet of items to be deployed, or moved to a different warehouse, or destroyed.

4.48 The department receives information from CargoWise through 'receive confirmation' notices emailed by the external service provider, rather than an online access portal. The notices advise of stock received, or other exception reporting, and include a weekly spreadsheet—known as the stock-on-hand report. The department advised the ANAO that it was not aware of the

129 The external service provider provides warehouse and logistic support for the non-pharmaceutical items in the Stockpile, such as personal protective equipment—gloves, masks, gowns, and other stock such as hand cleanser and syringes.

130 Identifying each pallet of stockpile items is based on its batch number, expiry date and lot number.

131 Radio frequency device scanning can also be used to associate that unique number with a warehouse racking location.

132 Similar to all the warehouse providers examined by the ANAO, stockpile items are co-located with items held on behalf of other customers.

existence of an online portal function, and had therefore not made use of the full functionality of the systems used by the external service provider.¹³³ The department further advised that future procurements will seek to use this capability but with due consideration of appropriate IT security requirements.

4.49 The accurate recording of an expiry date for items in the Stockpile facilitates the management of expiring stock. It is also a requirement under the contract with the department that the Cargowise system used by the external service provider enables reporting of expiry dates.¹³⁴ Some products entered into Cargowise before January 2012 had no expiry dates recorded.¹³⁵ This occurred because the service provider did not capture expiry dates when the items were first recorded in the system, and it was not possible to add this information to a current record at a later date.¹³⁶ The external service provider informed the ANAO that it began to consistently record the expiry dates for stockpile products in CargoWise from January 2012.¹³⁷ Correspondence between the department and the external service provider indicates that there have been efforts to improve the recording of product expiry dates in CargoWise.

Inconsistencies between stock recorded on contractor systems and the Stockpile database

4.50 The ANAO examined inventory information kept by the Northern Territory based contractor that used a warehouse management system other than CargoWise for managing stockpile inventory.¹³⁸ There were some inconsistencies between the stock recorded in the contractor's warehouse management system, in CargoWise, and in the department's Stockpile

133 The contract states that the service provider must provide the department with access to CargoWise and provide instructions and training on the use of the online system and reports.

134 Department of Health and Ageing, 'Deed of Variation No. 1: National Warehousing, Logistic Planning Support, Transportation and Related Services', 29 March 2011, p. 3.

135 As of October 2013, approximately nine per cent (660 pallets out of 7255 pallets) of stock had no expiry date or inadequate information for an expiry date to be ascertained. This was based on a CargoWise stock-on-hand report.

136 The external service provider advised the department that to back fill the expiry date information would have required the deletion of all current product records, the creation of new product shells, and the re-entry of all product records.

137 Expiry dates were entered into the field for 'description' of the product, or sometimes into the field for 'lot number'.

138 There are three warehouse contractors; the Western Australia and South Australia contractors use a warehouse management system called Sapphire Logistics, and in the Northern Territory the contractor uses a warehouse management system called S2 Logistics.

database.¹³⁹ These inconsistencies resulted from the contractor not recording the location of pallets in their warehouse management system, which meant that locations were not being recorded in CargoWise.¹⁴⁰

4.51 While the ANAO's physical count of selected items at the contractor's warehouse matched the contractor's records, the use of multiple systems combined with inconsistencies in recording has introduced risks in accounting for stock. The non-recording of pallet locations in this particular warehouse also represented a risk that stock may not be located when required.

Warehouse management systems for pharmaceutical stockpiled goods

4.52 The main inventory management system used by the storage provider for pharmaceutical goods is called Manhattan—an off-the-shelf warehouse management system primarily designed to control the movement and storage of inventories within a chain of warehouses and to process the associated business transactions, such as the transporting, receiving, storage, and dispatch of stock.¹⁴¹ While Manhattan 9 is the main and current version, not all of the storage provider's warehouses were using Manhattan 9. In June 2013, as part of an annual stocktake, the department identified that these arrangements introduced risks to data integrity.

4.53 A 2012 report on the Stockpile's information systems noted that the storage provider for pharmaceutical goods had 'traditionally maintained inventory manually in spreadsheets and over time have migrated this information from spreadsheets into their storage management systems'—Manhattan.¹⁴² However, this data migration was done manually and resulted in some data transmission errors which have required effort by the department and storage provider to reduce or resolve those errors. Following the 2012–13 stocktake, the department communicated with the storage provider to explore and resolve the data issues.

139 For example, some Stockpile stock had arrived in the contractor's warehouse over four weeks prior; it was receipted and reported to the service provider and was recorded in CargoWise, but was not in the contractor's warehouse management system, and had not been entered into the Stockpile database.

140 The contractor had also begun to use different units to measure 'items on hand'. Rather than recording the number of cartons, the number of individual units was recorded. Similarly, a stock item 'goggles' was recorded in the contractor's warehouse management system and in CargoWise as 47 cartons, however in the Stockpile database it was recorded as 15 cartons and 6768 items.

141 Manhattan 9 uses the automatic identification of goods and data-capture technology—such as bar code scanning. It is also integrated with other advanced technology for real-time monitoring and tracking of goods in movement.

142 KPMG, 'Department of Health and Ageing: National Medical Stockpile Migration Project Technology Enablers, Final Report', 2012, p. 19.

