PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT

Inquiry into Administration of Commonwealth Regulations

22 November 2024

PDR Number: IQ24-000208

Compliance priorities for the regulation of therapeutic goods

Written

Chair: Linda Burney

Question:

1. The ANAO found that while Health had established a risk-based strategic approach to the management of noncompliance, compliance plans and procedures, necessary to operationalise compliance activity, were out of date or in draft form.[1]
a. What are the 2024–25 compliance priorities for the regulation of therapeutic goods?
b. Has the department completed compliance plans for each of these priorities?
c. Have the remaining aspects of the compliance case workflow, specifically, the detailed workflows for stages of the process, and the standard operating procedures for individual tasks, been finalised?

Answer:

1a. The Therapeutic Goods Administration's (TGA) 2024-25 advertising, import and some supply compliance priorities[1] relate to:

- nicotine vaping products- all offence types
- unlawful advertising of medicinal cannabis, psilocybin and MDMA
- unlawful advertising and import of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries, including those intended to alter the body's performance and appearance
- unlawful import of substandard and falsified therapeutic goods with a particular focus on products that declare, or are otherwise suspected to contain, higher risk substances that pose a risk to human health or safety

[1] https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-25

- unlawful import, advertising and supply of medicines and medical devices advertised as traditional or alternative treatments, particularly those that contain substances that pose a risk to human health or safety.

b. There are Compliance Plans for each of the compliance priorities. These plans are living documents and are updated as matters progress, and as new information and findings are obtained.

c. The Health Products Regulation Group (HPRG) regulatory compliance area has finalised and implemented recommendation 2 of the ANAO audit, which required written investigation procedures for compliance investigations. Endorsement has been obtained from the Department of Health and Aged Care's Audit and Risk Committee for closure of this recommendation.

The HPRG regulatory compliance area's Internal Document Control Policy (IDCP) includes a requirement for a review of all investigation procedures every 6 months. This periodic review will enable alignment of process workflows with current priorities and focus areas for compliance and investigative work whilst ensuring regulation best practice.

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PDR Number: IQ24-000209

Compliance strategy concerns

Written

Chair: Linda Burney

Question:

2. The audit found procedures and arrangements that underpin Health's compliance strategy are at a low level of maturity.

How has Health strengthened its business and risk planning, as it relates to regulating therapeutic goods, to include information on how it will operate within Health's stated tolerance levels for regulatory activities?

Answer:

2. The Health Products Regulation Group (HPRG) Regulatory Practice and Support Division (RPSD) compliance area reviews its business and risk plan annually, in line with broader departmental process.

The RPSD 2024-25 business and risk plan details core priority areas surrounding regulation of therapeutic goods, and a detailed risk management plan to assist in management of risks that may prevent us from achieving those priorities. All risks include an associated risk rating and details of whether they fall within the Department of Health and Aged Care's risk tolerance levels.

This business and risk plan can be amended with updates at any time, should emerging or increasing risks be identified.

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PDR Number: IQ24-000210

Regulation of therapeutic goods annual review

Written

Chair: Linda Burney

Question:

3. The ANAO recommended the reported performance information for the regulation of therapeutic goods be reviewed annually to ensure it was appropriate and covered the significant components of Health's key activities. Health agreed.

a. Can you update the Committee on this work, including how Health will report on its key regulatory activities and the performance measures for this.
b. Does Health have a performance measure related to managing compliance? What is the nature of this measure?
c. What are the targets or benchmarks for Health's performance measures and how do they inform the requirement to engage in continuous self-improvement?

