Australian Government

Department of Health

To All Medical Officers & Division Heads, Department of Health

Dear Colleagues

The Chief Medical Officer, Professor Brendan Murphy initiated a review of the role of medical officers across the Department.

We have 89 medical officers working across the Department, the largest group of medical officers being within the TGA. We are reliant on a highly skilled workforce to provide robust policy advice, deliver effective health programs and ensure our regulatory functions meet the highest standards.

The medical officers contribute to our highly skilled workforce and the review looked at how effectively they are deployed and what we can do to maximise and integrate their skills and capacity into our work.

The Executive has received and accepted the review of Medical Officers in the Department of Health, completed late last year by A/Prof David Hillis. The Executive has also approved a series of management responses to the review. These documents are now provided to you.

The Executive strongly endorsed the view that the medical officers are a valuable resource in the Department; they provide unique clinical insight into policies and decisions in the Health Portfolio.

Collectively, we need to ensure that medical officers are used to their best value, where their special skills and experience are most required.

The Executive also confirmed the review's findings that medical officers should have stronger and more consistent engagement with SES officers.

Many of the specific recommendations contained in the review are already in progress or planning. We would encourage further feedback and suggestions that any of you might have, coming out of the Review or the Management Response. The Chief Medical Officer and the Chief Medical Advisor (HPRG) will be meeting medical officers to get their perspective on the review and future actions.

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This review is an internal document and not intended to be circulated beyond the medical officer group and SES officers in the Department.

We look forward to maximising engagement between our medical officers and the SES in undertaking our work.

Glenys Beauchamp on behalf of the Executive Team

19 February 2018

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Review of Medical Officers:

Commonwealth Department of Health

Report to:

Professor Brendan Murphy

Chief Medical Officer

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January 2018

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Summary

The Commonwealth Department of Health is a vital component of the Australian Health Care Sector. The complex network of providers that delivers health related services relies on the Commonwealth Government for key strategic direction, specific programs, significant funding, regulation and regulatory oversight. These activities provide essential services, safeguard the health systems as well as commit to innovation to ensure the future of a safe, effective and value-add health sector.

As a core component of the Department's workforce, the eighty-nine Medical Officers provide critical understanding of the health care system, the complex interactions between stakeholders as well as detailed technical advice. Their background is diverse and is derived from many clinical and administrative areas. A number of the Medical Officers deliberately seek out additional training and work experiences to develop in-depth knowledge of the many facets of our complex health system and its associated strategic and legislative framework.

However, the Australian health care systems share the issues of constant change with systems internationally. Priorities for funding, disease profiles, strategies and political 'pressure points' change and the department's approach continues to require adjustment. As a critical component of the Department workforce, the role of the Medical Officers needs ongoing review due to the changing environment. Priorities need to change, tasks need to be handled in differing ways and incorporate technological advances as well as closer international alignment. Health is increasingly team based and the work of the Medical Officers also needs to reflect allocation or delegation of tasks to other members of the multi-disciplinary teams, whenever it is safe and time effective to do so.

Within the cohort of eighty-nine Medical Officers, the largest groups of Medical Officers are located within Therapeutic Goods Administration (TGA) areas of Medicines Regulation Division, Medical Devices Product Quality Division and the Provider Benefits Integrity Division.

All areas of the Department are undergoing substantial change. The Review of Medicines and Medical Devices Regulation (Sansom review), raised possibilities of using international assessment studies more fully, increasing the use of other agencies in undertaking evaluation and the overall time responsiveness for assessment. The Provider Benefits Integrity Division has recently been moved to the Department of Health and is undergoing substantial strategic review and capability alignment. During this process, the requirement and approach to professional counselling for Medicare compliance issues should be comprehensively reviewed. There appears to be significant scope for redeployment of some medical officer tasks with the use of better data analytics and delegation of some roles

The review of the Medical Benefits Schedule is heavily dependent on substantial internal medical leadership in the Department and there are a number of other policy areas that would clearly benefit from additional Medical Officer resources, which could be made available by redeployment from other areas. The persistent theme through this review is the ongoing requirement for clarity of strategic priorities and clarity of expectations for the Medical Officers. The vast majority are committed to the goals of the Department of Health and understand the requirement for change. However, the roles, accountabilities and level of engagement, particularly for the Medical Officers in policy areas, need to be much clearer and consistent. This will be of substantial benefit to the individual Medical Officer and to the direction of the Department. It is the ability to engage and contribute to this direction that will add meaningfully to the role of the Medical Officers and their more strategic alignment with the Department's priorities.

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Recommendations

Recommendation One: The Chief Medical Officer and Senior Executive consider how negative variance comments from the survey and interviews can be further addressed within the Department, in the context of the People Strategy.

Recommendation Two: The CMO and SES in the Divisions, other than in Health Products Regulation, should examine the allocation of Medical Officer workload to the various policy and program areas, with a focus on the supporting the MBS review, indigenous health, aged care, primary care reform and meeting the reform objectives of the provider compliance division.

Recommendation Three: That Medical Officers remain embedded within a primary area of the Department, but with a broader involvement in 'cross department' initiatives, which is defined through an agreed accountability framework and workplan for each Medical Officer. Medical Officer accountability should ideally be to a Senior Medical Officer (directly or via a dual accountability) or to a Divisional Head, but with a clear set of responsibilities and tasks beyond that Division (if appropriate). Movement including rotation of Medical Officers from TGA to other parts of the Department of Health need to consider the funding complexities / cost recovery models in which TGA undertakes its work.

Recommendation Four: The Department more clearly articulates and acknowledges the generic and specific skills for Medical Officers at different levels of seniority. The Department critically reviews designated Medical Officer tasks to determine whether some could be performed by other staff with generic or alternative specific professional backgrounds.

Recommendation Five: The Department develops a stronger understanding, and potentially a register, of the broad experience and expertise of its Medical Officers and utilise these skills, where appropriate, in policy development, program delivery and reform initiatives.

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Recommendation Six: The Department considers formal linkages with a University to develop an appropriately scoped Masters of Public Health, especially for junior doctors. The Department investigates the feasibility of a rotational training program for MO2, MO3, and MO4 to enable more appropriate experience in policy development, regulatory science and health innovation. Such a rotation program would need to take account of operational requirements and in the case of the TGA, the special account funding of staff.

Recommendation Seven: The Department formally compares remuneration packages between Medical Officers in the Commonwealth Department and those in other jurisdictions and notes the importance of access to external private practice both to retain and to continue clinical medicine exposure for Medical Officers.

Recommendation Eight: The Department considers converting the PDA to 'salary' or investigates an alternative streamlined process appropriate for this limited funding.

Recommendation Nine: A review of the seniority of Medical Officers is undertaken to ensure that current roles, expertise and qualifications are appropriately reflected in the classifications.

Recommendation Ten: If an employee is not registered by AHPRA then their employment at a Medical Officer grade should be reviewed.

Recommendation Eleven: As a matter of some urgency work needs to be done in Medical Devices to determine:

- The appropriate strategy for obtaining external reviews
- The role of Medical Officers in the evaluation or the approval of the external reviews
- The appropriate balance between pre-market evaluation and post-market surveillance
- An appropriate reporting arrangement for the Medical Officers, reflecting a revised and higher level role in evaluation. The MO5 could work significantly more in partnership with the Division head (as in medicines regulation) in managing the Division.

Recommendation Twelve: Medicines Regulation review its approach to low risk applications and consider whether Clinical Pharmacists could undertake these reviews under delegation or utilise external evaluation teams.

Recommendation Thirteen: The Special Access Scheme be reviewed to significantly increase the drugs able to be classified as 'Class C' and the routine use of Clinical Pharmacists in providing the evaluation for the Scheme overall. This has already commenced.

Recommendation Fourteen: TGA limits its telephone support to documentation of adverse events. Clinical Support and Counselling should be provided by the individual's usual medical practitioner or a recognised and approved telephone based Counselling service. This has already commenced.

Recommendation Fifteen: Following the implementation of the Sansom Review, that the separation / integration of pre-market evaluation and post-market evaluation be reviewed.

Recommendation Sixteen: The 'peer counselling' process within the Provider Benefits Integrity Division be substantially reviewed to increase routine monitoring of billing practices being made available to Medicare Providers, use of artificial intelligence, streamlined interviews of providers by Medical and Non-medical staff. The Department should review the risks of unaccompanied site visits to practitioners and explore the greater use of telephone based counselling interviews to improve efficiency. The Department should explore strategies to retain and motivate this crucial group of Medical Officers, such as involvement in policy work or primary care health reform.

Recommendation Seventeen: Policy development and advocacy skills should be enhanced by rotations from across all the department into the appropriate policy area.

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Background

The key functions and components of the Australian health and aged care system are delivered through a complex network with many players that need to work with each other. These include:

- Patients, families and communities
- Health departments at both the Commonwealth and state and territory level
- Health and aged care providers
- Health service organisations
- Private companies, such as pharmaceutical companies; and
- Other organisations, including peak bodies and advocacy groups

The purpose of the Department of Health is to lead and shape Australia's health and aged care system and sporting outcomes through evidence-based policy, well targeted programs and best practice regulation. It also supports and partners with state and territory governments, non-government-organisations (NGOs) and private entities.

The challenge is always in ensuring policy change will deliver high quality, safe, effective, affordable, equitable care and provide a good patient experience. Optimising policy in one area may cause disruption in other parts of the system, or have unintended consequences including poorer overall health system performance. It is important to recognise that despite substantial health and medical research, there is still considerable uncertainty over which policies work best in delivering health and aged care. The input of comprehensive health system knowledge becomes more important given this uncertainty. This underscores the importance of taking a whole of system approach, understanding inherent risks, and using data and international experience to guide decisions

Recognising these complexities, the Department of Health is particularly reliant on a highly skilled workforce that understands the health sector complexity and the requirements to navigate it. This is a key area where the breadth of the Medical Officer experience can assist.

The Department's corporate priorities include implementing the 'People Strategy' that is based on the principles of 'attract, retain, motivate and inspire'. These principles will enable the department to shape the workforce to better deliver its outcomes. The People Strategy is critical as it underpins Health's ongoing cultural transformation towards becoming an employer of choice. It has four key areas of action:

- Managing workforce composition and agility
- Building the right capability
- Continuing to improve our culture and leadership; and
- Investing in career and succession

Like many similar workforce strategies, the ICARE approach has a strong base of values and behaviours such as being impartial, committed to service, accountable, respectful and ethical. These values then provide legitimacy and enable behaviours that emphasise trust and empowerment, collaboration to innovate, listening and appreciation, walking the talk and investing in high performance.

Documentation concerning the People Strategy provides key behaviours that are pertinent to the roles undertaken by the Medical Officers and include:

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- Contribute to activities outside my immediate work area to strengthen the organisation
- Coach and mentor people to reach their full potential
- Work across teams and participate in open and challenging discussions
- Promote and support networking across work areas and levels
- Recognise and celebrate efforts and achievements
- Show respect and don't accept bad behaviour
- Remain supportive and visible, even in times of adversity
- Connect my work across the organisation to achieve better outcomes
- Provide clarity about context, expectations, roles and responsibilities

Survey responses

The results of the recent surveys undertaken within the Commonwealth Department of Health, with focus on the Medical Officers within the Department and particularly the Medical Devices area highlight perceptions of substantial variances to the principles and behaviours as outlined in the People Strategy documentation.

Positive variances

The responses that were substantially positive (75% positive or more) or at substantial positive variance to the Department more broadly included:

1. Having the skills to undertake the role, particularly around data analysis
    a. Includes the ability to use feedback for improvement
    b. Going the extra mile
    c. Being prepared to accept responsibility for actions / recommendations
2. Work-life balance
    a. Flexible arrangements
    b. Non-monetary conditions
3. Expectation to make suggestions to continuously seek improvement
4. Diversity of workforce and the ability to accept and work with the diversity
5. Encouragement of ethical behaviour

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Negative variances

The responses that were substantially negative (25% or less positive) or at substantial negative variance to the Department more broadly included:

1. Job performance criteria and outcomes not clear
    a. Poor recognition and reward
    b. Agency does not handle poor performance
    c. Employees not valued and not consulted
    d. Employees do not go 'beyond job' for department
    e. Lack of personal attachment or accomplishment
2. Lack of respect for those in supervisory / managerial / senior roles
    a. Not visible
    b. Poor communication
    c. Lack of support for staff
    d. Poor articulation or ownership of strategy
    e. Leaders do not 'live values'

3. Strained working relationships
    a. Sense of fear, and fear of failure
4. Corporate service support poor

These perceptions lead to a lack of personal attachment and the employees would not recommend the department to others for career opportunities. These perceptions were explored further in the individual interviews.