4.54 In the course of an annual stocktake in July 2013, the department identified that warehouses used to store pharmaceutical goods for the Stockpile in four capital cities had their inventory information uploaded into Manhattan 9. However, only two of these warehouses could use Manhattan 9 live—introducing data integrity risks. The department observed that:

All other capital cities record stock on either an Excel spreadsheet or on an earlier version of Manhattan 4. There are risks that systems outside of Manhattan 9 will be updated but those changes won't be reflected within Manhattan 9.

4.55 To examine whether the use of multiple systems may be causing data integrity issues, the ANAO conducted a spot check of the data in a backup spreadsheet used by the service provider against the same information in Manhattan 9. The ANAO's testing indicated the backup spreadsheet contained errors, as the spreadsheet had not been updated to reflect the outcome of the annual stocktake.

4.56 The service provider for pharmaceutical goods informed the ANAO that all warehouses went live with Manhattan 9 in December 2011. However, a departmental document produced by the service provider¹⁴³ indicated that stock storage information is stored on an Excel spreadsheet. Duplicate data systems have the potential to affect the integrity of Stockpile information.

4.57 The department advised the ANAO that each week a stock-on-hand report is downloaded into a Microsoft Excel spreadsheet and emailed to the department. The department uses a standalone stockpile database to manage the whole of the Stockpile inventory. Once the stock-on-hand report has been examined and signed off by the departmental delegate, any necessary adjustments are made to the department's stockpile database. The department further advised that ongoing liaison with service providers occurs as required, to address issues arising in the stock-on-hand report and the annual stocktake of items.

Access controls for warehouse management systems

4.58 The inventory management systems used by warehouse service providers have a built-in security component which can restrict user access to information; a control that can help preserve data integrity. Different types of users have different level of access to the information held in the warehouse management systems through information segregation. The ANAO was

143 Department of Health, 'Stock Deployment Procedure', 25 February 2013.

advised by the two service providers that when external customers interact with their respective warehouse management systems (either Manhattan 9 or CargoWise), via an online portal or more advanced integrated systems, they may only access data related to their own inventory. The department advised the ANAO that the use of a shared online portal, particularly one which other organisations may access, presents security risks that would need to be considered before an online portal is used for the Stockpile.

Effectiveness of data integrity controls

4.59 Accuracy of data is the extent to which it is free from errors.¹⁴⁴ Data integrity describes the reliability of the data, and whether it is current and relevant.¹⁴⁵

4.60 To assess the effectiveness of the controls over data quality in the various information management systems relating to the Stockpile, the ANAO:

- examined the department's internal systems (the Stockpile database, deployment folder, and other spreadsheets) which are used to manage the Stockpile records;
- compared records held in the Stockpile database with results from the department's 2012–13 stocktake;
- compared records held in the Stockpile database with records held in the warehouse management systems of external service providers for pharmaceutical and non-pharmaceutical goods; and
- validated records held within the internal systems and warehouse management systems of service providers for pharmaceutical and non-pharmaceutical goods (including the use of spreadsheets by the service provider for pharmaceutical goods).

4.61 As discussed, the ANAO identified a number of data integrity issues including:

- data discrepancies between information held in the deployment folder, when compared with the Stockpile database records and with the results of the 2012–13 stocktake¹⁴⁶;

¹⁴⁴ Data accuracy refers to whether the data values stored for an object are the correct values. To be correct, a data value must be the right value and must be represented in a consistent and unambiguous form.

¹⁴⁵ Data quality is dependent on data accuracy and integrity.

- data discrepancies between information held in the Stockpile database and warehouse system records by both external service providers¹⁴⁷;
- data integrity issues relating to the use of several information systems, including spreadsheets, by the pharmaceutical warehouse provider;
- some discrepancies in one of the warehouses between Manhattan 9 records held by the external service provider and its warehouse spreadsheet; and
- systems and processes being used to manage the department's stockpile inventory, specifically the use of Manhattan 9 and spreadsheets by the external service provider for pharmaceutical goods, may be contributing to data integrity issues.

4.62 Taken together, the range of issues identified by successive reviews—including this audit, the 2012 KPMG information technology report¹⁴⁸ commissioned by the department and the 2011 Strategic Review—indicates that the department should review its information management arrangements for the transfer of Stockpile data.

Recommendation No.3

4.63 To improve the management and integrity of data relating to the National Medical Stockpile, the ANAO recommends that the Department of Health review its information management arrangements for the transfer of Stockpile data.

Department of Health response:

4.64 *The department agrees with this recommendation.*

4.65 *New Prime Vendor arrangements will include new IT and data management systems.*

146 The ANAO observed that the deployment folder was not up-to-date. Six out of 25 influenza items contained inaccuracies, in particular listing expired stock; and six out of 19 CBRN items contained inaccuracies, in particular listing expired stock.

147 There were discrepancies between the Stockpile database records and stock-on-hand reports provided by the external service provider for storage of pharmaceutical items. These related to stock identified for destruction by the department which had not been destroyed according to the records of the storage provider. There were some inconsistencies in the recording of stock across warehouse management systems used by the external service provider (and its contractors) and the Stockpile database. These included the non-recording of pallet locations and the use of different units of measurement. These represent a risk that stockpile items may not be able to be located when required.

148 KPMG, 'Department of Health and Ageing: National Medical Stockpile Migration Project Technology Enablers, Final Report', 2012.

