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MEDICINES SCHEDULING AND SCHEDULING POLICY *AD HOC* WORKING GROUP MEETING

Meeting Two – 6 March 2018

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Health Products Regulation Group, Department of Health

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Objectives for today's meeting - discuss

- The **mandatory statement(s) and requirements for advertisements for Schedule 3 (Pharmacist only) medicines**
- Requirements in the context of the **revised Therapeutic Goods Advertising Code**, to commence on July 1 2018 following public consultation
- Approaches to the **proactive review of Schedule 4 substances** (prescription only medicines) for rescheduling consideration
- The approach to the **newly created "Appendix M"** in the Scheduling Policy Framework

Reforms to the advertising of S3 pharmacist only medicines

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Therapeutic Goods advertising reforms

- Specific requirements for advertising of prescription-only medicines are a subset of those in the **Therapeutic Goods Advertising Code**
- **New Code** to be live from 1 July 2018
- **Needs to be finalised** in May to give all stakeholders certainty
- **Targeted consultations** have been underway late Feb-early March
- **Public consultations** on code planned (late March – through April)
- **Presentation on the current draft code** now from Mick O'Connor

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Where did we get to last meeting

1. Advertising is subjective
2. It is very challenging to be highly prescriptive regarding specific requirements due to the variety of advertising media to be covered
3. Everyone takes different messages from advertisements; need to keep the mandatory requirements simple to increase the chance of getting the message across
4. Some questioned whether the current requirements needed much change.
5. There was a view that they could be improved - with an emphasis on ensuring the role of the pharmacist in being the decision-maker as to whether a particular S3 product is appropriate is made clear to the consumer.

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Where did we get to last meeting

Current general advertisement requirements are generally considered adequate. These are that an advertisement for a therapeutic good cannot:

- Arouse unwarranted and unrealistic expectations of effectiveness
- Lead to consumers self-diagnosing or inappropriately treating potentially serious diseases
- Mislead, abuse trust or exploit lack of knowledge of consumers
- Lead people to believe they are suffering from a serious ailment
- Suggest that harm may result from the product not being used
- Encourage inappropriate or excessive use
- Claim that it is effective in all cases, safe or have no side-effects
- Be directed to minors
- Be endorsed by government, hospitals or individual healthcare professionals

These will be revised, and made less subjective, in the new Code.

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Consensus

- If possible, there should only be one mandatory statement in advertisements for S3 substances that include elements of both

  "Your pharmacist must decide if this product is suitable for you"

  "Ask your pharmacist about side effects relevant to you"
- The mandatory statement should reflect the need for pharmacist interaction and decision to supply
- Minimum requirements for prominence/clearly communicated should be specified, and be applicable to all advertising styles.
- The advertising code will need to balance the need for flexibility across a range of media with clarity and specificity in guidance to the advertiser
  - especially given that mandatory advertising pre-approvals will be removed in 2 years' time.

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There were a range of views

- Regarding the **mention of side effects in advertisements**, including:
  - Listing side effects may cause undue concern among consumers
  - Not listing side effects may result in consumers believing there are no side effects or risks associated with the medicine
  - If there are numerous side effects, it would be impractical to list them all in an advertisements
  - If only selected side effects should be included in advertisements, how should they be selected? This may also result in some consumers assuming there are no side effects relevant to them.
  - Since the emphasis elsewhere on the role of the pharmacist, they are best placed to discuss potential side effects with consumers
- Need for a general awareness campaign for consumers of the **role of pharmacists with Schedule 3 medicines** to be run in parallel with changes to their advertising

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Communicating side effects

Proposal for discussion today (and possibly in the public consultation paper):

1. TGA to conduct an information campaign regarding side effects of OTC medicines
   - At the time of S3 advertising changes, these will be emphasised in the campaign
   - Will work with Pharmacy Guild, PSA and ASMI to encourage them to run similar campaigns
2. It will be mandatories for S3 advertisements will emphasise the role of pharmacist.
3. We need to see what the prevailing view today - is on whether
   - Requiring - major side-effects to be mentioned/ listed in advertisements for S3 medicines
     OR
   - Voluntary - Sponsors can chose to list side effects, these will be subject to the requirements to be clear and easily understood

Mandatory statements in advertisements

1. *Following consultation, your pharmacist will decide if this product is right for you*
2. *Talk to your pharmacist, they will decide if this product is right for you*

- Feedback on these statements was also divided
- Some preferred “consultation” as it conveys interaction with a professional
- Conversely, “talk to” is plainer English, is simpler and more readily understood
- Could strengthen the second statement to “You must talk to your pharmacist…”

Discussion - How do we go forward?

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Requirements for the mandatory statement

The following statement is to be "clearly communicated" wherever a Schedule 3 substance is advertised.