Answer:

3a. The Department of Health and Aged Care reviews and, where necessary, updates program performance reporting annually as part of performance planning. Following the 2023-24 Annual Performance Statement audit, the department is implementing a revised procedure to guide 2025-26 program performance planning. Program 1.8 Health Protection, Emergency Response and Regulation, which includes the Therapeutic Goods Administration, is working with Assurance Branch to implement the revised procedure and respond to the Recommendations from the ANAO on both the Performance and Annual Performance Statement audits. The department will report on its key regulatory activities through updated performance measures in the 2025-26 Annual Report, as required by RMG-128.

b. Updated performance measures related to managing compliance will be available in the 2025-26 Portfolio Budget Statements as part of the 2025-26 performance planning for Program 1.8.

c. Targets and benchmarks for performance measures are reviewed annually and updated as appropriate. A change for 2025-26 performance planning is the introduction of a key that defines performance thresholds relative to targets or benchmarks (achieved, substantially achieved, or partially achieved), and the rationale for why those thresholds have been chosen.

As performance planning for 2025-26 is currently underway, both the performance measures and their associated targets or benchmarks are yet to be set. Continuous improvement is one of the factors considered when reviewing and updating performance measure targets or benchmarks.

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Department of Health and Aged Care

JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT

Inquiry into Administration of Commonwealth Regulations

22 November 2024

PDR Number: IQ24-000211

Standard operating procedures for monitoring therapeutic goods advertising on digital platforms

Written

Chair: Linda Burney

Question:

4. In 2022–23, Health proactively requested the removal of almost 14,000 advertisements and pieces of content on digital platforms. Requests for removal have increased significantly, from 569 in 2020-21. The standard operating procedures for this work remained in draft form as at March 2023.

a. Has Health finalised the standard operating procedures for monitoring therapeutic goods advertising on digital platforms?

b. How comprehensive is Health's proactive scanning of digital platforms?

c. What is the reason for the significant increase in requests, for instance, does it reflect increasing amounts of unlawful behaviour, repeat noncompliance, greater intelligence and monitoring, and/or a failure of Health's education strategy?

d. Has Health updated its education strategy to reflect current compliance priorities, including for import and supply, not just advertising? If so, how?

Answer:

4a. The Health Products Regulation Group (HPRG) regulatory compliance area has completed implementation of recommendation 2of the ANAO audit and obtained endorsement from the Department of Heath and Aged Care's Audit and Risk Committee for closure. This means that all required written investigation procedures for compliance investigations have been finalised and implemented, including for digital platforms.

b. The HPRG regulatory compliance area addresses community concerns expressed in reports made to us, while also proactively monitoring digital platforms to identify potential non-compliant advertising of therapeutic goods. We work closely with digital platforms- such as Meta, TikTok and Amazon- to deter and address advertising of unapproved therapeutic goods.

Our proactive scans focus on our Import, Advertising and Supply Compliance Priorities[1], in addition to emerging issues of concern.

When alleged unlawful advertisements on social media or other platforms are identified or brought to our attention, we work closely with the identified platform who action within their user policies.

In late 2023 the TGA also established a framework to support website disruption requests for websites unlawfully advertising therapeutic goods. When identified, the TGA can request internet service providers (ISPs) block specific websites containing unlawful information under Section 313(3) of the *Telecommunications Act 1997*[2]. From the implementation of the framework in late 2023 to November 2024, ISPs have assisted in redirecting over 120 domains via a disruption request.

The HPRG regulatory compliance area also has regular discussions with digital platform companies to discuss the rules for advertising therapeutic goods and to help enhance their monitoring systems and to improve their content filters.

c. The volume of requests sent to digital platforms to remove content vary for a combination of reasons:

- an increase in volume of removal requests can be due to the degree and type of attention given to the sector, resulting from both community reports and proactive monitoring by the TGA
- a decrease in removal requests may be following a targeted education campaign or activity aligned to our Advertising and Compliance Education Plan.

Historically, the HPRG regulatory compliance area would engage with advertisers using more resource-intensive approaches, such as formalised compliance correspondence and investigations. However, we are now able to address identified non-compliance in a more direct manner by requesting action by platforms under their terms of service or similar mechanisms.

We also work with sectors to promote compliance on digital platforms. For example, extensive guidance has been published on complying with advertising rules, including social media advertising and an education campaign targeting content creators.

d. The HPRG regulatory compliance area is currently updating the *Therapeutic goods import, advertising and supply compliance education strategy*. This strategy will align to the TGA's Import, Advertising and Supply Compliance Priorities 2023-25.