The annual stocktake as a key control for data integrity

4.66 Currently, the department relies on one key control to maintain data integrity—the annual stocktake conducted by the department and an external contractor. The department conducts an annual stocktake in order to gain assurance that its stockpile records reflect the true status of the inventory at warehouse level, and to ensure that warehouse contractors are fulfilling their contractual obligations in storing the stock. Information collected during the stocktake is subsequently used to adjust information management system records—such as the Stockpile database.

4.67 The Department of Health's 2012–13 stocktake identified that 54 799 143 stockpile items were present, and of these, 53 303 186 were identified in the Stockpile database. This represents a variance of 1.96 per cent of items identified but not recorded in the Stockpile database. The variance indicates that there are some risks in relying on the Stockpile database as an authoritative source of information.

4.68 In reporting the results of the 2012–13 stocktake, the external contractor stated that 'the majority of items in the Stockpile counted in the stocktake correlated to the department's inventory records. A minor range of variances was detected', and recommended that the department should 'establish formal reconciliation processes prior to stocktake visits so that updates to the department's and warehouse inventory management systems ensure any potential variances are addressed in a timely manner'.¹⁴⁹ The department advised the ANAO that it will be making changes to the 2013–14 stocktake process to enable more timely management of stocktake variances.

Conclusion

4.69 The department has completed two reviews of the CBRN components of the Stockpile, in 2004 and 2008. The 2008 review made nine recommendations, including obtaining government agreement on the purpose of the Stockpile. The then Government agreed to high level outcomes for the Stockpile in March 2011, while a number of other recommendations are still being progressed; such as the development of criteria for item selection and pre-deployment of CBRN items with state governments.

¹⁴⁹ Ernst & Young, 'National Medical Stockpile Stocktake 2012–13', Department of Health and Ageing, 30 June 2013, pp. 1,2.

4.70 The initial stockpiling of antivirals in Australia was carried out in 2003–04 as a response to increasing concerns about avian influenza and the potential for an influenza pandemic. In its 2007–08 audit report, the ANAO concluded that Australia had addressed the minimal and desirable elements of the WHO planning framework for a pandemic including stockpiling of antivirals. In the current audit the ANAO examined the Department of Health’s recent evidence gathering to support decisions for inventory selection and the quantity of antivirals and PPE purchased in preparation for an influenza pandemic. The department has commissioned two modelling projects—one on antivirals and one on PPE—to inform its consideration of the evidence base for the pandemic component of the Stockpile. The department’s approach is intended to provide assurance that the items and quantities purchased to maintain the currency and capability of the Stockpile are informed by appropriate evidence.

4.71 The 2011 Strategic Review identified significant costs associated with expiring stock and the lack of cost-effectiveness analysis in the selection of the Stockpile’s inventory and quantities. The main focus of the department’s activities since the Strategic Review has been on replenishing expiring stock and responding to the review’s recommendations. The department has commenced development of a more systematic approach to selecting items for the Stockpile, including a draft inventory selection framework. The Department of Health and stakeholder agencies have also explored a range of strategies to reduce Stockpile management costs, including: shelf life extension; stock cycling and rotation; returning expired pharmaceuticals to manufacturers in return for fresh stock; and purchasing generic antivirals as they become available. The department has also conducted progressively larger destruction programs to reduce the costs of storing expired items.

4.72 The ANAO assessed the effectiveness of selected controls for the management of the Stockpile, including processes for monitoring, reconciling and reporting on stock levels. The ANAO did not assess processes for the disposal or destruction of expired stock as this was the subject of an internal audit by the department in 2012. The internal audit report identified weaknesses in some of the controls associated with the department’s processes for disposing of expired stock, such as disposal guidelines, disposal planning, stock reconciliation and management reporting. The department advised the ANAO that the recommended process improvements for disposing of expired stock had been implemented.

4.73 The ANAO reviewed controls for the identification, recording and deployment of stock, with weaknesses in some controls resulting in data integrity issues. The department relies on a number of information management systems and processes to administer the Stockpile. In the absence of system interfaces to support automatic data transmission between the information management systems, the department employs emails and attachments (including manual forms and spreadsheets) to transmit key information. This has affected the completeness and accuracy of data stored for individual items in the department's Stockpile database resulting in information discrepancies between the Stockpile database and the contractors' warehouse system records.

5. Deployment

This chapter examines arrangements for deploying the Stockpile, including agreements with other jurisdictions, deployment planning and testing.

Introduction

5.1 A critical factor in managing the Stockpile is to ensure the efficient and effective deployment of items to those in need. The Australian Government has established collaborative arrangements to deliver stockpile items to the states and territories, which have responsibility to manage and distribute the items within their respective jurisdictions.

5.2 The department has developed a deployment framework that includes: memoranda of understanding (MoUs) between the Australian, state and territory governments; a departmental deployment plan, policy and procedures¹⁵⁰; and contracts with the Stockpile warehouse providers.

Deployment framework

5.3 Formal agreements, such as MoUs, can provide clarity by defining areas of agreed responsibility between jurisdictions involved in joint activities. The Department of Health has entered into MoUs with all state and territory health authorities. They outline the agreed obligations of the states and territories regarding the receipt and safekeeping of national stockpile items, and agreed arrangements for deployment of the Stockpile. The arrangements include a requirement that states and territories will develop distribution plans for the Stockpile.

