MMDR consultation: Reforms and Operations
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

DUE DATE: 5 May 2017

Dear Sir/Madam

Medicines Australia welcomes the opportunity to provide comment on the proposals presented in the Therapeutic Goods Administration (TGA) consultation paper, *Consultation: The scheduling policy framework and advertising of pharmacist only medicines (Schedule 3 substances)*. These mainly relate to Recommendation 11 and 12 of the Medicines and Medical Devices Review report recommendations. Our detailed feedback and questions we have identified as relevant to the proposals presented for implementation by the TGA, are contained in Attachment 1. Note that the comments included only relate to aspects of the scheduling policy framework for medicines and not chemicals.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members of RAWG are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector. Medicines Australia views on scheduling are also aligned with those of the Australian Self Medication Industry (ASMI), noting that when appropriate, down scheduling prescription medicines is a pathway in the product life-cycle to development of new over the counter medicines.

We would be happy to provide further comment on any aspect of our response and we appreciate learning of further developments as they are worked through from here.

Yours faithfully

[redacted]

**Larissa Karpish**
**Manager, Industry & Regulatory Policy**

**Consultation: Scheduling policy framework and advertising of pharmacist only medicines (Schedule 3 substances)**

| Governance | Recommendation/Topic | Response / Comments |
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| Scheduling Policy Framework (SPF) | Scheduling Model | MA welcomes the proposed improvements to the scheduling model, however the continued need to separately obtain a scheduling decision and a marketing authorisation increases complexity and regulatory burden for sponsors. Whilst outside the scope of the current consultation, to achieve the full intent of the Medicines Review ie to reduce red tape and stimulate innovation, Medicines Australia recommends decisions on scheduling would need to be fully integrated as part of the medicines registration process, as occurs in other major jurisdictions. This goal should continue to be pursued in relevant forums to make further improvements to the framework. |
| **Recommendations**<br><br>**Policy Recommendation 1** | **Split the SPF into a policy document and a guidance handbook**.<br>These documents would also incorporate changes to the current SPF that are agreed following the current consultation. | MA agrees with the recommendation. This will provide a more useable format for applicants and enable more timely updates to reflect evolving practices and stakeholder input. |
| **Policy Recommendation 2** | **Establish an informal working group to provide advice on possible amendments to the SUSMP**<br>Establish an informal Working Group comprising state and territory representatives, industry, healthcare professionals and consumers to provide advice on possible amendments to the SUSMP to ensure it remains up to date. | MA agrees with the recommendation. Allowing opportunities for dialogue between key stakeholders will facilitate better understanding of different perspectives and needs. This will assist industry with optimising any applications for future scheduling changes. |

| Decision Making Principles | Recommendation / Topic | Response/comments |
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| Scheduling Classification Process | Cascading principles | There is a general lack of understanding of the classification process and how the cascading principles are applied which feeds into the perception that the process is unpredictable and non-transparent. The proposals to create an SPF guidance handbook together with alignment of advice to applicants with the SPF principles is strongly supported. |
| | Interactions with ACMS | Rejections of initial applications for down scheduling from Rx to OTC are common and this creates extra regulatory burden for Sponsors and the Committee.<br>The lack of a formal process to seek advice through a 'presubmission' meeting or directly interact with the ACMS or Scheduling Delegate to address concerns is a significant barrier for applicants to optimise their submission and create a predictable and transparent scheduling process. These interactions are possible in other jurisdictions, including in NZ where applicants can attend Classification committee meetings.<br>Further consideration should be given to a more extensive means of interaction with the secretariat, ACMS or TGA scheduling Delegate to address these procedural deficiencies.<br>MA is unaware of any formal legal barriers that prevent interactions between applicants and the ACMS and the scheduling Delegate on rescheduling matters. MA considers that interaction and dialog is mutually beneficial for all parties to ensure a common understanding and will result in the best outcomes to facilitate medicines access for patients.<br>The TGA should consider adopting a similar model to that currently used by the MHRA in the UK. Companies are |

| Decision Making Principles | Recommendation / Topic | Response/comments |
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| | | encouraged to ask for scientific advice from the MHRA on how to apply for a classification change and what evidence needs to be submitted. This is especially useful for a major switch application to establish data requirements and content of the application such as indication, dose, population, pack size, proposed controls for supply including risk management activities as appropriate. It also allows identification of any special data requirements to highlight any potential issues beforehand to ensure that a sound, well supported application is submitted with an appropriate risk minimisation plan. A link to the MHRA guidance is provided: https://www.gov.uk/guidance/medicines-reclassify-your-product |
| **Recommendations Ongoing Improvements 1** | **Applicants presenting to the advisory committees** A pilot exercise to assess the value of applicants presenting directly to the advisory committees should be undertaken. | MA agrees with the proposal to assess the value of applicants presenting directly to the advisory committees. Being able to directly discuss and address issues may resolve concerns and improve process transparency and efficiency. An opportunity should also be given for provision of further information relevant to concerns, within a specified time frame, following the advisory committee meeting. Interactions between the applicant and TGA scheduling Delegate should also be open and transparent to enable both parties to have a common understanding of concerns to increase the likelihood of a successful rescheduling application at the first attempt and reduced regulatory burden for both parties. |
| **Business Improvement Measures 1** | **Structure and content of the committee's advice** a) A clearer explanation of the cascading principle and how it is applied should be included in the SPF. | MA agrees with the proposal which should enable the applicant to fully understand how the cascading principle was utilised in consideration of risk and benefit. |