Clearly communicated implies that the statement is easily read or heard and understood.

- Feedback from the homework was that this approach is could be acceptable.
- Suggestions were also provided for including requirements for both spoken and written presentation in audio-visual advertisements to ensure it is accessible
- Also proposed that the mandatory statement should stand out from other messages in advertisement

Proposal – include the requirement as presented above. The effectiveness of this will be assessed as part of the review of advertisements, and also during the pre-approval process which will be continuing until 30 June 2020.

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Existing "Factors for the Delegate for deciding if a substance should not be advertised"

- The potential impact on public health (positive and negative)
- The likelihood that advertising of the substance could lead to inappropriate patterns of medication use or misuse
- The provisions of the Code and any prohibited and restricted representations relevant to the substance
- Available Consumer Medicine Information
- The level of patient education necessary to ensure safe and effective use
- Any other information that is relevant to the decision making

Feedback on the “factors for the delegate”

- Most thought the current list was acceptable, others felt some factors were redundant
- Some felt that whether there are any products on the ARTG should be an additional factor for consideration (but how to handle pre-launch awareness/ promotion)?
- Public health benefit (although implicit in permitting OTC use/ advertising)
  - must be clearly articulated in decisions to build trust in the process
  - must be based on locally relevant data
- Potential waste in the health system from patients seeing a doctor for minor ailments/ S3 products should be considered here as well

Factors for the Delegate - proposed

- The potential impact on public health (positive and negative)
- The likelihood that advertising of the substance could lead to inappropriate patterns of medication use or misuse
  - Noting that other provisions in the Code, such as restricted representations apply
- The level of patient education necessary to ensure safe and effective use
  - Given pharmacists should have a role in provision of all S3 medicines, this may only be appropriate for a subset of newly-down scheduled substances
  - S3 products will require a CMI to be available
- Any other information that is relevant to the decision making

Classes of substances that should not be advertised

The original list:

- Injectables
- Substance for use in emergency situations
- Where safer analogues or therapeutically equivalent medicines are available
- Where there is potential for inappropriate use, abuse or diversion
- Where the substances form part of surgical procedure
- Medicine for treatment of chronic condition that requires a doctor as part of the treatment

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Classes of substances that should not be advertised

- There was a preference in responses that injectables and emergency use have a place in advertising.
- There as a preference for consideration to be on a case-by-case basis rather than blanket exclusions
- This will be the case anyway, but is **guidance** on the types of substances that may be considered for exclusion from Appendix H helpful ?

Is there a better way…

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Different approach – helping the delegate decide

The delegate needs to decide if there is a reason a substance should NOT be advertised

Factors to consider to assist that decision:

1. Potential impact on public health, positive and negative
2. Potential for inappropriate use, abuse, diversion and the further impact advertising may have
3. Are there potential interactions with the substance (drug-drug, drug-food) that require increased patient education to ensure safe use?
4. Is there an ARTG entry for this substance (or will there be)?
5. Is the substance part of a surgical procedure?
6. Are there additional risks associated with the dosage form that may impact on safe use?
7. Any other information that may be relevant

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The proposed process – an overview

Substances that are currently in Schedule 3 but not in Appendix H

- Will NOT require a specific application from a sponsor to move to Appendix H
- Using feedback from this group including the previous criteria and comments on the substances
  - A list of substances proposed to be added to Appendix H will be published and subject to public consultation
  - Concurrently, a list of substances in S3 that won't be added to Appendix H will also be published, with a justification
- Based on the feedback to consultation, the delegate can:
  - finalise the decision and add substances to Appendix H
  - Reconsider the initial decision, and seek further comment on a different proposal for example initially a substance wasn't to be included, e.g. to include in Appendix H with specifications
  - Refer to the ACMS for further advice (not expected that most cases will go to the Committee)

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The proposed process – an overview

Future entries in Schedule 3

- Will NOT require a separate, specific application for Appendix H entry
- As part of the rescheduling consideration, the delegate will also consider the appropriateness of advertising the substance in line with the factors discussed before.
- The proposed advertising decision will be included with the interim decision for public comment
- Based on the feedback to consultation, the delegate can:
  - finalise the decision and add substances to Appendix H
  - Reconsider the initial decision, and seek further comment on a different proposal for example initially a substance wasn't to be included, new proposal may be to include in Appendix H with specifications
  - Refer to the ACMS for further advice on a substance

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The proposed process – an overview

- In the interests of natural justice if the delegate decides not to include a substance in Appendix H
- The sponsor / interested party can submit an application to the delegate to reconsider this decision by addressing the reasons given by the delegate why advertising was not acceptable.