5.4 Alongside the MoUs, the Department of Health has established a 'National Medical Stockpile Deployment Plan' and 'National Medical Stockpile Deployment Procedures' to provide guidance for departmental staff on the process to be followed for deploying the Stockpile.¹⁵¹ The states and territories

150 Department of Health, Office of Health Protection, National Medical Stockpile Management Policy, January 2012; Department of Health, National Medical Stockpile Deployment Plan, December 2012; Department of Health, National Medical Stockpile Deployment Procedures, December 2012; and Department of Health, Communication Protocols for Deployment of National Medical Stockpile Items, August 2012.

151 The deployment plan, policy and procedures were updated and re-issued during 2012.

have also developed stockpile distribution plans. These documents are discussed in the following paragraphs.

Deployment plan and procedures

5.5 The department's deployment plan and associated deployment procedures were internally reviewed and re-issued to staff in December 2012. The deployment plan describes the higher level deployment processes that departmental staff should follow, including how a request should be received and approved. The deployment procedures provide staff with more detailed information on selecting items for deployment and on engaging with warehouse and transport contractors to deploy items. Both the deployment plan and deployment procedures focus on the department's response to requests for Stockpile items from state jurisdictions. Requests from Commonwealth agencies for deployment or pre-positioning of stockpile items, and any requests for international or extraordinary deployments, are considered on a case-by-case basis.¹⁵²

Deployment process

5.6 The deployment process requires Office of Health Protection (OHP) staff¹⁵³, in collaboration with relevant jurisdictions, to identify the stock required and the deployment location. The department advises the warehouse provider of the stock that needs to be deployed by batch number and expiry date. The provider's warehouse management system is capable of identifying and selecting the oldest unexpired stock first through a computer algorithm which selects stock based upon First-In, First-Out (FIFO) principle. The department advised that while the FIFO principles are considered, the ultimate priority is to meet deployment requirements.

5.7 The FIFO principle provides an effective basis for selecting unexpired stock for deployment. However, a number of factors can increase the risk that the oldest unexpired stock is not selected, including:

- not all PPE stock has a recorded expiry date¹⁵⁴;

152 Department of Health, 'National Medical Stockpile Deployment Plan', December 2012, pp. 1, 2.

153 Specifically staff from the Health Emergency Management Branch.

154 Expiry details of some stock has not been recorded on warehouse management systems.

- the PPE warehouse provider's FIFO date resets when stock is moved from one warehouse to another warehouse—an event which has occurred in recent years;
- data integrity issues, arising from inconsistencies between the department's information management systems and warehouse provider data; and
- the warehouse providers for PPE and pharmaceutical items have not consistently labelled stock with a physical label, attached to each pallet, which includes expiry details.¹⁵⁵

5.8 During the course of the audit, the non-pharmaceutical warehouse contractor acknowledged that some of its pallet labelling was inconsistent with the contractual requirements and advised that it had begun to improve the consistency of labelling. Pallet labelling is an important control as it provides a visual check on the stock at the time of deployment or disposal; informing the warehouse operator of the stock expiry date.

5.9 The department also identified the non-recording of pallet locations in a warehouse during the 2011–12 stocktake and took action in June 2013 to select a new warehouse contractor. Further, the ANAO's inspection of a Northern Territory warehouse in September 2013 indicated that the warehouse contractor was not recording pallet locations in its WMS and that the department was not aware of this.

5.10 To manage the potential risks arising from inadequate pallet labelling and recording, there would be benefit in the department appropriately monitoring pallet labelling and the recording of pallet locations by warehouse contractors, to improve contract compliance.

State stockpile distribution plans

5.11 The MoUs provide that states and territories (states) will distribute Stockpile items in accordance with a distribution plan developed by each jurisdiction, consistent with their responsibility for the management of their respective health delivery systems and their operational responsibility for distributing stockpile items.

¹⁵⁵ The contracts require warehouse contractors to affix such labels which provide the: product code and description, batch number (where available), quantity on the pallet, expiry date, and the words 'Property of the Australian Government—Department of Health'. In addition, the pharmaceutical warehouse contractor is required to include on the label the total loaded weight of each pallet.

5.12 In its 2007–08 audit report, the ANAO observed that for the deployment arrangements to be effective, the national and jurisdictional plans needed to be well-integrated and underpinned by cooperative planning and information sharing. The ANAO also observed that while the department had received individual jurisdictional plans, some were several years old and had not been reviewed by the department, and some were in draft form and had not been finalised.¹⁵⁶

5.13 In November 2013, the ANAO examined the MoUs and state distribution plans, which are a specific requirement of the MoUs. All MoUs were current, having been updated in 2010, consistent with the requirement to conduct a review every five years. However, the department held current distribution plans for only four of the eight jurisdictions. During the course of the audit, one jurisdiction advised the ANAO that it intended to review its distribution plan, but was waiting for the release of the revised draft of the Australian Health Management Plan for Pandemic Influenza (AHMPPI) before doing so. There would be benefit in the department liaising with the remaining jurisdictions which have not updated their plans.

Stakeholder relationships

5.14 Effective stakeholder engagement facilitates both planning and the successful deployment of the Stockpile. This theme was reiterated by key stakeholders interviewed by the ANAO, including Chief Health Officers (CHOs), the warehouse contractors, and professional associations.

5.15 The ANAO interviewed senior managers and representatives of the CHOs for four jurisdictions and a senior representative of the Royal Australian College of General Practitioners; all reported favourably on the quality and effectiveness of the working relationships developed by departmental officers and the Commonwealth's Chief Medical Officer (CMO).