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[1] https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-25

[2] s313(3) requires that carriers and carriage service providers give officers and authorities of the Commonwealth, states and territories such help as is reasonably necessary to enforce the criminal law and laws imposing pecuniary penalties - TELECOMMUNICATIONS ACT 1997 - SECT 313 Obligations of carriers and carriage service providers (austlii.edu.au)

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JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT

Inquiry into Administration of Commonwealth Regulations

22 November 2024

PDR Number: IQ24-000212

Review and update of the investigation procedures

Written

Chair: Linda Burney

Question:

5. The audit found Health's investigation policies and procedures were not mature and did not fully comply with the Australian Government Investigations Standards (AGIS).

a. The audit recommended Health finalise its investigation procedures and ensure their alignment with AGIS, and establish an internal control for the regular review and update of the investigation procedures. How has Health progressed with implementing this recommendation?

b. What proportion of TGA investigators currently have a relevant qualification?[9]

c. Have all officials involved in investigations and compliance activities made declarations of interest?[10]

d. Health agreed to develop an Investigations Quality Assurance Policy, as required by AGIS. How has Health progressed this matter?

Answer:

5a. The Health Products Regulation Group (HPRG) regulatory compliance area has completed implementation of recommendation two of the ANAO audit and obtained endorsement from the Department of Health and Aged Care's (the Department) Audit and Risk Committee (ARC) for closure. This means that all required written investigation procedures for compliance investigations have been finalised and implemented.

In addition, a supporting Internal Document Control Policy (IDCP) has been implemented by the HPRG regulatory compliance area to ensure a consistent approach to preparing, reviewing, approving, maintaining and accessing policies and procedures. The IDCP includes a requirement for review of all investigation procedures every 6 months.

b. As of 25 November 2024, all relevant regulatory compliance staff within the HPRG regulatory compliance area have obtained relevant qualifications, are working towards completion, or are being enrolled to obtain relevant qualifications within required timeframes.

c. As of 25 November 2024, all relevant staff within the HPRG regulatory compliance area have completed a declaration of interest, noting that new staff and staff on extended leave have one month from commencement/re-commencement with the Department to complete their declaration.

All HPRG regulatory compliance area staff are informed of their obligations and a regular review of declaration of interest is occurring to ensure continued compliance with this obligation.

d. Recommendation 6 to develop a comprehensive Quality Assurance Framework (QA Framework) has been established and implemented by the HPRG regulatory compliance area, and closure endorsed by the Department's ARC.

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Inquiry into Administration of Commonwealth Regulations

22 November 2024

PDR Number: IQ24-000213

Improvements in record keeping

Written

Chair: Linda Burney

Question:

6. During the audit, the ANAO commented on deficiencies in recordkeeping. What actions has Health taken to improve recordkeeping, especially in the case management systems?

Answer:

6. The Health Products Regulation Group (HPRG) regulatory compliance area has taken several actions to improve record keeping in response to the ANAO's recommendations and final report. All related recommendations are now complete and endorsed by the Department of Health and Aged Care's (the Department) Audit and Risk Committee for closure.

To support comprehensive record keeping practices, the HPRG regulatory compliance area established an Internal Document Control System (IDCS). The IDCS provides step by step instructions and guidance on how master documents such as policies and procedures must be prepared, reviewed, approved, distributed, maintained and managed for regulatory compliance teams.

All staff within the Department are required to complete mandatory Record Keeping training modules each year to ensure they are adhering to record keeping requirements. All HPRG regulatory compliance staff are currently up to date in this mandatory training, with any new starters on track for completion within required timeframes.

Decision record keeping has also been improved within the HPRG regulatory compliance area, with a Case Management Committee (CMC) established to ensure best practice decision-making and associated documentation systems are in place. The CMC is focused on documented evidence-based decision-making for critical decisions and the prioritisation and allocation of resources for case treatment.