Recommendation One: The Chief Medical Officer and Senior Executive consider how negative variance comments from the survey and interviews can be further addressed within the Department, in the context of the People Strategy

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Methodology

Having undertaken an initial review of the overall workforce, the Commonwealth Department of Health committed to further analysis of the medical workforce through Oban Consulting. The Terms of Reference are attached in Appendix A.

This took the form of a more detailed survey of all Medical Officers undertaken by the Department of Health / CMO and interviews with all Medical Officers and First Assistant Secretaries in the Department who had responsibility for Medical Officers. The majority of the interviews were face to face in Canberra, Sydney, Parramatta, and Melbourne. Although notes were taken, no recording nor transcripts were made. This was explained to each interviewee. This was supplemented by an additional survey of the Medical Officers concerning qualifications, ongoing clinical involvement and experience and possible areas for extension of experience.

The interview approach highlighted key findings within the Department of Health / CMO questionnaire. The headings of the questionnaire were:

- Hours worked per week
- Reasonable nature of work demands
- Length of service within department and within current role
- Accessing rights of private practice
- Clinical expertise and other skills
- Delegated authority
- Breakdown of type of work
- Appropriate use of time in current activity mix
- Suggestions on how the department can better utilise the skills and experience of the Medical Officers
- Interest in secondment or temporary transfers and to what areas
- Professional development. Adequacy and access
- Reason for joining the Department of Health
- How long do you intend staying in current role or within Health
- Other suggestions as to how the Medical Officers can make greater contributions to the Department

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In particular the interviews explored some of the themes that had emerged within the 'suggestion' related questions of the survey. The themes that had been repeatedly stated on the survey questions were:

Do you have any suggestions on how the department can work with Medical Officers to better utilise their skills and experience?

- Better HR related processes with job descriptions / appointments / reviews / use of IDP and PDS / better induction (multiple comments)
- Clarity over ability to successfully apply for other roles (multiple comments)

- Formal rotations across department to break down siloes, improve interest of work and more fully use skills (multiple comments)
- Formal training programs across the department particularly highlighting regulatory requirements (multiple comments)
- Training of managers in managing Medical Officers and also the requirements around clinical practice entitlements (multiple comments)
- Recognition of the breadth of skills that Medical Officers bring from management, policy development, health systems understanding (multiple comments)
- Maintenance of a register of skills so Medical Officers can be identified more readily when skills are required (multiple comments)
- Utilise medical officers earlier in policy development and preferably embed them in all areas (multiple comments)
- Better access to professional development and the ability to develop national / international networks (multiple comments)
- Better use of external assessors and better choice of work to go to the external assessors (multiple comments)
- Better use of non-medical clinical staff who can appropriately action work, without a Medical Officer being involved (multiple comments)
- Better consultation around changes (multiple comments)
- Streamlined systems around updating work such as Product Information, when already achieved internationally
- Review of some MO5 roles that are 'overwhelmed' by decision making requirements

Do you have other suggestions about how you and other Medical Officers could be helped to make an even greater contribution to the Department?

- Better involvement with management and with decision making (multiple comments)
- Address cultural issues of respect (multiple comments)
- Better career development (multiple comments)
- Formalised network of Medical Officers across the department and also beyond e.g. Defence (multiple comments)
- Greater engagement with Universities (multiple comments)
- Encouragement of holding external leadership positions (multiple comments)
- More Medical Officers
- Greater independence from industry
- Quieter work environment

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Please provide any other comments that you think are relevant that have not been captured above.

- Better reward and recognition processes (multiple comments)
- Encouragement around external representation
- IT support in regional offices (multiple comments)
- Much more careful supervision of Medical Officers who are not fully registered (multiple comments)
- Handling reform fatigue and dysfunctional management

In the interview based discussion around these themes further depth was provided that related to

- Medical Officers are viewed as too variable in their skills with much depending also on individual personalities and their previous experience. There is no consistent approach to addressing skill gaps for the jobs.
- There was a sense that some roles were filled by Medical Officers "because they always have been" or to provide a sense of confidence in a process, without a critical evaluation supporting that the skill set (complex health evaluation) of a Medical Officer is required.
- SES managers are very varied in their confidence in and approach to the use of medical officers. In some Divisions there is a strong partnership and early engagement. In others, SES managers of Medical Officers seem unsure how to use medical officers, appear to block engagement in policy work (particularly at the formative stage) and are almost resentful of the Medical Officer group.
- Many Medical Officers expressed a desire to be involved much more fully in policy and program work, but need an accountability and engagement framework to make that work. Medical involvement should just not be a "clinical opinion" or "sign off" but rather full involvement (for relevant projects) from the initiation stage.
- A sense of 'learned helplessness' combined with comments similar to 'there are lots of embittered people here'. These were general comments but were particularly noted in the Medical Devices Division.
- Some medical officers have taken on branch and section head leadership roles (particularly in TGA). They feel that they have been able to achieve significant outcomes from a leadership position, overcoming the frustrations of being seen as advisory in other areas. These MOs in leadership roles expressed the view that specific leadership training would be of value for them and for others contemplating such a role.
- There were occasional Medical Officers for whom the accountable manager could not describe a clear profile of the work of that Medical Officer or how the manager could / should manage the Medical Officer.

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Key findings

The breakdown of the Medical Officer Profile is best described in the table below. Table 1(a) is the breakdown before the most recent restructure and Table 1(b) after.

Table 1(a)

Group / Division	MO 2	MO 3	MO 4	MO 5	MO 6	May FTE Total
Health Benefits Group		**9.94**	**4.30**	**2.00**		**16.24**
Medical Benefits DIV				2.00		2.00
Provider Benefits Integrity DIV		9.94	4.30			14.24
Health Products Regulation Group	**10.72**	**10.80**	**15.98**	**12.07**	**1.00**	**50.56**
HPRG Executive DIV					1.00	1.00
Medical Devices Product Quality DIV	2.12	2.00	2.00	2.83		8.94
Medicines Regulation DIV	8.61	8.80	13.98	9.24		40.62
Health Protection Group			**1.11**	**2.00**		**3.11**
Office of Health Protection DIV			1.11	2.00		3.11
National Program Delivery Group				**1.80**	**0.52**	**2.32**
Health Workforce DIV				0.80	0.52	1.32
Population Health and Sport DIV				1.00		1.00
Strategic Policy & Innovation Group					**3.00**	**3.00**
Health Services DIV					1.00	1.00
SPIG Advisers DIV					2.00	2.00
Grand Total FTE	**10.72**	**20.73**	**21.39**	**17.07**	**5.32**	**75.23**
Grand Total Headcount	**15**	**24**	**24**	**20**	**6**	**89**

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Table 1(b)

Group / Division	MO 2	MO 3	MO 4	MO 5	MO 6	DEC FTE Total
Health Financing Group		**10.83**	**5.0**	**2.0**		**17.83**
Medical Benefits DIV			1.0	2.0		3.0
Provider Benefits Integrity DIV		10.83	4.0			14.83
Health Products Regulation Group	**13.50**	**5.09**	**17.88**	**11.86**	**1.0**	**49.32**
HPRG Executive DIV					1.0	1.0
Medical Devices Product Quality DIV	4.0	0.52	2.48	2.04		9.04
Medicines Regulation DIV	9.5	4.56	15.4	9.82		39.28
Chief Medical Officer Group			**0.81**	**2.8**	**1.0**	**4.61**
Office of Health Protection DIV			0.81	2.0	1.0	3.81
Health Workforce DIV				0.8		0.8
Aged Care, Sport & Population Health Group				**1.0**		**1.0**
Population Health and Sport DIV				1.0		1.0
Health Systems Policy & Primary Care Group					**2.0**	**2.0**
Primary Care & Mental Health DIV					1.0	1.0
Chief Nurse and Midwifery Officer					1.0	1.0
Grand Total FTE	**13.50**	**15.92**	**23.69**	**17.66**	**4.0**	**74.77**
Grand Total Headcount	**15**	**24**	**24**	**19**	**7**	**89**

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The total salary budget for the Medical Officers is $15.5 million per annum. The breakdown of salaries by band is in Appendix B.

In response to the survey (82 responses) the Divisional breakdown is analysed:

Table 2

	%	Count
Health Services DIV	1.22%	1
Health Workforce DIV	2.44%	2
Medical Benefits DIV	3.66%	3
Medical Devices Product Quality DIV	10.98%	9
Medicines Regulation DIV	53.66%	44
Office of Health Protection DIV	4.88%	4
Provider Benefits Integrity DIV	19.51%	16
TGA Executive DIV	2.44%	2
Did not specify	1.22%	1
Total	**100%**	**82**

The classification of Medical Officers is:

Table 3

No.	Answer	%	Count
1	Medical Officer 2	18.29%	15
2	Medical Officer 3	26.83%	22
3	Medical Officer 4	28.05%	23
4	Medical Officer 5	20.73%	17
5	Medical Officer 6	6.10%	5
	Total	**100%**	**82**

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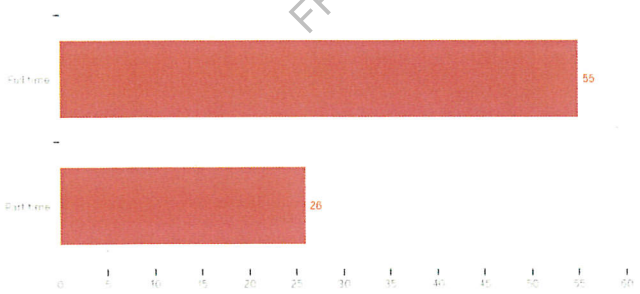
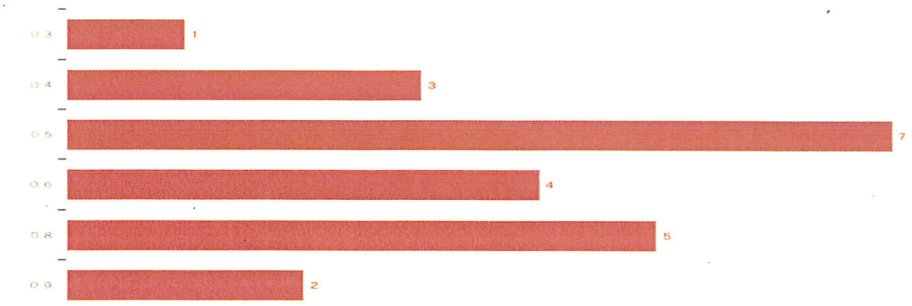
The full time / part time percentage was:

Graph 1



The part-time time fraction is demonstrated graphically with the largest profile at 0.5

Graph 2



Consequently, with the response to the question of hours worked in the last week, the significant number of part timers is reflected.

Table 4

No.	Answer	%	Count
1	37.5 hours or less	37.80%	31
2	More than 37.5 hours to less than 40 hours	21.95%	18
3	40 to less than 45 hours	20.73%	17
4	45 to less than 50 hours	8.54%	7
5	50 to less than 60 hours	4.88%	4
6	60 hours or more	0.00%	0
7	Not applicable (e.g. graduated return to work, on leave)	6.10%	5
	Total	**100%**	**82**

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This was viewed as typical of the average week by the substantial majority

Table 5

No.	Answer	%	Count
1	Yes	87.80%	72
2	No	12.20%	10
	Total	**100%**	**82**

Importantly a substantial majority viewed the workload as reasonable

Table 6

No.	Answer	%	Count
1	Strongly Disagree	0.00%	0
2	Disagree	7.50%	6
3	Neither agree nor disagree	23.75%	19
4	Agree	60.00%	48
5	Strongly Agree	8.75%	7
	Total	**100%**	**80**

An exception was seen in the medicines regulation of TGA where a number of Medical Officers found the combination of change management activities along with the usual decision making roles was creating a significant workload burden for them.