Administration of deployment processes and procedures

5.16 The department monitors international health threats and may obtain advance notice of developing pandemics and emergencies through its Health Surveillance section. A state or territory may also advise the department of a potential health emergency. Depending on the threat, the department may

156 ANAO Audit Report No.6 2007–08, *Australia's Preparedness for a Human Influenza Pandemic*, p. 106.

place itself in a state of standby readiness, conduct alert briefings with state colleagues, place the warehouse contractors on alert and, if necessary, then formally activate the National Incident Room (NIR).¹⁵⁷

5.17 A request for items from the Stockpile can be made through the NIR if it is formally activated. A request may also be made via phone call from a state/territory CHO to the CMO, to the Office of Health Protection or via a dedicated phone line. Where an item from the Stockpile has been granted an exemption under the *Therapeutic Goods Act 1989*, approval must first be sought from the Secretary of Health to deploy. An approval to deploy an exempted item may also require a direction by the Secretary which sets conditions on its use, storage and record-keeping arrangements. This approval must be granted before administrative approval for deployment is granted by the CMO.

5.18 The Australian Government Crisis Committee¹⁵⁸ may also request items from the Stockpile in response to a major incident, including a terrorist incident. The CMO and the head of the Office of Health Protection are members of this committee and would lead the department's response through the NIR.

5.19 Once a deployment request has been approved, the contracted warehouse providers are required to have the items for deployment ready for transport within six hours of the receipt of an Official Order Form. The transport provider then delivers the items to the nominated jurisdictional receiving site. A receiving site may, for example, be a public hospital or pharmacy.¹⁵⁹ The receiving jurisdiction is required to notify officers from the Office of Health Protection of the receipt of stockpile items.

5.20 Stockpile items remain the property of the Australian Government until the Department of Health and the relevant state agree to transfer title, or until the items are used. The obligations of the Commonwealth and the receiving state or territory, regarding the receipt and safekeeping of the items, are outlined in the relevant MoUs.

157 Formal approval of the CMO is required to activate the NIR.

158 The Australian Government Crisis Committee is the primary forum for coordinating the Australian Government's response to a major incident including consolidating information and coordinating information exchange. The National Crisis Committee is the primary forum for coordinating a whole-of-government response to an incident of national significance, specifically a terrorist incident.

159 These sites are nominated in advance by the jurisdictions, agreed to by the Department of Health and are recorded in the relevant MoUs.

Twenty-four hour access to the Stockpile

5.21 The Department of Health's Emergency Management Branch has a Duty Officer and Watch Officer roster system than monitors all calls on a dedicated phone line. The Duty Officer is the point of contact after hours. The ANAO examined the response arrangements for the Watch Officer and Duty Officers. The Duty Officer, for example, is required to: not drink alcohol, have access to a phone at all times and to answer it, and remain within a range of 30 minutes travel time of the NIR. The Duty Officer Manual was examined by the ANAO and was found to be up to date. The NIR also provided information on recent training of Watch and Duty Officers.

5.22 The NIR staff rely on the deployment folder for information on the Stockpile and details of specific stock items.¹⁶⁰ The ANAO examined the deployment folder in July 2013 and again in August 2013, and it was not up to date. In the July 2013 examination of the deployment folder: six out of 25 influenza items contained inaccuracies, in particular listing expired stock; and six out of 19 CBRN items contained inaccuracies, in particular listing expired stock. The August 2013 analysis (comparing stock levels and amounts in the folder against the stocktake) also identified discrepancies in the counts and the items. These errors make the deployment folder unreliable. Following the ANAO's review of the deployment folder, the department advised that it has updated the information contained in the deployment folder, and has commenced a review of the deployment folder business processes. Maintaining an up-to-date deployment folder would strengthen the Stockpile's deployment processes.

Timeliness of deployment

5.23 An effective deployment from the Stockpile requires the timely approval of a jurisdictional request, selection of the correct stock, dispatch of stock from a warehouse, and delivery of the stock to the jurisdiction's receiving site. The department has developed two related timeliness standards for deployment of Stockpile items, set out in the deployment plan, which states:

If possible, medicines from the Stockpile should be delivered to the requesting jurisdiction within 24 hours of receipt of the deployment request, or sooner. Bulky items such as PPE or vaccination packs should be delivered within

160 Department of Health, 'National Medical Stockpile Deployment Procedures', 13 December 2012, p.2.

72 hours by road transport; [and] contracted storage providers are required to maintain a capacity to prepare NMS [Stockpile] items for deployment on six hours notice.¹⁶¹

5.24 The contract for the non-pharmaceutical warehouse provider requires the contractor (if using its own transport) to deliver the goods to the relevant jurisdiction's receiving site within 24 hours after receipt of the official order form, to provide a track and trace capability for the consignment, and to notify the NIR immediately upon delivery. However, the pharmaceutical warehouse provider's contract does not include this 24 hour delivery timeframe as a requirement¹⁶², notwithstanding the 24 hour timeliness standard set out in the deployment plan and other departmental documents.¹⁶³

Reporting on timeliness of deployment

5.25 The department's 2011–12 Annual Report listed the key performance indicator (KPI) for the Stockpile as the 'capacity for timely deployment of the National Medical Stockpile' with a reference point 'deployment of the Stockpile, either through exercise or live deployment, meets the six-hour response time'.¹⁶⁴ The 2010–11 Annual Report reported against the same KPI for the Stockpile and stated that the department undertook five deployments from the Stockpile in 2010–11 and all had met the six-hour response benchmark.¹⁶⁵

5.26 The 2012–13 Annual Report ceased listing the six-hour response KPI. The department informed the ANAO that it had developed its performance reporting at a higher, more strategic level which included removing the KPI for a six-hour response.