| Decision Making Principles | Recommendation / Topic | Response/comments |
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| | b) The structure and the content of the Committee's advice, and the delegate's reasons should be revised to ensure they are meeting the needs of stakeholders. Particular consideration should be given to explaining how the advice and reasons relate to the scheduling factors, and how the information that applicants have submitted has been reflected in the decision-making process. | MA agrees with this proposal. Providing clarity on how the information that applicants have submitted were assessed relevant to the scheduling factors will assist in providing transparency of the decision-making process. |

| Transparency | Recommendation/Topic | Response / Comments |
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| Information for applicants and the public | Public summary | Currently, the initial public consultation process undertaken includes minimal information on the application other than the name of the active substance and proposed scheduling classification. This makes commenting on proposals difficult as it is unclear what approach is being proposed to enable the scheduling factor criteria to be met.<br>In order to ensure that applicants create an appropriate summary for the general public, information included should be relevant and easily understood such as the active ingredient, indication, precautions, dosage and pack size. A summary template aligned with the scheduling factors under consideration would provide a link to the relevant criteria and decisions of the ACMS and Scheduling Delegate to assist with transparency of decisoin making.<br>Clear transparency principles should be available and applied where there is disagreement on the level of information included by an applicant. These should be agreed by all stakeholders. |

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| **Recommendations**<br><br>**Business Improvement Measures 2** | **Public summary of the scheduling submission and other communication processes**<br>a) A summary for public dissemination should be provided by scheduling applicants, and this would be published as part of the public consultation process. This could be included in the application template. If an appropriate summary is not provided by the applicant, the default option could be that the entire (de-identified) application would be published for public consultation. | MA agrees with the proposal to publish a summary of the submission that will facilitate the public consultation process. A template and detailed guidance should be developed with stakeholders that should align with the scheduling factors being considered.<br>There should be no default position of publishing an entire submission which could provide significant, and unwarrated, competitive advantage to other applicants. This would potentially undermine any incentives such as a period of marketing exclusivity for applicants of initial rescheduling applications, designed to reward innovation by recognising the significant investment of time and resources required to generate the information included in a rescheduling application. |
| | b) A mechanism should be developed to alert stakeholders of items being considered for scheduling. For example, the delegate could identify a small number of affected stakeholders for comment, and the Secretariat could contact them directly. | MA agrees that an alert system should be in place, however it would seem unfair if only selective sponsors were contacted. The rationale for this approach is unclear. All affected parties should be included in any proactive communication activities.<br>A monthly alert service that provided advance notice of pending activities for the following quarter (for example, new consultations, interim and final decisions and final entries) in the SUSMP would enable more visibility of upcoming activities and enable resource planning to contribute to any consultation activities.<br>For applicants a clear timetable of next steps including planned dates for receipt of any evaluation reports or optional discussions with the Scheduling delegate or ACMD would be valuable. A reference model would be the planning letters provided to Sponsors by the prescription medicines branch when submitting applications for new medicines or major variations. |

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| | c) Develop communication milestones and application tracking to improve communication between the Secretariat and applicants. | MA agrees with this proposal. A formal timetable should be provided to applicants with milestones for receipt of any evaluation reports and responses additional to the public consultation processes. |

| Risk-benefit value tree | Recommendation/Topic | Response / Comments |
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| Benefit-risk assessment | Value Tree | The Brass model is an established approach for considering the benefit-risk of over the counter medicines and is used by the FDA and in the EU when considering Rx to OTC switch applications. These require the highest level of technical supporting data and represent the most complex scheduling decision that would be considered under the SPF. For these types of complex applications benchmarking with international standards is important to support harmonisation and enable documentation prepared for one jurisdiction to be utilised elsewhere, thus reducing regulatory burden. Adapting the framework to enable more flexibility when the scheduling changes proposed are more minor in nature is a practical solution to provide applicants with a range of fit for purpose regulatory options. |
| **Recommendations**<br><br>**Business Improvement Measures 3** | **Greater emphasis on benefits as well as risks**<br>When updating the SPF guidance for submissions, consider how greater emphasis can be placed on potential benefits as well as risks of proposed rescheduling of substances. | MA are pleased to note the intention for greater emphasis of potential benefits for rescheduling of substances so that there is balanced assessment of benefit risk. The Brass model provides a suitable methodology for considering potential benefits that can serve as a reference point for developing a fit for purpose scheme that can accommodate both complex and minor changes to the scheduling classification. |
| **Ongoing Improvements 2** | **Improved guidance on risk and benefit**<br>Prepare worked examples of the risk: benefit tree for recent scheduling considerations and assess the utility of this approach for scheduling applications. | Worked examples are highly valued by industry and provide a tool kit which help applicants to provide high quality applications. As outlined above the Brass model provides a suitable model for supporting development and assessment of a risk:benefit value tree for major rescheduling applications and offers a reference point in determining suitable options for more minor changes. |