Over 50% of the Medical Officers have formal delegations in their areas of responsibility

Table 7

No.	Answer	%	Count
1	No	45.12%	37
2	Yes	54.88%	45
	Total	**100%**	**82**

The length of tenure in the department demonstrates a large number being in their role for five years or less

Table 8

No.	Answer	%	Count
1	Less than 1 year	7.32%	6
2	1 - 2 Years	23.17%	19
3	3 - 5 Years	24.39%	20
4	6 - 10 Years	19.51%	16
5	11 - 15 Years	12.20%	10
6	16 - 19 Years	3.66%	3
7	20+ Years	9.76%	8
	Total	**100%**	**82**

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With the length of tenure in the current role being similar

Table 9

No.	Answer	%	Count
1	Less than 1 year	18.29%	15
2	1 - 2 Years	29.27%	24
3	3 - 5 Years	24.39%	20
4	6 - 10 Years	17.07%	14
5	11+ Years	10.98%	9
	Total	**100%**	**82**

Despite this significant turnover in the last five years the roles are generally perceived positively with the following comments being made as to the reason for wishing to work at the Department of Health

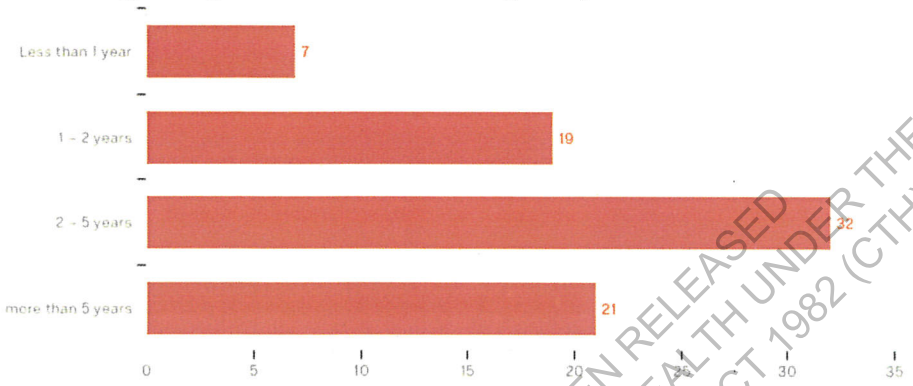
- Work life balance (multiple comments)
- Enjoy public health or the ability to use varying skills such as pharmacology, statistics (multiple comments)

- Enjoy involvement in health policy (multiple comments)
- Different career options (multiple comments)
- Wanted to work in Canberra (multiple comments)
- Was moved under Machinery of Government changes (multiple comments)

Most people viewed themselves as having a future for more than five years within the Department of Health although only a shorter time in their current role

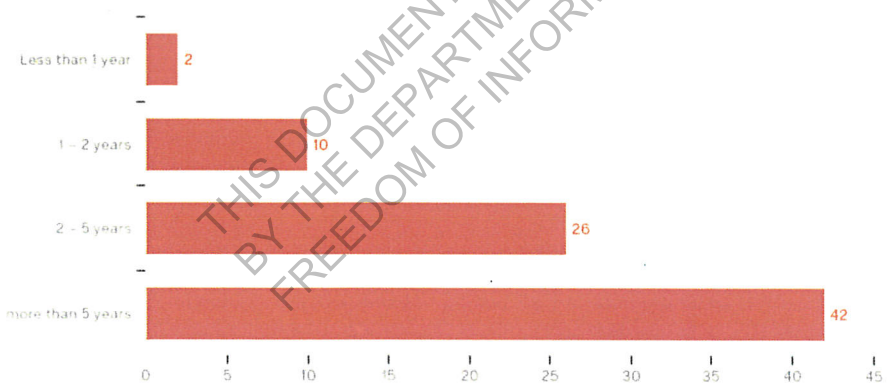
Graph 3

How long do you intend to stay in your current role?



Graph 4

How long do you intend to stay in Health?



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What are the key functions / areas of Department of Health where clinical / medical officer input can be valued?

There was widespread agreement that Medical Officers 'value-add' to the activities of the department and that a model that had ongoing interaction and input would be preferred. However, the particular skills required of the Medical Officers differed between departments from technical analysis, compliance, assistance with policy development and strategy advice to advocacy at a medical and political level. Separate to this, medical officers can also have sophisticated management and leadership skills and experience and would be appropriate managers within the Department of Health structure. However, Medical Officers are not always included in health reform processes, where their expertise self-evidently

would assist. There were anecdotes of how some medical officers were not able to work within a team based environment or were not included in relevant teams.

Areas where some respondents indicated that increased medical input would be positive included

1. Medical benefits
2. Technology assessment and access
3. Health protection, specifically restoring public health expertise
4. Health systems policy
5. Medical Research
6. Preventative Health programs
7. Indigenous health
8. Primary Care reform and Primary Health Networks
9. National cancer screening
10. Ageing and Aged care

In particular, a number of interviewers identified the need for much stronger and embedded Medical Officer involvement in Indigenous Health (where there is expertise in the Medical Officer group). The critical need for replacement medical leadership in the MBS review was also highlighted as was the inconsistent Medical Officer involvement in all stages of primary care reform projects (health care homes was an example cited).

On the other hand, there was a description of a recently departed medical officer, who had been underutilised significantly in the workforce division for some years, after the transfer of GP training out of the Department, with no apparent process for redeployment.

The Department does not operate in isolation, it is a large and vital component of the Australian Health Care system needing to be strategic in many issues as well as reactive and politically astute and committed. Some recent areas requiring a reactive response from Medical Officers include:

1. Political / media demands such as Lyme disease, mesh side-effects, flu prevention, indigenous health, up scheduling of codeine containing analgesics, medicinal cannabis
2. Impact of multiple review and more recently the Sansom review of the TGA
3. Issues arising from the MBS reviews
4. Increased concerns around standards in Aged Care

Recommendation Two: The CMO and SES in the Divisions, other than in Health Products Regulation, should examine the allocation of Medical Officer workload to the various policy and program areas, with a focus on the supporting the MBS review, aged care, indigenous health, primary care reform and meeting the reform objectives of the provider compliance division.

Various models of clinical and medical input were discussed with the Medical Officers and the First Assistant Secretaries. These included:

1. External experts: through use of committees or possibly having expert individuals on part-time retainers

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2. In house – centralised in a 'Clinical advice unit'
3. In house – embedded with focus on specific department
4. In house – embedded with both specific and corporate wide engagement

Overwhelmingly the embedded model across one or more divisions, with corporate wide engagement as appropriate, was viewed most positively. This would enable Medical Officers to have earlier interaction with issues particularly around policy development where a health care systems awareness could be most useful.

However as this model is further developed it will be critical to define the accountability and responsibility that go with both the specific department focused and corporate wide activities. This is particularly the case with Medical Officers who work across more than one division and whose accountability for performance is unclear.

Recommendation Three: That Medical Officers remain embedded within a primary area of the Department, but with a broader involvement in 'cross department' initiatives, which is defined through an agreed accountability framework and workplan for each Medical Officer. Medical Officer accountability should ideally be to a Senior Medical Officer (directly or via a dual accountability) or to a Divisional Head, but with a clear set of responsibilities and tasks beyond that Division (if appropriate). Movement including rotation of Medical Officers from TGA to other parts of the Department of Health need to consider the funding complexities / cost recovery models in which TGA undertakes its work.

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What is the required skill set for Clinicians / Medical Officers?

The tasks currently undertaken by the Medical Officers was surveyed in detail and grouped by both seniority and divisional grouping (Appendix C).

The majority of the medical workforce time, particularly at MO2, MO3, and MO4 is committed to undertaking the detailed assessments of therapeutic agents within TGA or in the compliance work of the Provider Benefits Integrity Division. In the survey, the compliance work undertaken by Provider Benefits Integrity was grouped under 'other' activities.

With increased seniority the Medical Officer tasks become more committed to preparation of policy advice and documentation, leading or participating in external stakeholder committees or other engagements with external medical bodies.

Within the actual job descriptions the core skill set for more junior medical officers includes

1. Analysis
2. Creation of advice and recommendations
3. Policy review
4. Representation within Committees

As the seniority increases

1. Analyses are increasingly more complex and related across multiple areas of the health sector or department
2. Advice and recommendations are required to be more strategic and politically aware
3. Policy review becomes policy creation in more nuanced areas.

4. Representation becomes more externally focused at a national and then progressively international level

The most senior positions require

1. Highly developed leadership and communication skills
2. Sophisticated policy development skills
3. Ability to manage teams across multiple disciplines
4. Provide advice and recommendations to the most complex and politically sensitive issues with a comprehensive understanding of the health care system
5. Expects ongoing liaison and networking across multiple sectors and stakeholders
6. Ability to undertake and deliver on change management and system change concerns

It is recognised that a critical mass of expertise is required to provide the required diversity of experience, flexibility in back-up, avoidance of conflict and interest, oversight and professional support. It is important that 'back-up' is more fully recognised as, at present, key positions may be 'vacant' with the areas dependent on that advice having to obtain it in an ad-hoc manner or complete work without important perspectives.

The Department should articulate the skills required for the Medical Officers of both a generic and specific nature. The generic include

- Ability to work in multi-disciplinary teams, with multiple experts, but with a designated leader who may often have policy and not clinical expertise
- Ability to work with expert committees
- Ability to advocate to the external world about the approved policies and approaches of the government
- Understand the system requirements of health and its delivery and the political interfaces at local, state and national levels

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The specific skills include:

- Regulatory science and frameworks of evidence assessment
- Knowledge of medical device manufacture and associated standards
- Clinical Trials
- Legal and international standards required of documentation
- Statistics and Epidemiology
- Policy development
- Advocacy

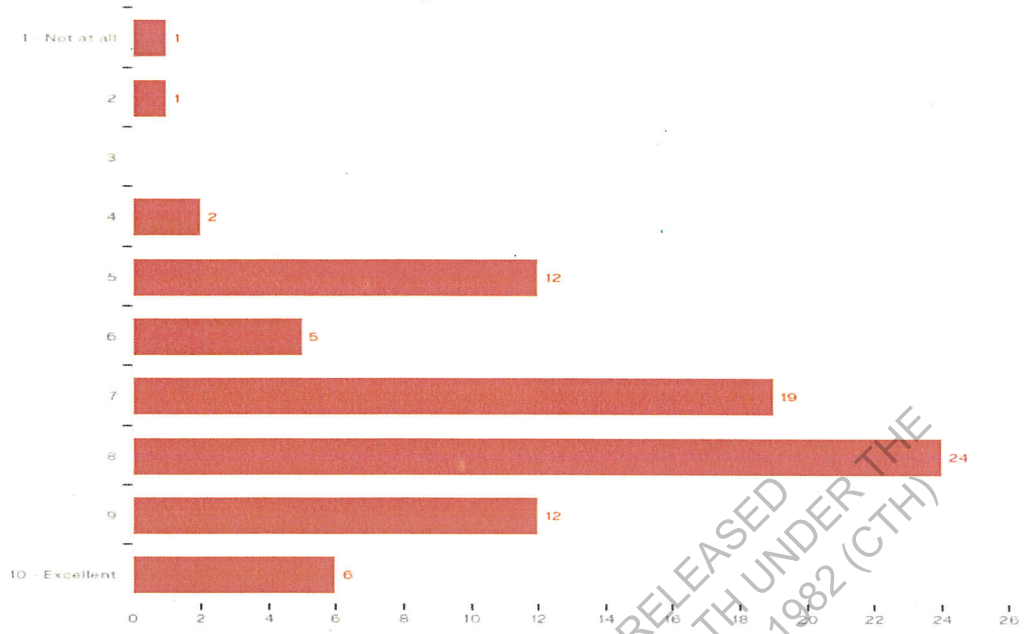
There are a range of tasks, both regulatory and non-regulatory that are performed by medical officers seemingly for historical reasons, without a clear justification that these tasks need the specific skill set of a medical practitioner.

Recommendation Four: The Department more clearly articulates and acknowledges the generic and specific skills for Medical Officers at different levels of seniority. The Department critically reviews designated Medical Officer tasks to determine whether some could be performed by other staff with generic or alternative specific professional backgrounds.

In assessing whether the department was appropriately utilising their time the Medical Officers responded largely in the positive.

Graph 5

(1 not at all – 10 excellent)



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There was a free text response for suggestions as to how their time could be utilised more effectively. Comments were varied but the dominant groups included:

- Would be more productive with additional administrative support / IT support (multiple comments)
- Inappropriate use of time and skills with current SAS approval system. Approvals after the initial approval could be delegated to non-medical staff eg; Pharmacists (multiple comments).
- Inappropriate use of time taking calls from public about quasi-clinical issues. This was particularly related to the Medicines regulation division (multiple comments).

How are these skills developed or recruited for?