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22 November 2024

PDR Number: IQ24-000227

Melatonin dosage overseas versus Australia

Spoken

Senator: Linda Burney

Question:

CHAIR: This may not be a relevant question, and maybe it's not your role, but I'm really interested in what you're saying. I've just come back from an extended stay in America, and it seems to me that you can just walk into a pharmacy and buy a loaf of bread, beer or something to make you feel better. One thing was very noticeable. In Australia, the highest strength you can get for melatonin is two milligrams, whereas in the United States, you can get up to 25 milligrams. I'm sure people order melatonin from America. Does that fall within your bailiwick or not?
Ms Lutton: It does but it doesn't. I'm happy to also take it on notice and provide you a more fulsome response for the areas I can't answer. In regard to the supply or the milligrams available in Australia, that's not my remit. I'm very happy to pass that on. Consumers can import unapproved therapeutic goods, internationally, under the Personal Importation Scheme. What they need with that is a valid script from an Australian registered health professional.
We work closely with Border Force, who obviously may pick something up coming through any of those channels. They will work with us to ensure there is a valid script accompanying that.
CHAIR: I see.

Answer:

Scheduling of Melatonin

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules in the Poisons Standard according to the risk of harm and the level of access control required to protect public health and safety.

The implementation of the Poisons Standard, as it affects access to and supply of medicines and chemicals, is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.

Currently, a pharmacist may supply melatonin over the counter as a Pharmacist only medicine (Schedule 3) where it is in the form of:

- modified release tablets containing 2 mg or less of melatonin for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over, in packs containing not more than 30 tablets
- immediate release preparations containing 5 mg or less of melatonin for the treatment of jet lag in adults 18 years and over, in a primary pack containing no more than 10 dosage units.

All other uses of melatonin must be supplied as a Prescription only medicine (Schedule 4).

Melatonin was first scheduled as a Pharmacist only medicine (Schedule 3) following a final decision made by the TGA in September 2020. This allowed consumers to access modified-release melatonin tablets for the treatment of insomnia with restrictions with respect to age and pack size. The maximum dose of 2 mg was based on that proposed in the application to amend the Poisons Standard. The limit was also in harmonisation with the scheduling of melatonin in New Zealand. This decision aimed to enable consumers, especially older people, to access medicine with a better safety profile compared to existing over-the-counter treatment options for insomnia.

Since 1 June 2023, adult consumers have been able to access melatonin for jetlag as a Pharmacist only medicine (Schedule 3). The decision was made on the basis that the entry for melatonin immediate-release preparations is consistent with the Australian Therapeutic Guidelines for the treatment of jet lag. The maximum dose of 5 mg is also consistent with the therapeutic guidelines in the United Kingdom.

<u>Importation of Melatonin</u>

The TGA always encourages the use of medicines which have been approved for supply in Australia. A number of registered medicines containing melatonin are included in the Australian Register of Therapeutic Goods (ARTG), with a variety of strengths and for various indications.

However, consumers can access unapproved therapeutic goods, including melatonin at higher dosages than the products approved for use in Australia, where their medical practitioner finds them to be clinically suitable. This access is available via the Personal Importation (PI) Scheme, if certain conditions are met.

- Consumers can import up to 3-month supply of most unregistered medicines for their use, or the use of immediate family.
- If the product is a Schedule 4 prescription, the import would need to be supported by an Australian registered medical practitioner who has provided a written authority- usually a prescription.

The decision to treat a patient with an ‘unapproved’ therapeutic good is a clinical decision made at the discretion of the prescribing practitioner, as they assume all medico-legal responsibility for endorsing supply of unapproved therapeutic good to their patient.

The TGA advises caution before importing unapproved medicines into Australia for personal use, as it does not evaluate unapproved medicines for quality, safety and efficacy, including when imported via the Personal Importation Scheme. Products the TGA does not regulate may not meet Australian manufacturing quality standards and could be fake, or contain undisclosed harmful ingredients.