Reviewing what current S3 substances should be advertised

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Current S3 substances – possible additions to Appendix H

These lists are a summary of the feedback from this group. They are in no way a decision of the Delegate or an indication of what the decision will be.

ADRENALINE
CICLOPIROX
CLOTRIMAZOLE
DICLOFENAC
ECONAZOLE
ESOMEPRAZOLE
FAMCICLOVIR
FLUCONAZOLE
GLYCERYL TRINITRATE
HYDROCORTISONE and HYDROCORTISONE ACETATE
IBUPROFEN
ISOCONAZOLE

ISOSORBIDE DINITRATE
KETOPROFEN
LANSOPRAZOLE
LEVONORGESTREL
MICONAZOLE
NALOXONE
NAPROXEN
NYSTATIN
OMEPRAZOLE
OXICONAZOLE
PANTOPRAZOLE

PARACETAMOL
PODOPHYLLOTOXIN
PODOPHYLLUM EMODI (podophyllin)
PODOPHYLLUM PELTATUM (podophyllin)
RABEPRAZOLE
SALBUTAMOL
SALICYLIC ACID
TERBUTALINE
TIOCONAZOLE
TRIAMCINOLONE
ULIPRISTAL
VITAMIN D

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Current S3 substances – further consideration required

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ALCLOMETASONE

BUTOCONAZOLE

CHLORAMPHENICOL

CHLORBUTANOL

CHLORPHENAMINE

CLOBETASONE

CYCLIZINE

CYPROHEPTADINE

DEXCHLORPHENAMINE

DIHYDROCODEINE

DIIODOHYDROXYQUINOLINE (iodoquinol)

DIMENHYDRINATE

DIMETHINDENE

DIPHENHYDRAMINE

DIPHENOXYLATE

DITHRANOL

DOXYLAMINE

FLUORIDES

GLUCAGON

MACROGOLS

MALATHION

METOCLOPRAMIDE

NICOTINIC ACID

NICOTINYL ALCOHOL

ORLISTAT

PHENIRAMINE

PROMETHAZINE

SODIUM PICOSULFATE

SULFACETAMIDE

TRIPROLIDINE

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Current S3 substances – not suitable for advertising

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ALIMEMAZINE

AMINOPHYLLINE

AZATADINE

BROMPHENIRAMINE

BUCLIZINE

CIMETIDINE

CLEMASTINE

ERYTHRITYL TETRANITRATE

FLAVOXATE

GLYCOPYRRONIUM

INOSITOL NICOTINATE

MAGNESIUM SULFATE

MANNITYL HEXANITRATE

METHDILAZINE

PROCHLORPERAZINE

PSEUDOEPHEDRINE

SANTONIN

SODIUM PHOSPHATE

THEOPHYLLINE

Proactively identifying S4 medicine substances for consideration for down-scheduling

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Where we got to last meeting

- The objective is to **develop a potential process for identifying substances that may be suitable for rescheduling**, as agreed by AHMAC
- The group noted precedents **from overseas regulators which** explored options for increasing consumer access – UK, Ireland, Denmark and Singapore
- While the *ad hoc* group would assess the potential of products for down-scheduling and identify factors to be considered e.g. risk mitigation, **subsequent formal application to TGA** would still be required for rescheduling consideration
- As discussed, the driver for this change to the SPF is in encouraging public health through **better access to medicines** and **supporting appropriate self-care**

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What factors should be considered to determine therapeutic classes to be assessed

- Documented unmet need in the community
- Successful and unsuccessful cases – individual and classes - from other countries
- Role of proactive identification of substances for rescheduling in practice changes and health care professionals working more collaboratively (NZ)
- Potential benefit from access to pharmacists and avoidance of costs and inconvenience from requiring a doctor's visit

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- Opportunity cost for not seeing a doctor, e.g. vaccinations, diagnosing other conditions

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Questions to be considered – in light of the discussion and international experience

- Given agreement by AHMAC and the Minister to progress some form of review of S4 substances for potential down scheduling, how should this be progressed?
- Is the current ad hoc group the appropriate group to be convened to undertake such a review?
- Is there unmet need in the community for particular substances or types of prescription medicines currently in S4 that should be considered for S3? What can we learn from decisions made (and safeguards put in place) in other countries?
- What is the relationship with existing non-medical prescribing activity?