The skills required in Medical Officers are diverse. The majority of Medical Officers are within Medicine Regulation, Medical Devices and Provider Benefits Integrity and are employed at MO2, MO3 and MO4 levels. These are mainly technical assessment or compliance roles but interface repeatedly with policy review, policy creation and advocacy roles.

One of the key reasons for having a Medical Officer in these roles is to bring a substantial degree of understanding about Clinical Practice within the Australian Health Care Sector – the clinical world where regulation, compliance or policy development will impact.

Although a medical degree addresses some of the skills required in these roles, the fuller understanding of the health system only develops after some years of experience. Additional training is required particularly around the specialist skills. This is certainly present in the current cohort of Medical Officers although the true depth and breadth of the

incredible experience and expertise does not appear to be recognised or fully utilised. As an example in the seventy five responses to the additional survey of skills, experience and interests, qualifications included over twenty Masters degrees in Law, Science, Public health, Business Administration and Health Administration. Additional degrees in Epidemiology and Statistics had been frequently obtained. Broader clinical qualifications in Child Health, Psychiatry, Family Medicine and Pharmacology were common. There were over twenty advanced research degrees such as PhD or MD.

The breadth of acknowledged clinical achievement and expertise is clearly demonstrable through more than twenty Fellowships of the Colleges of General Practice or Rural Medicine, ten Fellowships of the College of Physicians or Faculty of Public Health Medicine. There are four trainees in Public Health Medicine as well as trainees in General Practice, Surgery and Medical Administration. A number of the Medical Officers have formal roles with Universities including senior academic appointments.

This broader knowledge is encouraged through rights to outside medical practice. Almost fifty percent of the Medical Officers access this on a regular basis. The ongoing Clinical practice is broad and the table of current clinical practice below demonstrates this.

Table 10

General Practice (multiple – twenty) Interests of:	Other specialty practice
HIV / Sexual health	Paediatric Endocrinology
Surgical assisting	Pathology
Education	Haematology
Defence Forces	Emergency Medicine
Sedation	Psychiatry
Hospitalist	Paediatrics
Accreditation of GP practices	Public health Medicine
Travel medicine	Endocrinology
After hours practice	University based teaching
	University base research

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Recommendation Five: The Department develops a stronger understanding, and potentially a register, of the broad experience and expertise of its Medical Officers and utilise these skills, where appropriate, in policy development, program delivery and reform initiatives.

The Commonwealth will be most successful in having an engaged committed workforce by improving the comprehensiveness of training possibilities, the clarity of skills required at different levels and greater consistency in appointment processes, particularly of external candidates. In the review interview process, comments were made about appointments being made that did not appear to be consistent or processes not being uniformly applied.

To have an effective approach to the Medical Officer workforce, the Department needs to continue to recruit junior Medical Officers but must provide training and professional development opportunities. The Department also needs to recruit more senior and experienced staff with additional expertise but will require substantial induction as to the Department approach and expectations. Having defined the skills required at the different seniority levels it will be most important that if appointments are made where skill gaps exist

that a dedicated training program is available and oversighted by senior medical officers and the Chief Medical Officer.

Although the current experience and qualifications of the Medical Officers is in many ways extensive and diverse it is important to understand how the skills can be augmented through a comprehensive training program for junior medical officers. The training program relating to Public Health Medicine appears the most aligned with the current skill mix. Other programs could include Clinical Pharmacology, Medical Administration or special interest components for General Practice. At this point, there are more trainees in Public Health involved with Department activity, although General Practice and Medical Administration trainees are also employed. The training programs for Medical Administration and Public Health would require formal qualifications in areas such as a Masters of Public Health and this could be combined with a structured experiential program to gain competencies in key areas. Many staff are trying to achieve this already in a serendipitous manner. Indeed a significant majority in the survey identified one or more areas where they would have substantial interest in either a secondment or temporary transfer to another agency. This would enhance training opportunities, professional development opportunities as well as the broader areas of interest in the Medical Officer role.

Being selected as a trainee into these programs has a requirement of at least two years clinical experience. The Commonwealth Department of Health could then provide high value training opportunities in the specialist areas, particularly if connections to other departments or other jurisdictions were considered.

Possible experiential rotational program examples include

a. TGA Therapeutics 12 months
b. TGA Devices 12 months
c. D of H – policy 12 months
d. D of H – compliance 12 months
e. Legal department of TGA – 12 months
f. Department of Defence – policy 12 months
g. ACT Health – infectious diseases 12 months
h. NSW Health – infectious diseases 12 months

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The terms and ongoing rotations could maximise the awareness and skills required for an embedded and corporate contributing Medical Officer. These terms could be recognised for Faculty of Public Health Medicine, FRACGP advanced skills and RACMA.

Experiential programs are combined with formal academic teaching such as a Masters of Public Health. There would be substantial advantage in working collaboratively with a University to ensure a Masters level course is appropriately scoped to achieve the University requirements and the skill set required by the Department. Components of a Master's program could then be offered more broadly as specific subjects such as Epidemiology and Statistics. It is noted that there are some academic links with the Australian National University (ANU) through the National Centre for Epidemiology and Population Health (NCEPH). These could be strengthened and made more formal with advantage to both parties as well as the Medical Officers.

Beyond the training possibilities and requirements, the MO2, MO3 and some of the MO4 roles should be considered for rotation every 2 or 3 years. Many of the individuals interviewed expressed interest in this and provided 'Areas of interest' in the additional

survey. It will certainly assist with an understanding of the breadth of activities within the Department of Health and assist with limiting the negative impacts of 'silo-ism'. However, this will need to be balanced when the role particularly at the MO4, MO5 and MO6 requires such specific expertise that rotations would be significantly counterproductive.

Recommendation Six: The Department considers formal linkages with a University to develop an appropriately scoped Masters of Public Health, especially for junior doctors. The Department investigates the feasibility of a rotational training program for MO2, MO3, and MO4 to enable more appropriate experience in policy development, regulatory science and health innovation. Such a rotation program would need to take account of operational requirements and, in the case of the TGA, the special account funding of staff.

There are ongoing professional development events on a weekly, fortnightly or monthly basis that Medical Officers can attend. Although a significant majority felt that they had access to relevant learning and development opportunities, timing and regional access to these will always challenge. This is particularly so for the part-time workforce. The training program and the rotational program should be interfaced to this ongoing and active Continuing Professional Development. This needs to be more fully IT supported to be delivered across all sites of the department.

Training and ongoing professional development is placed in a supportive environment and context. During the review process many comments were made about the variable approach and support provided by non-clinical managers. The Medical Officers can easily be construed as 'difficult to manage' with 'additional benefits not available to other staff'. However some managers openly engage the Medical Officers in the activities of their Division and extract all possible value whilst understanding but ignoring that there is a difference in remuneration and conditions. Many comments were made about the management challenges being negatively 'entrenched'. Change will not occur without an active program to ensure that Medical Officers are more effectively included in multi-disciplinary teams by all managers and that the Medical Officers' interactions emphasise responsibility and accountability to the activities of the Department.

A substantial number of HR related issues and line management challenges were highlighted by the survey and interviews. These will require ongoing assessment and training to address.

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How does the Department achieve these changes?

The Medical Officers should be embedded within one area, but have a more 'corporate' view with a role in other areas. It will be most important that the accountabilities are clear. This more corporate focused 'network of medical officers' does not happen without resourcing, senior level ownership and some central oversight across the Department. It would be of value to allocate portfolios to the more senior Medical Officers to maintain momentum for cross department and Medical Officer professional issues that include:

- Training and ongoing CPD
- Rotations
- Maintenance of a skills register of all Medical Officers
- Appropriate engagement in research & publications
- University and College liaison
- External body representation

However, it will also be important that the line management responsibilities within the Department of Health are not confused by this increased 'networking' within the Medical

Officer grouping. The Chief Medical Officer does not line manage the staff. However, he does need to provide advice as to the best strategies to ensure the expertise of the Medical Officers is available for the most important tasks at hand.

The 'leadership' group could also assist in identifying and resolving issues that contribute to the frustrations and 'learned helplessness' that was described.

Industrial issues

The Medical Officers are attracted and continue in their roles due to the ability to contribute to 'all of health' issues, their interest in technical analysis and emphasis on flexibility and work-life balance benefits. As an example a third of the Medical Officer workforce is part-time and a third access the right to outside medical practice. Overwhelmingly, individual Medical Officers feel that the demands of the role were matched by their skills and the time available. However, there were some individual concerns raised about HR practices, the requirement for experience and expertise in more senior roles, the apparent comparison of salaries to comparable government groups (ACT health and NSW health) and the size and application of the Professional Development Allowance. It is recommended that ongoing comparison of pay-scales is undertaken particularly to ACT Health and NSW Health, noting that non salary conditions (such as superannuation are different in different jurisdictions). The capacity for Medical Officers to access part time private practice during their paid time to some extent compensates for salary disparity. Retention of external clinical practice arrangements appears to be important to attract and retain good staff. Some individual perceptions of inequitable treatment need to be explored and, if necessary addressed

Recommendation Seven: The Department formally compares remuneration packages between Medical Officers in the Commonwealth Department and those in other jurisdictions and notes the importance of access to external private practice both to retain and to continue clinical medicine exposure for Medical Officers.

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The department provides a Professional Development Allowance (PDA) to help ensure that Medical Officers employed by the department maintain professional standards and continue to provide a high level of advice and services. Professional development may be achieved by:

- attaining and maintaining professional skills as recognised by the Medical Board of Australia or the relevant specialty college
- engaging in outside medical practice (OMP)
- Maintaining relevant professional registration.

Subject to approval, a Medical Officer may, during work hours, undertake OMP for a maximum of a half day per week (averaged over 12 months) and up to an additional half day per week (averaged over 12 months) based on make-up time or leave without pay.

The PDA is paid for reasonable and acceptable expenses relating to the professional development of a Medical Officer. Both full-time and part-time Medical Officers are eligible to receive a PDA of $4,750 each financial year on a reimbursement basis. The PDA is criticised and regarded as inadequate by almost fifty percent of the Medical Officers for two reasons. It is set at a low level compared to other Health Departments particularly if the Medical Officer is trying to attend an overseas conference through this funding. In addition, the administrative requirements to access it, appear very burdensome particularly if it is combined with approval to travel overseas. These administrative processes are likely to be costly to the Department and seem unwarranted for the amount involved.

For the relatively small amount of reimbursement concerned, a more stream lined approach appears reasonable. One suggestion would be to roll this allowance into normal salary and allow Medical Officers to privately undertake professional development and claim the appropriate tax deduction. Alternatively, it could be paid annually (as a tax free allowance) on receipt of evidence of matching expenditure in CPD. The intent of the PDA is not to provide funding for attendance at Conferences at the direction / request of the Commonwealth Department.

If the payment of the PDA cannot be streamlined as outlined, then a list of payments that should be automatically approved needs to be provided to all managers of Medical Officers to facilitate appropriate payments.

Recommendation Eight: The Department considers converting the PDA to 'salary' or investigates an alternative streamlined process appropriate for this limited funding.

Seniority is very important to the Medical Officers. The Department of Health is inherently hierarchical and the following scale of seniority was provided to the reviewer and was apparently used in the recent Machinery of Government changes. The rationale for the different classifications for some of the medical officer roles was not readily apparent or clearly related to job size or work value.'. A more detailed review and recognition of additional skills / qualifications would be appropriate,

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Table 11

Medical Officer Class	Clinical Equivalent	Comments
MO1	Resident / RMO / HMO / CMO	
MO2	SRMO / SHMO / Junior Registrar / CMO	
MO3	Registrar (accredited) / Senior Registrar / Advanced trainee with experience	
MO4	Staff Specialist / Specialist Consultant	Specialist Fellowship
MO5	Senior Staff Specialist / Senior Specialist / Senior Consultant	Specialist Fellowship
MO6	Department Head	Specialist Fellowship

Recommendation Nine: A review of the seniority of Medical Officers is undertaken to ensure that current roles, expertise and qualifications are appropriately reflected in the classifications.

Equally being classified as Medical Officer should require registration and maintenance of CPD requirements to the satisfaction of AHPRA. If this is not achieved then the individual circumstances should be reviewed as they may not be necessarily employed on these pay scales. If a medical officer is unable to satisfy the registration requirements of AHPRA it appears unlikely that he/she will have the capacity to undertake the complex health system associated tasks that justify employment as a Medical Officer at a higher salary

Recommendation Ten: If an employee is not registered by AHPRA then their employment at a Medical Officer grade should be reviewed.