Deploying CBRN items

5.27 The 2008 CBRN Review undertaken by the department identified the need to deploy CBRN antidotes within short time frames and recommended that where an item had to be delivered in less than 24 hours, consideration be given to pre-positioning the item within the jurisdiction where it was

161 Department of Health, 'National Medical Stockpile Deployment Plan', December 2012, pp. 3–4.

162 The Department of Health may engage a separate transport provider for deployment, or it may travel by air.

163 Both warehouse contractors have established systems that enable dispatched goods to be tracked to the jurisdictional receiving site.

164 Department of Health and Ageing, *Annual Report 2011–12*, 2012, p. 282.

165 *ibid.*, p. 329.

potentially required.¹⁶⁶ The 2008 CBRN Review identified, for example, a poison antidote and recommended that it be held in all jurisdictions.¹⁶⁷

5.28 The department has held preliminary discussions with state health departments about potential changes to stockpiling arrangements which would involve the Commonwealth taking responsibility for providing high risk, low use products (for example, CBRN response items and antivirals) and the states taking responsibility for low risk, high use items that could be cycled through the health system (for example, PPE items). Discussions have also been held about pre-deploying items with states that require delivery within relatively short timeframes.

Recent deployments and the management of returned items

5.29 Deployment from the Stockpile is not a common occurrence. In the last three years stockpile items have been deployed four times. Three deployments were of CBRN items and one deployment involved PPE. Items were deployed in: March 2011 and May 2011 (with two pre-deployments of items to two Commonwealth government agencies in September 2012 and January 2013).¹⁶⁸

5.30 The ANAO examined the department's records for these four deployments. The two pre-deployments in March and May 2011 were largely completed in accordance with procedures and guidelines. In January 2013, the department pre-deployed a CBRN antidote to New South Wales (NSW) at the request of the NSW CHO, to be used by its ambulance services to cover a CBRN item normally held by NSW and which had expired.¹⁶⁹ The items remain the property of the Commonwealth, and the Department of Health expects they will be returned when NSW has acquired its own stock. The arrangements demonstrate how the national Stockpile can be used to support the states and territories outside an emergency situation.

166 Pre-positioning CBRN items in several locations and not centrally has implications for the quantity of items required.

167 Department of Health, 'Final 2008 Review of the National Medical Stockpile', November 2008, pp. 3,7,8 & 12.

168 Pre-deployment refers to pre-positioning items to agencies, or states and territories, so that they are in place in advance of need. They remain Commonwealth property and are managed by the receiver.

169 Pending completion of an order by NSW for the supply of the antidote.

Authorisation for deployment of Stockpile items

5.31 Many of the CBRN items in the Stockpile are antidotes for poisoning which are not available in the Australian pharmaceutical market, and are purchased by governments for use in response to terrorist or health threats. As such, these antidotes are not approved by the Therapeutic Goods Administration for use within Australia. The department purchases such medicines using the exemption powers of the Minister for Health, or the Minister's delegate—the Secretary of the Department of Health—under s18A of the *Therapeutic Goods Act 1989* (the TGA Act).

5.32 As discussed, where an item from the Stockpile has been granted an exemption under the *Therapeutic Goods Act 1989*, approval must first be sought from the Secretary of Health to deploy. An approval to deploy an exempted item may also require a direction by the Secretary which sets conditions on the use, storage and records that must be kept. This approval must be granted before administrative approval for deployment is granted by the CMO. However, the National Health Emergency Response Arrangements and the current deployment policies and procedures state that the CMO approves the deployment of Stockpile items.¹⁷⁰ In November 2013 the department confirmed with the ANAO that only the Secretary was delegated to provide deployment approval under s18A of the TGA Act, and there would be benefit in clarifying internal guidance on these issues.

The management of returned stock

5.33 The 2011 Strategic Review of the Stockpile observed that there was not a recording mechanism that could accurately determine how returned stock was treated after deployment, thereby guaranteeing its condition prior to its receipt.¹⁷¹

5.34 The relevant Australian code¹⁷² requires that medicines which have left the care of warehouse providers should only be returned if they are examined and assessed by a person authorised to do so, and 'there is no reason to believe that they have been subject to adverse environmental conditions'.¹⁷³ The department's

170 Department of Health, *National Health Emergency Response Arrangements*, Australian Health Protection Committee, 2011, p. 16.

171 Department of Finance, 'Review of the National Medical Stockpile', February 2011, Canberra, p. 9.

172 *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*.

173 National Coordinating Committee on Therapeutic Goods, *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*, 2011, p. 12.

warehouse providers are required to follow the code, and if stockpile items are returned, they must first place them in ‘quarantine’—separated from other stockpile items—and contact the department for directions.

5.35 The MoUs contain guidance on the return of deployed stock and require the relevant jurisdiction to provide advice to the department about any unused stockpile items, and information on how the items were stored while in the jurisdiction’s care, so that the department can make an informed decision as to their suitability for return to the Stockpile.¹⁷⁴

5.36 The ANAO’s analysis of a deployment of CBRN poison antidote, which was subsequently returned to the national Stockpile, shows that there was no consideration of the conditions under which the item had been transported and stored after deployment by the department. Further, the item was returned to the Stockpile a month later without examination and assessment by an authorised person as required by the code.¹⁷⁵ The department has advised the ANAO that whilst:

Stock returning from a deployment was always quarantined until examined by a departmental officer prior to the stock being entered back into the Stockpile, budget constraints have prevented this occurring in recent times.