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Some recent down-schedulings to OTC internationally

- **Triptans** for migraine – UK and several EU countries
- **Simvastatin** for cholesterol – UK (but discontinued 2010)
- **Tamsulosin** for benign prostate hypertrophy – UK
- **Sildenafil** – UK, Poland and NZ
- **Ulipristal** - Emergency hormonal contraception – UK, NZ, Australia
- **Transdermal oxybutynin** for overactive bladder – US
- **Topical adapalene** for acne – US, Singapore and NZ
- **Clindamycin** and **erthromycin** for acne – Singapore
- **Calcipotriol** for mild psoriasis – NZ, UK
- **Oseltamvir** for influenza – NZ
- **Trimethoprim** for urinary tract infections – NZ
- **Proguanil** for malaria prophylaxis – UK
- **Melatonin** for sleep – US, Canada, Singapore
- **Combined oral contraceptives** - one prescription required every 3 years - NZ, NL, some US states

Adding a new appendix to the poison standard to provide additional safeguards when down-scheduling

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Appendix M - Additional requirements for S 3 medicines

Appendix M - *The Secretary may, in consultation with ACMS, require additional controls or supply requirements for certain Schedule 3 substances to enable them to be provided by a pharmacist. This Appendix is intended to facilitate down scheduling from Schedule 4 to Schedule 3 where, for example, there is community need for access to a medicine but additional controls and oversight, including by the dispensing pharmacist are needed.*

- The substance and the proposed intervention/additional requirement(s) will be listed in the Appendix
- All proposals for inclusion in Appendix M must be referred to ACMS and undergo public consultation

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Where we got to last meeting…

- Heard about how a similar approach has been implemented in New Zealand
- Discussed the promise of the MyHealth record for recording prescription and potentially OTC medicine use and the current situation
- Discussed the interface with regulation of professional practice of pharmacists
- Agreed that neither TGA nor the States and Territories should be required to design pharmacist training

Main concerns:

- What should be included in Appendix M as controls?
- How could/should these requirements be enforced?
- Who to design training programs ? Integration with CPD ?
- Issue of uneven uptake of training between pharmacies ? (Not an issue in NZ ?)

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NZ model for newly down-scheduled medicines

- Like Australia, NZ has a pharmacist-only medicine classification
- **Controlled pharmacist-supply model** for newly rescheduled medicines can involve
  - pharmacist training being mandated before supply
  - strict criteria for supply, screening tools
  - comprehensive documentation about supply
- **Monitoring of risks and benefits is critical** e.g. for sildenafil
  - Risks – inappropriate use, cardiac safety, failure to refer for physical or psychological causes of erectile dysfunction
  - Possible benefits - Earlier treatment for erectile dysfunction, detecting other conditions during the consultation, avoidance of internet or nightclub sales

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UK model for OTC Sumatriptan (Imigran recovery®)

Specific criteria for who should see a doctor before being provided the product

"Your pharmacist will need to ask you various questions about your health and other medicines you may be using before they can sell you this medicine"

Imigran recovery ® - You will need to see a doctor if:

- You had your first ever migraine attack in the last twelve months
- You've had fewer than five migraines in the past
- You're aged 50 years or over and are having migraine attacks for the first time
- The pattern of your migraines has changed, or your attacks have become more frequent/ persistent/ severe, or you don't recover completely between attacks
- You have four or more migraine a month or migraines last for longer than 24 hours
- You are pregnant or breastfeeding
- You have three or more risk factors for heart disease
- You are taking a combined oral contraceptive and your migraine attacks started within the last three months, your migraines have got worse, or you get migraines with aura.

NZ entry for sildenafil - could that be applied here?

Ingredient	Conditions	Classification
Sildenafil and its structural analogues	except sildenafil in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35-70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand	Prescription

Schedule 4	Schedule 3 #denotes Appendix M entry as well	Appendix M
Sildenafil except when in Schedule 3	**Sildenafil** when in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35 – 70 years #	**Sildenafil** – to be dispensed by a registered pharmacist who has successfully completed a training program endorsed by the Pharmaceutical Society of Australia

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NZ entry for sumatriptan and how that could be applied here

Ingredient	Conditions (if any)	Classification
Sumatriptan	**except** when specified elsewhere in this schedule	Prescription
Sumatriptan	for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets that has received the consent of the Minister or the Director-General to its sale as a restricted medicine	Restricted

Schedule 4	Schedule 3 #denotes Appendix M entry as well	Appendix M
Sumatriptan except when in Schedule 3	**Sumatriptan** in medicines for oral use containing 50 milligrams or less per tablet in a pack containing not more than 2 tablets for the treatment of acute relief of migraine attacks with or without aura. #	**Sumatriptan** – to be dispensed by a registered pharmacist who has successfully completed a training program endorsed by the Pharmaceutical Society of Australia to determine the patient has stable, well-established pattern of symptoms

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Where to from here?

- Establish a set of guidelines / requirements for substances included in this Appendix.
- For example, pharmacist training requirements.

OR

- Leave the Appendix open ended to allow inclusion of specific requirements on a case by case basis for substances as required.
- Any proposed entries in Appendix M, should be created in collaboration with the PSA and SHPA and subject to public consultation.

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Therapeutic Goods Administration