Therapeutic Goods Administration – Devices

All medical devices supplied in Australia must have clinical evidence sufficient to demonstrate an appropriate level of safety and performance when used for the intended purpose(s). They must also be included on the Australian Register of Therapeutic Goods (ARTG). This requires clinical evidence to be systematically reviewed periodically as new information based on post-market surveillance activities and product experience becomes available.

To continue to provide confidence in the Australian healthcare system, and to help ensure the health of the Australian population, the Review of Medicines and Medical Device Regulation (Sansom Report) established five principles for its recommendations

Principle 1. The role of regulation is to manage risk in order to protect public health and safety

Principle 2. The level of regulation should be commensurate with the risk posed by the regulated products

Principle 3. A risk benefit approach to the regulation of therapeutic goods is appropriate

Principle 4. The regulation of therapeutic goods should take a whole-of-life cycle approach. As a result, the regulatory system must:
- Have the capacity to source and analyse data as it becomes available
- Recognise and respond in a timely way to changes in the risk profile of products across their lifecycle
- Provide for whole of life solutions
- Be transparent and understood by all stakeholders

Principle 5. The ultimate responsibility for medicines and devices should remain with the Commonwealth. This means Australia should have capacity to undertake assessments for safety, quality and efficacy. The role of the regulator undertaking this assessment should be considered in light of approaches taken internationally.

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Of the International Medical Device Regulator Forum (IMDRF) members (Australia, Brazil, Canada, China, European Union, Japan and Russia) only the Europeans fully outsource medical device assessment for market approval. This includes high risk devices. Some IMDRF members utilise third party assessments for low risk devices, without a requirement for a mandatory application audit.

It is important that the risk benefit profile continues to be reviewed and updated. Although reviews by comparable overseas regulators could be increasingly utilised there are differences between Australian and overseas regulatory requirements. There will be differences in the time when the medical device was assessed, availability of post market data including records of adverse events, and different expectations regarding safety of medical devices. The outcome of assessment can validly differ. Also, Australian based expert groups could be utilised more fully, but consideration of the risk profile of work allocated to these groups will require ongoing review.

Medical Officers are actively involved in the assessment and ongoing review of the very broad range of Medical Devices that are being assessed for the Australian Register of Therapeutic Goods (ARTG). Medical Devices has 9 FTE of Medical Officers in its staff profile with seniority from MO2 to MO 5. This number was only recently increased to deal

with a substantial back log of applications for assessment. This is in comparison to the 40 FTE in Medicines Regulation.

In the interviews of Medical Officers it became evident that greater clarity of purpose and approach to assessment was required. The Sansom report advocates that expertise in evaluation is still maintained within TGA and this will be important to have at a level that can deal with the more complex evaluation issues. Other external evaluation teams need to be identified that have appropriate expertise, will not be conflicted due to other activities and will hopefully establish links at a strategic level as well as individual assessment level with the TGA. These strategic links need to consider workforce development, evaluation of the regulatory framework and research / publications.

Of all the groups of Medical Officers in the Department, this group seemed to be the most dissatisfied with their jobs. This was due to the lack of clarity of purpose (referred to above) and also because many of this group of medical officers perceive their role as being low level assessors reporting to junior (EL) staff without a clear rationale or respect for their particular medical experience.

This dysfunction was acknowledged by the Division head and Group head and an accelerated reform program is underway.

Importantly the profile of work needs to be confirmed with the appropriate balance of low / medium / high risk achieved. This should be considered in light of the final review and approval still residing with the TGA and the maintenance of the evaluation skills within the TGA. Clearer statements of how the first Sansom principle will be achieved are required. In protecting public health and safety, what is the goal and what is the evidential base required for 'safe' or 'not unsafe'? The current uncertainty about this has contributed greatly to the antagonism and tension between staff members and concerns about the influence of the industry.

Post marketing surveillance will become increasingly important. The number of Medical Officers within the Medical Devices area to undertake this activity will need review. Appropriate processes and performance indicators will be required.

Recommendation Eleven: As a matter of some urgency work needs to be done in Medical Devices to determine:

- The appropriate strategy for obtaining external reviews
- The role of Medical Officers in the evaluation or the approval of the external reviews
- The appropriate balance between pre-market evaluation and post-market surveillance
- An appropriate reporting arrangement for the Medical Officers, reflecting a revised and higher level role in evaluation. The MO5 could work significantly more in partnership with the Division head (as in medicines regulation) in managing the Division.

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Therapeutic Goods Administration – Medicines

The principles of the Sansom review apply to the Medicines Regulation area more prominently that Medical Devices. Medicines regulation has a substantial cohort of Medical Officers (40 EFT) with seniority from MO2 to MO5. The 'decision makers' for medicines are clearly defined and their role understood through regulation and ongoing activity and has appropriate structures to handle the complex assessment and post-market surveillance. Key issues to be confronted by the Division are the timelines for assessment and the increasing

sophistication of post-market surveillance. The workload of this group of medical officers is significant and increasing, some reporting considerable pressure with the added responsibility of the reform agenda. The current EFT of Medical Officers would be insufficient to cope with the growth in demand, in the absence of a detailed re-assessment of the roles of MOs in this Division and the potential of some role substitution and process review.

It is critical that Medicines Regulation bring a more multi-disciplinary team approach to their risk profiling and evaluation processes. Increased use and dependence of international regulatory assessments as outlined by the Sansom review would contribute to improved timeliness. Clearer stratification of the risk profile would allow non-medical Clinicians to undertake more of the reviews and in particular the low-risk areas could have higher involvement by Clinical Pharmacists. It will be important that into the future that TGA maintains the skills to be able to undertake the more complex assessments

Recommendation Twelve: Medicines Regulation review its approach to low risk applications and consider whether Clinical Pharmacists should undertake these reviews under delegation or utilise external evaluation teams.

Although the TGA has recently updated the Special Access Scheme information technology support, it requires ongoing review as to the classification of drugs to Class C agents and consideration that much of the SAS process could be undertaken by Clinical Pharmacists. Many Medical Officers regard the SAS requirements as very limited value. In an environment where resource utilisation is important all effort should be made to delegate appropriate tasks to other team members. The increased use of Clinical Pharmacists may need to be 'piloted' in a number of categories of medicines prior to a fuller roll-out.

Recommendation Thirteen: The Special Access Scheme be reviewed to significantly increase the drugs able to be classified as 'Class C' and the routine use of Clinical Pharmacists in providing the evaluation for the Scheme overall. This has already commenced.

TGA provides support to the public about adverse events due to use of medications. Although a component of the post-marketing surveillance approach, it is critical not to extend the scope of this to become the provider of clinical advice. Telephone enquiries should always be directed to the usual treating practitioner. Although anecdotal, there were numerous examples of distressed members of the public being directed to Medical Officers on staff. TGA should not provide a quasi 'counselling service' particularly for emotionally distressed individuals. There has been no formal training for this role and there is no capacity for an ongoing clinician-patient relationship. The provider of this service should be the usual treating practitioner or an accredited telephone based counselling service such as Life-line.

Recommendation Fourteen: TGA limits its telephone support to documentation of adverse events. Clinical Support and Counselling should be provided by the individual's usual medical practitioner or a recognised and approved telephone based Counselling service. This has already commenced.

TGA has undertaken a number of reviews concerning the correct 'balance' between pre-market and post-market assessments. As the impact of the Sansom report is felt, it will be important to reassess this integration to ensure coherent surveillance across all medicine groups.

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Recommendation Fifteen: Following the implementation of the Sansom Review, that the separation / integration of pre-market evaluation and post-market evaluation be reviewed.

Provider Benefits Integrity Division

The Provider Benefits Integrity division has 14 FTE of Medical Officers deliberately distributed across the various State Offices. This is important for their ongoing interaction with medical practitioners 'in the field'.

The Integrity Division has moved organisationally a number of times, most recently by 'machinery of government'. Being MOGED has become a frequent descriptor that covered some loss of organisational identity, with decreased benefits in both salary and professional development allowances.

The Provider Benefits Integrity division is still under substantial internal review and change in strategy and direction. There is an extensive reform program underway, particularly in data analysis, use of statistics and even the application of Artificial Intelligence.

There have been few changes to date in the compliance area involving the Medical Officers. Assisted by detailed statistical analysis, the Medical Officers undertake 40 detailed reviews including professional counselling of medical practitioners each year. These individuals (mainly General Practitioners) are identified principally through the identification of high volume practices. The review and referral to the more legalistic processes of the Director of Professional Services has always been politically contentious and challenged frequently by the AMA. Consequently the Medical Officers view themselves in a 'Counselling role' providing advice to the concerned practitioners as to how their clinical activities are substantially different to the norm. The approach to this 'peer counselling' appears to have changed little over the past ten years.

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The counselling is usually provided in the consulting rooms of the concerned practitioner following initial telephone contact. Given these can become 'hostile interactions' there is the potential to have a second Departmental staff member present for high risk encounters. Following the discussion with the practitioner, the clinical activity profile is then monitored for six months. If positive changes are achieved the review ceases. If there is no change then the practitioner is referred to the Director of Professional Services.

At only 40 reviews per medical officer per year, further analysis to streamline processes would be justified. The process does not appear efficient if less than one review a week is undertaken. With 14 FTE doing 40 interviews each year this is less than 600 in total. This is despite a generally strong commitment and apparent work ethic from this group of medical officers. Different models of approach apart from 'counselling' should be considered as should enhanced analytics to prepare for the counselling interaction. Incorporation of artificial intelligence at a basic level could provide substantial advantage. Given the importance of the Medicare Reviews currently being undertaken, it is vital that the review process incorporate a significant increase in monitoring the 100,000 medical practitioners who may be billing Medicare. International benchmarking clearly supports an enhanced approach and this is in scope for the current reform agenda.

The statistical analyses should be provided to the Medical Officers in a format that can be utilised and not require time spent by Medical Officers on additional interrogation of Department databases. Support from a legally trained staff member, skilled in documentation requirements could be of value. The utilisation of skills specifically trained in administrative law would potentially streamline documentation.

One Medical Officer described that the counselling based process can be achieved through telephone based discussions. This may not reveal information about the practice / rooms but is considerably more time effective. This should be explored particularly when there is no provider compliance Medical Officer close to the practitioner being reviewed.

The group of provider compliance Medical Officers include some very experienced and committed general practitioners. Provider compliance work is stressful and confrontational. Retention and motivation of these Medical Officers is very important to the reform agenda of the Division. It would be of value to explore the possibility of these Medical Officers having some involvement in other policy and program work. Areas like PHN, health care homes and primary care reform closely match their clinical experience.

Recommendation Sixteen: The 'peer counselling' process within the Provider Benefits Integrity Division be substantially reviewed to increase routine monitoring of billing practices being made available to Medicare Providers, use of artificial intelligence, streamlined interviews of providers by Medical and Non-medical staff. The Department should review the risks of unaccompanied site visits to practitioners and explore the greater use of telephone based counselling interviews to improve efficiency. The Department should explore strategies to retain and motivate this crucial group of Medical Officers, such as involvement in policy work or primary care health reform.

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Policy Advisor Role

Medical Officers can contribute very effectively to policy development. From both survey results and interviews, the preferred model was to embed Medical Officers within a specific area as that facilitated early and ongoing interaction. It will be important that the areas are prioritised for involvement and this will need active review and also a clear understanding of the expertise of the Medical Officers. There is most substantial expertise across the Medical Officer cohort that could positively contribute to policy discussions around Indigenous Health, Aged Care, Primary Health Care reforms and the ongoing Medicare Benefits reviews. Over twenty Medical Officers are actively engaged clinically in various areas of General Practice including development of standards and accreditation with at least ten others involved in other specialities. These Medical Officers have a detailed and up to date understanding of clinical practice within the Australian Health sector as well as a detailed and in many cases very exhaustive appreciation of the constraints imposed on the Department.

To facilitate the utilisation of these skills, it would be important to actively involve Medical Officers across the Department and also to provide ongoing rotations for 2 to 3 years of more senior Medical Officers so their skills in policy development and advocacy can be enhanced.

Recommendation Seventeen: Policy development and advocacy skills should be enhanced by rotations from across all the department into the appropriate policy area.