5.37 Emergent risks to Stockpile management arrangements, and difficulties in complying with relevant requirements, should be assessed and treatments considered, in the context of the operational risk management plan.

Testing the deployment arrangements

5.38 In its 2007–08 report, the ANAO recommended that the department review and adequately test its deployment plans in conjunction with the states and territories.¹⁷⁶ In 2006, the department tested the deployment readiness of the Stockpile in response to a pandemic through Exercise Cumpston. At that time, this was the largest health simulation exercise ever undertaken in Australia and the first major exercise conducted by the Department of Health. The Council of Australian Governments (COAG) also conducted an exercise in

¹⁷⁴ See for example, Department of Health and Ageing, *Memorandum of Understanding between the Commonwealth of Australia and the Northern Territory, in relation to the Receipt, Storage and Use of Pharmaceutical and Equipment Items from the National Medical Stockpile*, 3 June 2010, pp. 12, 13.

¹⁷⁵ A stock of antidote was deployed in September 2012 to a detention center for possible use. It was not used, but remained at the center until October 2012 when it was returned to the Stockpile.

¹⁷⁶ ANAO Audit Report No.6 2007–08, *Australia’s Preparedness for a Human Influenza Pandemic*, Recommendation 4(b), p. 32.

2008, Exercise Sustain, which assessed the national, whole-of-government preparedness for human influenza pandemic.¹⁷⁷

5.39 The 2009 human influenza pandemic was a full-scale deployment of the Stockpile which further tested the department's deployment capability over a seven-month period.¹⁷⁸ The 2011 *Review of Australia's Health Sector Response to Pandemic (H1N1) 2009: Lessons Identified*¹⁷⁹ concluded that while the department had effectively deployed stockpile items to meet the demands of the pandemic, the moderate nature of the pandemic had limited the demands made upon it. The review also identified that the department's early deployment of items to jurisdictional warehouses was an effective strategy, particularly for large volumes of PPE items, which had reduced the distribution response time. The review observed that:

Planned arrangements, including transport, for distributions of NMS [Stockpile] supplies from the Australian Government to jurisdictional receiving facilities generally were effective and enabled timely movement of consignments.¹⁸⁰

5.40 In September 2012, the department's audit committee considered the department's progress in implementing the ANAO's 2007–08 recommendation, with regard to testing the deployment plans. The audit committee noted that while there had been no testing between 2009 and 2012, testing would occur in late 2012 or early 2013. However, the department advised the ANAO that it had not tested deployment of the Stockpile in the four years to February 2014. In effect, the deployment of the Stockpile has not been tested since the 2009 pandemic. The department also informed the ANAO that no testing of the deployment of CBRN items had been conducted in the last five years. To provide assurance that deployment arrangements will be effective in a national health emergency, the department should undertake planning to test the current Stockpile deployment arrangements, in consultation with other jurisdictions.

177 House of Representatives: Standing Committee on Health and Ageing, *Diseases Have No Borders: Report into the Inquiry into Health Issues across International Borders*, Canberra, March 2013, p. 100.

178 The first deployment occurred on 30 April 2009 and the last on 17 November 2009.

179 Department of Health and Ageing, *Review of Australia's Health Sector Response to Pandemic (H1N1) 2009: Lessons Identified*, 2011, p. 55.

180 *ibid.*, p. 55.

Recommendation No.4

5.41 To provide assurance that deployment arrangements will be effective in a national health emergency, the ANAO recommends that the Department of Health undertake planning to test the current Stockpile deployment arrangements, in consultation with state and territory health authorities.

Department of Health response:

5.42 *The department agrees with this recommendation.*

Conclusion

5.43 The department has developed a deployment framework that includes: MoUs with the states and territories; a departmental deployment plan, policy and procedures; and relevant provisions in contracts with the Stockpile warehouse providers. The states and territories have also developed stockpile distribution plans, a specific requirement of the MoUs. All MoUs were current, having been updated in 2010, with the requirement for a review every five years. However, the department held current distribution plans for only four of the eight jurisdictions, and there would be benefit in the department liaising with jurisdictions which have not updated their plans, to address this deficiency.

5.44 The department advises its warehouse providers to select stock for deployment which has not exceeded its expiry date, and has adequate stock life for at least a month before its expiry date. The PPE warehouse provider's warehouse management system is capable of selecting unexpired stock on a First-In, First-Out (FIFO) basis; an approach which can provide an effective basis for selecting unexpired stock for deployment. However, the efficacy of this approach can be affected by factors such as: not all PPE stock having a recorded expiry date; the PPE warehouse provider's FIFO date resetting when stock is moved from one warehouse to another; data integrity issues arising from inconsistencies between the department's information management systems and warehouse provider data; and warehouse providers not consistently attaching to pallets labels that record expiry details.

5.45 The 2011 Strategic Review of the Stockpile observed that there was 'no recording mechanism that can accurately determine how returned stock was treated after deployment, thereby guaranteeing its condition prior to its receipt'. The relevant Australian code requires that medicines which have left the care of warehouse providers should only be returned if they are examined

and assessed by a person authorised to do so, and ‘there is no reason to believe that they have been subject to adverse environmental conditions’. The ANAO’s analysis of a deployment of a CBRN poison antidote, which was subsequently returned to the national Stockpile, indicated weaknesses in a number of controls. There was no consideration of the conditions under which the item had been transported and stored after deployment. Further, the item was returned to the Stockpile a month later without examination and assessment by an authorised person as required by the Australian code.