Appendix A

Proposed Review of Medical Officers/Medical Advisors in the Department of Health (including TGA)

Background

The recent Nous Review of Department of Health programs proposed this as a body of work to be undertaken. Medical Officers/Advisors (Medical Officers) are a highly valuable but more expensive workforce in the Department. The significant medical input obtained across many programs is seen broadly as a material "value-add" to much policy and program work. There are 89 MOs (75.2 EFT) divided between TGA (69 MOs, 50.6 EFT) and the remainder of the Department (28 MOs, 24.7 EFT). The annual salary cost to the Department of the Medical Officers is $15.5 million. In addition, each Medical Officer is entitled to a professional development allowance (on a reimbursement basis) of up to $4,750 per financial year. Many Medical Officers work part time; those on a full time contract have an arrangement where they can spend some time per week in private practice (or other activity) and retain the additional income for this work (this has been allowed as it promotes retention and clinical currency). The tables at the end of this document provide more detail on EFT and salary costs.

Within the TGA, most Medical Officers are involved in complex evaluation functions in areas where a medical training background is seen to be important. Elsewhere in the Department, Medical Officers are generally assigned and report to a particular Division but may provide a number of services across other Divisions (for example many Medical Officers are involved in the Medical Benefits Schedule Review).

Medical Officer involvement in an issue may be on the basis of technical knowledge/clinical experience or sometimes to facilitate consultation/discussion with an external (largely medical) group. It is not always clear what issues definitely require Medical Officer engagement and there would appear to be some inconsistency in approach across different parts of the Department. There are some anomalous areas that have no Medical Officer assigned and others (like TGA and OHP where there are a number of Medical Officer positions, given the technical nature of the work).

There is a view that some Medical Officers are working extremely long and pressured days and others have a more balanced workload. Because of the diverse roles that some Medical Officers have, it is sometimes difficult to get visibility of how they divide their time. Some of the roles undertaken by Medical Officers have traditionally had Medical Officer involvement for many years without regard to whether the extent of Medical Officer involvement is still necessary. Recently developed policy or program areas (including the TGA regulatory reforms), that could require increased Medical Officer involvement, have not had a clear opportunity or mechanism to source such involvement.

It will be important to stress, in the review, that the Medical Officer group are considered highly valuable and there is no *a priori* intent to reduce the number of Medical Officers in the Department. Rather the intent is to ensure that we are currently getting the best value from this important staff group.

Proposed Review

Given the diverse nature of the Medical Officer roles and the sensitivity of any such review, it is likely that the review process will need to include a personal interview with each Medical

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Officer (approximately 40 minutes each). Some with small time fractions or similar functions could have a smaller or group interview.

These would be preceded by a paper based survey to guide the interview; the survey would ask for a broad description and time allocation of activities undertaken by Medical Officers, the perceived value of such activities and any missed opportunities. The survey could then be used to guide the interview at a later date.

It would be valuable to then have the interviewer consult with each relevant Division Head (and/or other relevant senior staff) to supplement the information.

A steering group comprising the CMO, Deputy CMO, Principal Medical Advisor TGA and a senior HR representative would oversee the process.

Key Questions for the Review

1. Are tasks currently undertaken by Medical Officers all required to be done by Medical Officers (could some be substituted, for example, by pharmacists or other technical specialists)
2. Are their important areas/functions in the Department where there is no Medical Officer involvement but Medical Officer involvement would be of material and specific benefit
3. Are there areas of Medical Officer involvement where Medical Officer resources are severely stretched and more Medical Officer resources need to be applied
4. Are there Medical Officers who have potentially have available time and interest in supporting other areas in the Department
5. Recognising that some Medical Officers work across multiple divisions and will never be perfectly captured in the structure, are the current Divisional location/reporting lines appropriate?
6. How can the highest priority projects such as the MBS Review best be supported from the Medical Officer group.

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Appendix B

Classification	No. of staff (headcount)	Sum of Salary
MEDOFF 2	15	$ 1,915,226
MEDOFF 3	24	$ 3,582,737
MEDOFF 4	24	$ 3,931,610
MEDOFF 5	19	$ 4,138,856
MEDOFF 6	7	$ 1,905,505
Grand Total	**89**	**$ 15,473,934**

Does not include professional development allowance payments (up to $4750 each) and income derived from private practice sessions worked during contracted hours.

Medical Officer Level and salaries

Medical Officer Level	Equivalent Classification	Before lodgement of EA	On commencement (3/2/2016)	12 months after commencement	24 months after commencement
Medical Officer Class 5	SES B2	$260,000	$265,200	$270,504	$275,914
		$250,000	$255,000	$260,100	$265,302
		$235,000	$239,700	$244,494	$249,384
		$220,000	$224,400	$228,888	$233,466
Medical Officer Class 5	SES B1	$220,000	$224,400	$228,888	$233,466
		$210,000	$214,200	$218,484	$222,854
		$200,000	$204,000	$208,080	$212,242
		$192,000	$195,840	$199,757	$203,752
Medical Officer Class 4	EL 2	$160,691	$163,905	$167,183	$170,527
		$151,676	$154,710	$157,804	$160,960
		$145,989	$148,909	$151,887	$154,925
Medical Officer Class 3	EL 2	$140,165	$142,968	$145,827	$148,744
		$133,871	$136,548	$139,279	$142,065
Medical Officer Class 2	EL 1	$126,150	$128,673	$131,246	$133,871
		$119,726	$122,121	$124,563	$127,055
Medical Officer Class 1	APS 6	$109,410	$111,598	$113,830	$116,107
		$99,115	$101,097	$103,119	$105,181
		$92,093	$93,935	$95,814	$97,730
		$85,012	$86,712	$88,446	$90,215

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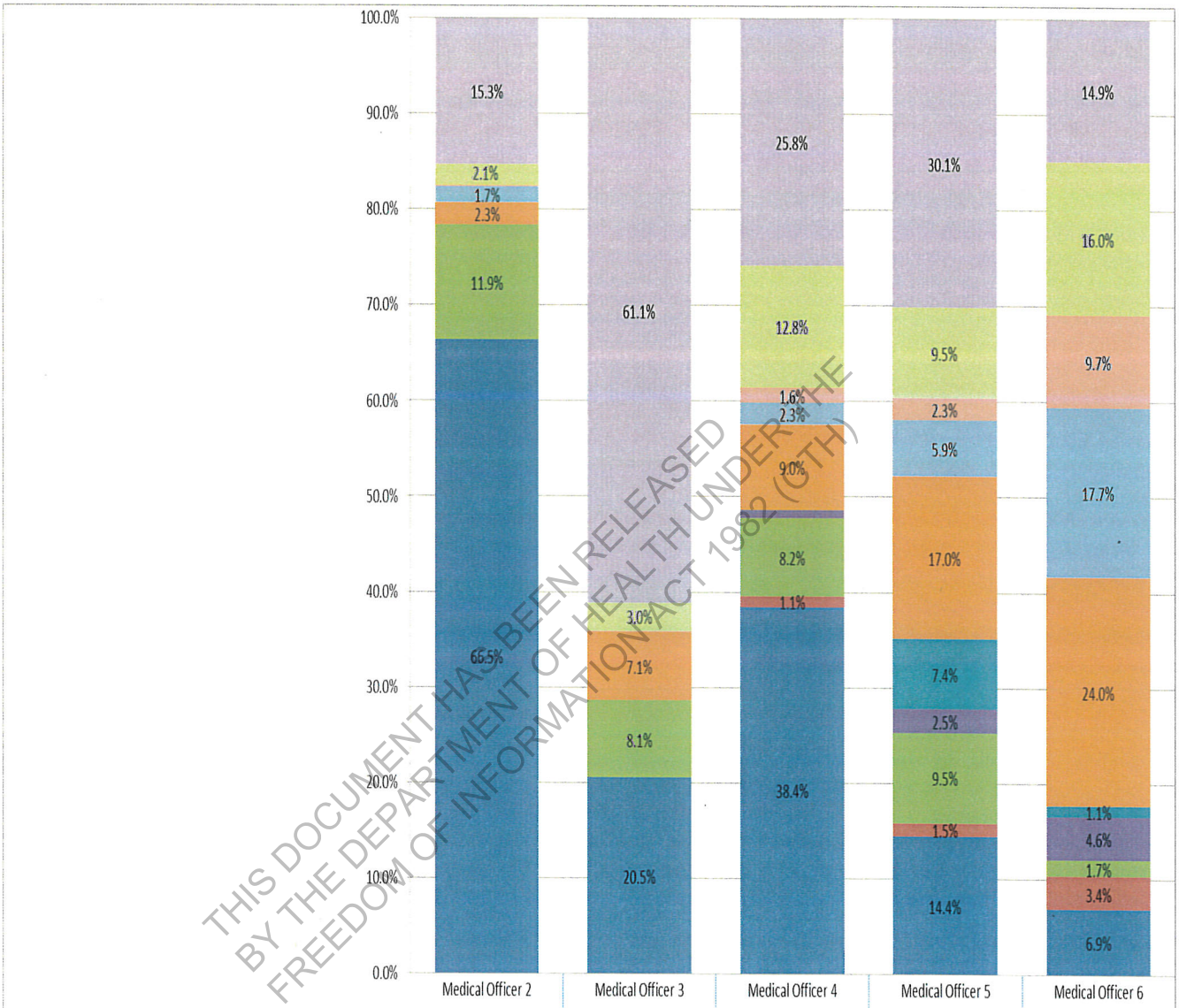
Appendix C

Function breakdown by classification – % of total time



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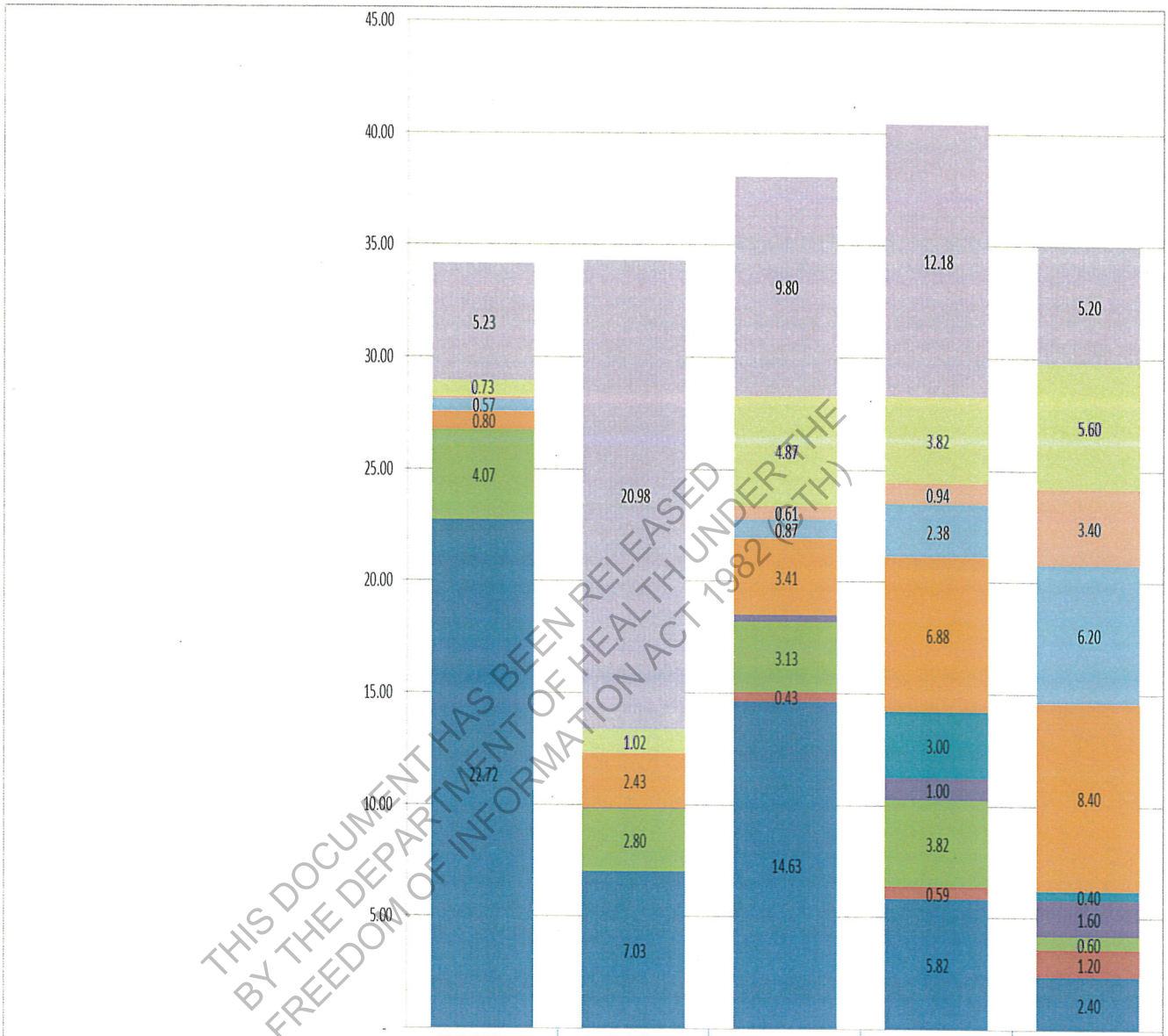
	Medical Officer 2	Medical Officer 3	Medical Officer 4	Medical Officer 5	Medical Officer 6
Other	15.3%	61.1%	25.8%	30.1%	14.9%
Providing clinical advice to other departmental staff on program/policy areas	2.1%	3.0%	12.8%	9.5%	16.0%
Other engagement with external medical bodies (Colleges AMA etc)	0.2%	0.2%	1.6%	2.3%	9.7%
Leading or participating in external stakeholder committees	1.7%	0.0%	2.3%	5.9%	17.7%
Preparation of policy advice and documents	2.3%	7.1%	9.0%	17.0%	24.0%
Special funding assessment (LSD and MTOP programs)	0.0%	0.0%	0.0%	7.4%	1.1%
MBS review	0.0%	0.0%	0.8%	2.5%	4.6%
Delegated approval processes (eg: TGA special access schemes)	11.9%	8.1%	8.2%	9.5%	1.7%
Health technology assessments for funding purposes (PBAC, MSAC)	0.0%	0.0%	1.1%	1.5%	3.4%
Assessment of agents or devices for registration	66.5%	20.5%	38.4%	14.4%	6.9%
Medical Officer FTE	**10.7 FTE**	**20.73 FTE**	**21.39 FTE**	**17.07 FTE**	**5.32 FTE**

Function breakdown by classification – average number of hours per week



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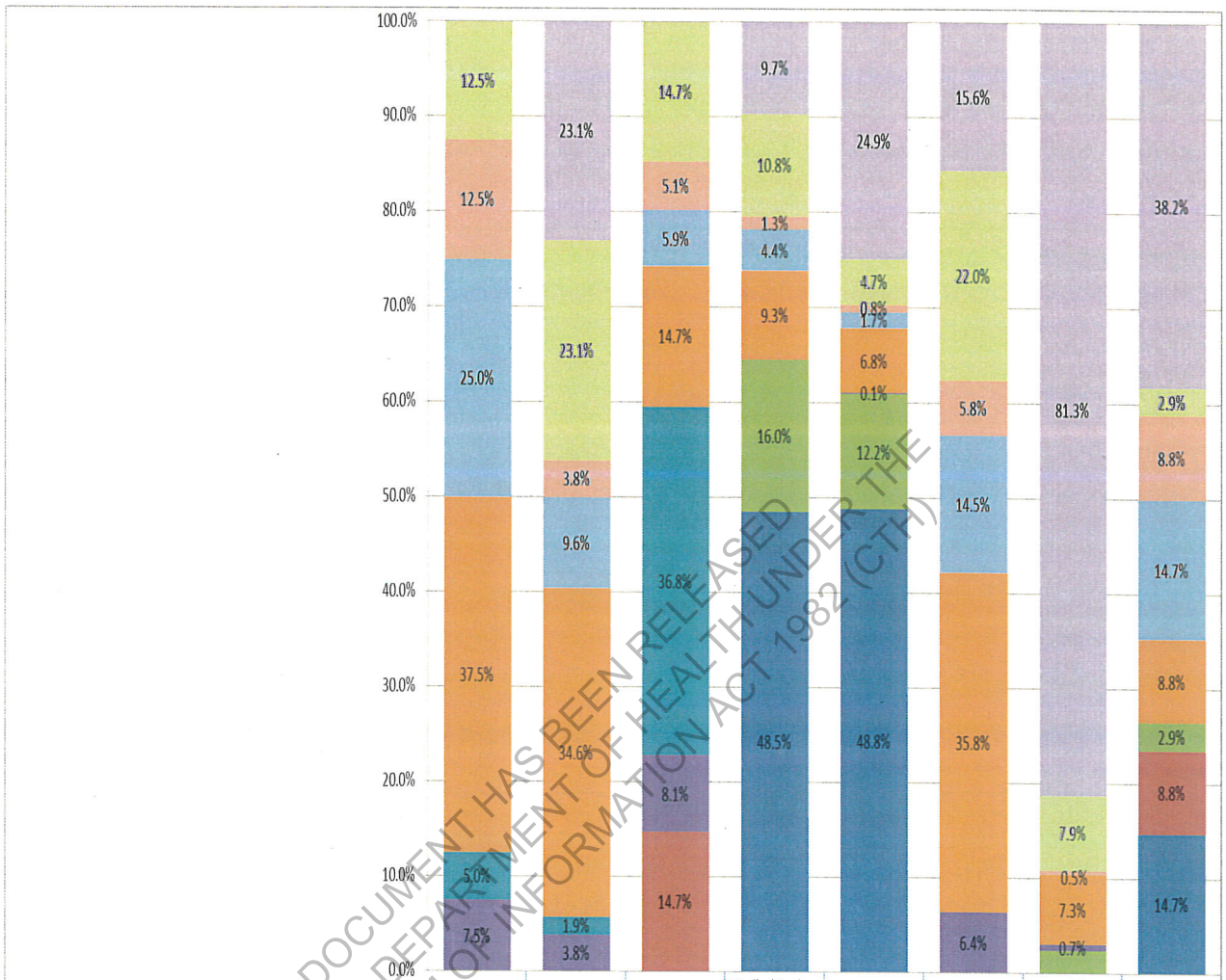
	Medical Officer 2	Medical Officer 3	Medical Officer 4	Medical Officer 5	Medical Officer 6
Other	5.23	20.98	9.80	12.18	5.20
Providing clinical advice to other departmental staff on program/policy areas	0.73	1.02	4.87	3.82	5.60
Other engagement with external medical bodies (Colleges AMA etc)	0.07	0.06	0.61	0.94	3.40
Leading or participating in external stakeholder committees	0.57	-	0.87	2.38	6.20
Preparation of policy advice and documents	0.80	2.43	3.41	6.88	8.40
Special funding assessment (LSD and MTOP programs)	-	-	-	3.00	0.40
MBS review	-	0.01	0.30	1.00	1.60
Delegated approval processes (eg: TGA special access schemes)	4.07	2.80	3.13	3.82	0.60
Health technology assessments for funding purposes (PBAC, MSAC)	-	-	0.43	0.59	1.20
Assessment of agents or devices for registration	22.72	7.03	14.63	5.82	2.40

Includes Part-time staff

Function breakdown by division – % of total time



	Health Services DIV	Health Workforce DIV	Medical Benefits DIV	Medical Devices Product Quality DIV	Medicines Regulation DIV	Office of Health Protection DIV	Provider Benefits Integrity DIV	TGA Executive DIV
Other	0.0%	23.1%	0.0%	9.7%	24.9%	15.6%	81.3%	38.2%
Providing clinical advice to other departmental staff on program/policy areas	12.5%	23.1%	14.7%	10.8%	4.7%	22.0%	7.9%	2.9%
Other engagement with external medical bodies (Colleges AMA etc)	12.5%	3.8%	5.1%	1.3%	0.8%	5.8%	0.5%	8.8%
Leading or participating in external stakeholder committees	25.0%	9.6%	5.9%	4.4%	1.7%	14.5%	0.0%	14.7%
Preparation of policy advice and documents	37.5%	34.6%	14.7%	9.3%	6.8%	35.8%	7.3%	8.8%
Special funding assessment (LSD and MTOP programs)	5.0%	1.9%	36.8%	0.0%	0.0%	0.0%	0.0%	0.0%
MBS review	7.5%	3.8%	8.1%	0.0%	0.1%	6.4%	0.7%	0.0%
Delegated approval processes (eg: TGA special access schemes)	0.0%	0.0%	0.0%	16.0%	12.2%	0.0%	2.4%	2.9%
Health technology assessments for funding purposes (PBAC, MSAC)	0.0%	0.0%	14.7%	0.0%	0.0%	0.0%	0.0%	8.8%
Assessment of agents or devices for registration	0.0%	0.0%	0.0%	48.5%	48.8%	0.0%	0.0%	14.7%
Medical Officer FTE	1.0 FTE	1.32 FTE	2.0 FTE	8.9 FTE	40.6 FTE	3.1 FTE	14.2 FTE	1.0 FTE

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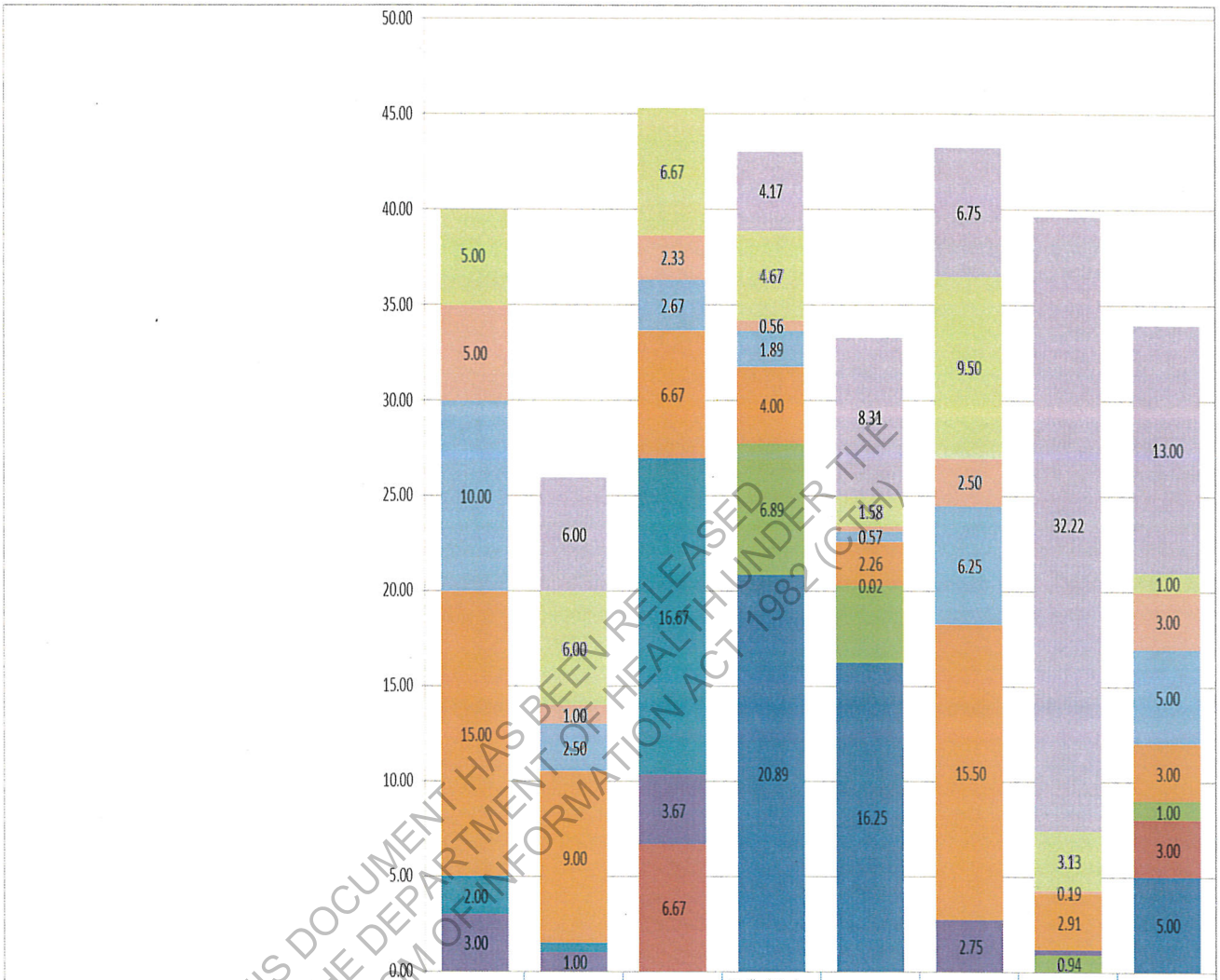
Function breakdown by division – average number of hours per week