5.46 In its 2007–08 audit, the ANAO recommended that the Department of Health adequately test its deployment plans in conjunction with states and territories. In September 2012, the department’s audit committee considered progress in implementing the ANAO’s recommendation, noting that while there had been no testing between 2009 and 2012, testing would occur in late 2012 or early 2013. In the course of the current audit, the department advised the ANAO that it had not conducted any operational testing of the deployment of pandemic items since the last pandemic in 2009. The department also informed the ANAO that no testing of the deployment of CBRN items had been conducted in the last five years. To provide assurance that deployment arrangements will be effective in a national health emergency, the department should undertake planning to test the Stockpile’s deployment arrangements, in consultation with other jurisdictions.



Ian McPhee
Auditor-General

Canberra ACT
26 June 2014

Appendices

Appendix 1: Agency Response



Australian Government

Department of Health

ACTING SECRETARY

Dr Tom Ioannou
Group Executive Director
Performance Audit Services Group
Australian National Audit Office
GPO Box 707
CANBERRA ACT 2601

Dear Dr Ioannou

**PERFORMANCE AUDIT
MANAGEMENT OF THE NATIONAL MEDICAL STOCKPILE**

I refer to your letter of 12 May 2014 and the enclosed proposed report on the Performance Audit of the Management of the National Medical Stockpile (NMS).

I note the report and the suggestions for improvements to the management of the NMS. I am pleased to advise that good progress is already being made in relation to improving the efficiency and effectiveness of the operation and management of the NMS. This reform work is further supported by the 2014-15 Budget Initiative 'Reinforcing Australia's Health Protection' which provides \$15.4 million over four years for implementation of reforms.

The Department's formal comments on the audit report and its recommendations are attached. The Department's response for noting in the report summary is:

The Department of Health notes the audit report and agrees with the recommendations. To date, the Department of Health has invested significant resources, including approximately \$4 million and a dedicated taskforce, to the development of reforms to enhance the efficiency and effectiveness of the management and operation of the National Medical Stockpile. Reform activities, that will address all of the recommendations in the audit report, will now be implemented under the 2014-15 Budget Measure 'Reinforcing Australia's Health Protection' that provides funding of \$15.4 million over four years.

Attached is some additional commentary and matters of minor editorial nature.

If you have further questions about the Department's response, please contact Mr Colin Cronin, Assistant Secretary, Audit and Fraud Control on (02) 6289 7877.

Yours sincerely

A handwritten signature in black ink, appearing to read 'DL', followed by a horizontal line.

David Learmonth
A/g Secretary
11 June 2014

Agency Response to ANAO Audit May 2014 - Recommendations

Recommendation 1:

To strengthen the management of the National Medical Stockpile, the ANAO recommends that the Department of Health:

- (a) Update the strategic management plan to identify objectives, priorities and strategies to be implemented in the short term and over the longer term; and
- (b) Review the operational risk management plan to incorporate emerging risks.

AGREE

A procurement was initiated in May 2014 to engage a consultant to assist the Department with development of a new strategic plan and operational risk framework.

Recommendation 2:

To gain additional assurance that contract requirements are being met, the ANAO recommends that the Department of Health review and clarify reporting arrangements for its warehousing contracts with external service providers.

AGREE

Procurement activity commenced in May 2014 in relation to outsourcing management of the Stockpile under a 'Prime Vendor' arrangement. The Prime Vendor system will include new arrangements for storage and maintenance of the Stockpile.

Recommendation 3:

To improve the management and integrity of data relating to the National Medical Stockpile, the ANAO recommends that the Department of Health review its information management arrangements for transfer of stockpile data.

AGREE

New Prime Vendor arrangements will include new IT and data management systems.

Recommendation 4:

To provide assurance that deployment arrangements will be effective in a national health emergency, the ANAO recommends that the Department of Health undertake planning to test the current Stockpile deployment arrangements, in consultation with state and territory health authorities.

AGREE

Appendix 2: Relevant recommendations from 2007–08 ANAO audit report on Australia’s preparedness for a human influenza pandemic

Recommendation No.2

To improve the management of the National Medical Stockpile, the ANAO recommends that the Department of Health and Ageing incorporate into its governance framework:

- a) an assessment of the risks associated with the Stockpile in a risk management plan that is periodically reviewed; and
- b) a performance management and reporting framework for the Stockpile.

Recommendation No.3

To improve the management of the National Medical Stockpile, the ANAO recommends that the Department of Health and Ageing develop and implement procedures for:

- maintaining the content of the Stockpile;
- approving sub-contracting arrangements;
- monitoring compliance with supply and storage contracts; and
- undertaking site visits and stocktakes.

Recommendation No.4

To improve the effectiveness of deployment arrangements for the National Medical Stockpile, the ANAO recommends that the Department of Health:

- (a) undertake an assessment of the risks associated with deploying the Stockpile and incorporate this analysis and mitigation strategies in a National Medical Stockpile risk management plan;
- (b) review and adequately test deployment plans in conjunction with states and territories; and
- (c) review and update procedures to cover all elements of the response arrangements outlined in the Memoranda of Understanding with State and Territory governments.

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