	Health Services DIV	Health Workforce DIV	Medical Benefits DIV	Medical Devices Product Quality DIV	Medicines Regulation DIV	Office of Health Protection DIV	Provider Benefits Integrity DIV	TGA Executive DIV
Other	-	6.00	-	4.17	8.31	6.75	32.22	13.00
Providing clinical advice to other departmental staff on program/policy areas	5.00	6.00	6.67	4.67	1.58	9.50	3.13	1.00
Other engagement with external medical bodies (Colleges AMA etc)	5.00	1.00	2.33	0.56	0.26	2.50	0.19	3.00
Leading or participating in external stakeholder committees	10.00	2.50	2.67	1.89	0.57	6.25	-	5.00
Preparation of policy advice and documents	15.00	9.00	6.67	4.00	2.26	15.50	2.91	3.00
Special funding assessment (LSD and MTOP programs)	2.00	0.50	16.67	-	-	-	-	-
MBS review	3.00	1.00	3.67	-	0.02	2.75	0.27	-
Delegated approval processes (eg: TGA special access schemes)	-	-	-	6.89	4.06	-	0.94	1.00
Health technology assessments for funding purposes (PBAC, MSAC)	-	-	6.67	-	-	-	-	3.00
Assessment of agents or devices for registration	-	-	-	20.89	16.25	-	-	5.00

Includes Part-time staff

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FOI 2192
DOCUMENT 1

List of other functions by division

Other functions include:

- Meetings
- Providing advice
- Administrative tasks
- General management
- Clinical advice
- Clinical practice
- Supervision of staff
- Reviewing new processes
- Self-directed learning
- Compliance work including being the delegate
- Legal, Federal court matters
- Media briefing
- Travel
- Preparation for talks

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Response to the Recommendations of the Hillis review of Medical Officers in the Department of Health

1 Feb 2018

Recommendation One: The Chief Medical Officer and Senior Executive consider how negative variance comments from the survey and interviews can be further addressed within the Department, in the context of the People Strategy.

Supported.
The Department will continue to focus on managing workforce composition, building capability, improving culture and leadership, and investing in career and succession for MOs. A number of preliminary actions that align with the priorities in the People Strategy have been identified elsewhere in this response. These include promoting leadership training aimed at technical and specialist leaders and focusing on the performance conversation process to encourage clarity of performance criteria and better involvement and communication with management.

The Department acknowledges that there is a need in particular to look at staff and mission alignment issues in the Medical Devices Branch. This is currently underway. The CMO has had discussions with People, Communication and Parliamentary Division (PCPD) and Division Heads to identify any other specific areas of concern.

Recommendation Two: The CMO and SES in the Divisions, other than in Health Products Regulation, should examine the allocation of Medical Officer workload to the various policy and program areas, with a focus on the supporting the MBS review, indigenous health, aged care, primary care reform and meeting the reform objectives of the provider compliance division.

Supported.
This is currently underway, particularly in the policy areas of the Department, with several potential realignments of roles under consideration. A primary care MO group is being created to provide a broad group of potential views on primary care issues. Provider compliance MO group will need to expand to meet the budget objectives but at the same time it is agreed that the operational model will need revision.

Recommendation Three: That Medical Officers remain embedded within a primary area of the Department, but with a broader involvement in 'cross department' initiatives, which is defined through an agreed accountability framework and workplan for each Medical Officer. Medical Officer accountability should ideally be to a Senior Medical Officer (directly or via a dual accountability) or to a Divisional Head, but with a clear set of responsibilities and tasks beyond that Division (if appropriate). Movement including rotation of Medical Officers from TGA to other parts of the Department of Health need to consider the funding complexities / cost recovery models in which TGA undertakes its work.

Supported with some caveats.
Individual work plans are being created for all MOs in the policy areas of the Department. Provider compliance has well defined work programs and KPIs which are under review and readily tracked. In the TGA, all MOs already have a clear accountability framework and work plan but a review of these will be required as the need for MO involvement in wider roles is reconsidered.

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There is general support for a program of rotation, particularly of junior MOs, but this will need detailed planning and piloting. In the meantime, it is proposed to create some policy review groupings to better utilise the expertise of the MO group. The primary care/GP group is being created from amongst all Divisions and will be used to provide broad input into policy and also monitor program delivery in the field.

Recommendation Four: The Department more clearly articulates and acknowledges the generic and specific skills for Medical Officers at different levels of seniority. The Department critically reviews designated Medical Officer tasks to determine whether some could be performed by other staff with generic or alternative specific professional backgrounds.

Supported.
Significant work in the area of "what tasks require MO involvement" has already been done and is being done in TGA. The potential of increasing pharmacist and scientist involvement to cope with growth in demand is being explored, whilst noting that international benchmarking suggests that there are a similar percentage of MO staff in TGA with other like regulatory authorities.

In provider compliance, a reform program is looking at what staffing configuration could release as much MO time as possible to conduct the interactions with providers (as opposed to preparatory data analysis). This will be particularly important in the significant expansion of provider compliance activity.

The CMO is meeting each of the MOs in the policy areas to better understand the value proposition of MO involvement and the best use of skills and experience.

Recommendation Five: The Department develops a stronger understanding, and potentially a register, of the broad experience and expertise of its Medical Officers and utilise these skills, where appropriate, in policy development, program delivery and reform initiatives.

Supported.
A register of qualifications and skills will be established and will guide future MO mobility and involvement in the future.

Recommendation Six: The Department considers formal linkages with a University to develop an appropriately scoped Masters of Public Health, especially for junior doctors. The Department investigates the feasibility of a rotational training program for MO2, MO3, and MO4 to enable more appropriate experience in policy development, regulatory science and health innovation. Such a rotation program would need to take account of operational requirements and in the case of the TGA, the special account funding of staff.

Supported in part.
There have been public health training programs operating in the Department in the past and the feasibility of re-establishing this will be explored. Developing a bespoke qualification is unlikely to be feasible or affordable. A stronger relationship with the Faculty of Public Health Medicine of RACP and Universities (for academic affiliations etc.) will also be explored with an initial approach already made to ANU.

A formal program of rotation is a complex proposition and will require more detailed consideration. Some realignment of roles will occur directly out of this review.

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Recommendation Seven: The Department formally compares remuneration packages between Medical Officers in the Commonwealth Department and those in other jurisdictions and notes the importance of access to external private practice both to retain and to continue clinical medicine exposure for Medical Officers.

Supported:
PCCD will undertake a comparison of remuneration packages in the Department compared to ACT Health and NSW Health, and with senior medical officers in the pharmaceutical and medical device industry. The Executive supports the continuation of limited external private practice arrangements both for retention reasons and to maintain clinical currency.

Recommendation Eight: The Department considers converting the PDA to 'salary' or investigates an alternative streamlined process appropriate for this limited funding.

Supported in part.
There are differing views on the administrative complexity of the current PDA approval and it would appear that there may not be a consistent process across different areas. In the first instance, this will be investigated by PCPD and a common, low burden approval process rolled out. There are mixed views about rolling the PDA into salary. There is a risk that MOs may stop doing some CME activities. This matter needs further discussion with the MO group and SES and any changes need to be considered during bargaining for the next Enterprise Agreement

Recommendation Nine: A review of the seniority of Medical Officers is undertaken to ensure that current roles, expertise and qualifications are appropriately reflected in the classifications.

Supported in part.
The key determinant for job classification in the APS is the work value of a job (nature, impact and accountabilities). Academic qualifications are a less relevant factor (for example there are junior APS staff with PhD qualifications). It is, however, important to examine the job size and spans of control issues for the MO group and this will be undertaken by PCPD through job design activities. This will include reviewing MO job descriptions and selection criteria to establish acceptable roles and responsibilities, better articulate core capabilities (technical and leadership accountabilities) and communicate differences between classifications.

Recommendation Ten: If an employee is not registered by AHPRA then their employment at a Medical Officer grade should be reviewed.

Supported in part.
Unregistered medical practitioners have only been employed within the TGA and would not be contemplated for roles within other parts of the Department. They have been used in the TGA as clinical evaluators where it is believed that their medical qualifications and experience are sufficiently comparable to registered medical practitioners for the purpose of the evaluation role that they are undertaking. TGA has also struggled to recruit Australian-registered MOs in an environment of growing workloads and with the specialised nature of the work. A counter argument is that those who are ineligible or unable to obtain registration may not have the breadth of medical cognitive experience for all circumstances. Part of the justification for the higher MO salary grade is also the need to attract practitioners who could otherwise earn clinical practice incomes externally as medical practitioners.

Recommendation Eleven: As a matter of some urgency work needs to be done in Medical Devices to determine:

- **The appropriate strategy for obtaining external reviews**

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- **The role of Medical Officers in the evaluation or the approval of the external reviews**
- **The appropriate balance between pre-market evaluation and post-market surveillance**
- **An appropriate reporting arrangement for the Medical Officers, reflecting a revised and higher level role in evaluation. The MO5 could work significantly more in partnership with the Division head (as in medicines regulation) in managing the Division.**

Supported and underway.
The Department has commissioned A/Prof Hillis to work with the medical devices MOs and the relevant SES officers to develop a more aligned approach to risk, in alignment with broader changes to business processes and career development for that team. This work will help determine the appropriate use of device assessments by external regulators and commercial bodies, the involvement of MOs in this process, the appropriate number and balance of MO numbers in pre-market evaluation and post-market monitoring, and MO reporting arrangements. It is expected that this work will be completed by end March 2018.

Recommendation Twelve: Medicines Regulation review its approach to low risk applications and consider whether Clinical Pharmacists could undertake these reviews under delegation or utilise external evaluation teams.

Supported.
The review notes the impact of the changes resulting from the MMDR and that the workload of the MO cohort in Medicines Regulation is "significant and increasing" with these reforms. The example is given of 14 priority review requests for new medicines in last four months.

Pharmacists and scientists already play a significant role in lower-risk medicine reviews, and we are exploring increasing this role where we can find suitable candidates. But given that the major growth in workloads is in complex, high-risk new medicines, a substantial cohort of medically-trained delegates and senior reviewers will continue to be needed.

Recommendation Thirteen: The Special Access Scheme be reviewed to significantly increase the drugs able to be classified as 'Class C' and the routine use of Clinical Pharmacists in providing the evaluation for the Scheme overall. This has already commenced.

Supported.
The Special Access Scheme (SAS) class C Category was only introduced on 1 July 2017. In September 2017 further medicines were added to the classification. A review is currently underway to increase the number of products on the scheme, and an additional list will be published in late February 2018. In parallel, more SAS B medicine evaluations are now being performed by pharmacists, with a decrease in about 1.0 FTE requirement for medical officer involvement.

Recommendation Fourteen: TGA limits its telephone support to documentation of adverse events. Clinical Support and Counselling should be provided by the individual's usual medical practitioner or a recognised and approved telephone based Counselling service. This has already commenced.

Supported and implemented.
The Executive of the Department, and of the Health Products Regulation Group was unaware that this was happening, and agrees that it is not an appropriate role. The practice has ceased.

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Incoming calls are now triaged and callers referred to their usual medical practitioner or the NPS help line which is funded for this purpose.

Recommendation Fifteen: Following the implementation of the Sansom Review, that the separation / integration of pre-market evaluation and post-market evaluation be reviewed.

Further discussion needed.
The medicines pre-and post-market organisational structures have already been changed after the implementation of the Sansom review and structural change was implemented in July 2016. There has been further fine-tuning of roles with the implementation of medicines priority review in late 2017 and in anticipation of medicine provisional approvals from early 2018.

There is the need to appropriately resource medical officer leadership in medical devices pre- and post-market evaluation. Currently there is not functional separation between pre-and post-market roles, which is not best practice. Post-market evaluation is an area of high risk for the department and government, noting that there has been a series of Parliamentary Inquiries in recent years..

Recommendation Sixteen: The 'peer counselling' process within the Provider Benefits Integrity Division be substantially reviewed to increase routine monitoring of billing practices being made available to Medicare Providers, use of artificial intelligence, streamlined interviews of providers by Medical and Non-medical staff. The Department should review the risks of unaccompanied site visits to practitioners and explore the greater use of telephone based counselling interviews to improve efficiency. The Department should explore strategies to retain and motivate this crucial group of Medical Officers, such as involvement in policy work or primary care health reform.

Supported.
All of these initiatives are currently under consideration or underway in the Division.

Recommendation Seventeen: Policy development and advocacy skills should be enhanced by rotations from across all the department into the appropriate policy area.

Supported.
See response to recommendation 6 above

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