| Interim Decisions | Recommendation/Topic | Response / Comments |
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| Public consultation | Red tape reduction | In the current consultation process the lack of any background information released at the time of the intial consultation means the rationale for any changes are not readily understood. This limits the ability to make appropriate comments. Only at the point that the interim decision is published do the relevant considerations for changes become visible allowing a more detailed assessment of any potential impacts.<br>The current requirement for a consultation submission to be made even in the absence of any comments of relevance, in order to be able to respond when more detailed information is available, is an example of red tape that any revised process should eliminate. |
| **Recommendations**<br>**Policy Recommendation 3** | **Public consultation on interim decision**<br>Amend the Therapeutic Goods Regulations to allow general public consultation and receipt of submissions from any interested parties on the interim decision and remove the prescriptive requirements on time available for submission | MA agree that comments on the interim decision should be open for full public consultation irrespective of whether comments were provided for the initial submission. This is particularly important for smaller organisations with limited resources.<br>MA also agrees that the timelines for submissions should reflect the complexity of the application in process. A longer consultation timeframe should not delay the final decision date, but should be achieved within the standard timeline. |
| **Business Improvement Measures 4** | **Guidance on legal nature of scheduling and scheduling decisions**<br>Include an explanation of the legislative nature of scheduling decisions and why they are not appealable in the SPF. | MA agree this is an important aspect to address, however the inability to appeal scheduling decisions remains a major deficiency within the SPF. Further work should be undertaken to find a mechanism to address this concern, recognising this would require legislative changes.<br>Consideration should be given to including in the terms of reference of the Informal working group of stakeholders that is proposed to be established the requirement to continue to consider procedural aspects not addressed during medicines review to continually improve the scheduling process. |

| Timing of Scheduling Decisions | Recommendation/Topic | Response / Comments |
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| Implementation of Scheduling Decisions | Communication planning | Significant logistics management is required when changes in scheduling occur that either support the launch of new products or mandate changes to existing products. Dialogue with key stakeholders including industry, HCP and consumer groups is critical to ensure realistic timings are applied for rescheduling decisions, particularly where items are recommended for upscheduling for example: OTC to Rx. Additionally, sufficient time needs to be allowed for development and implementation of a comprehensive communication plan so that HCP and consumers are alerted to the changes and can make relevant decisions on how ongoing access to medicines will be managed. |
| **Recommendations**<br>**Business Improvement Measures 5** | **Decision transparency and information sharing**<br>Include an explanation in the SPF of jurisdictional requirements for decisions to enhance stakeholder understanding.<br>Identify an early alert mechanism to ensure the initial applicant, the jurisdictions, and stakeholder groups have the maximum time available for activities associated with a decision. | MA agrees with any alerting mechanism that assists stakeholders and applicants in managing activities relating to a decision, particularly if the decision will have a major impact on the community such as a decision to upschedule an OTC medicine to a prescription medicine, or make a prescription medicine a controlled drug. However, alerting mechanisms alone are not sufficient and formal stakeholder engagement is required to ensure that optimal communication is planned and there are not unexpected consequences that may have an adverse impact on access to medicines. |

| Proactive Consideration of Candidate substances for Rescheduling | Recommendation/Topic | Response / Comments |
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| International benchmarking | Expanding the range of OTC medicines available in Australia | International benchmarking indicates that Australia has a more conservative approach to Rx to OTC rescheduling compared to other jurisdictions including the UK and NZ.<br>In the UK for some years a proactive approach to identifying candidates for rescheduling has resulted in an expansion of new OTC medicines following Rx to OTC switches. This supports innovative measures and enables consumers to appropriately self-manage their healthcare.<br>The UK approved list of compounds (see attached) would be a good starting point to identifing potential candidates for Australia. The comparable regulatory standards between the MHRA and TGA and extensive experience of safe use in the OTC setting for a similar population demographic would provide a degree of reassurance that candidates would be equally suited to the Australian environment.<br>The lack of inclusion of a substance on any agreed list should not however preclude an applicant from making a submission for rescheduling if the relevant criteria are met. |
| **Recommendations**<br>**Ongoing Improvements 3** | **Proactive identification of substances for rescheduling**<br>Implement a system for proactively identifying substances for rescheduling, similar to schemes in place in some comparable international jurisdictions. | MA agrees with the proposed pro-active approach to identify candidates for potential rescheduling.<br>Any recommendations should be considered by a representative stakeholder panel that includes all parties including consumers, pharmacists, physicians, industry and regulators. The terms of reference for the group should be formalised and transparent, and a clear mandate and procedural guidance should be made available. The model that has operated in the UK for some years is a good benchmark for this process. |

| Tools for Better 'Management' of Rescheduled Medicinal Substances | Recommendation/Topic | Response / Comments |
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| Additional pharmacy supply provisions | 'Restricted' medicines | For OTC medicines containing compounds where there is a potential risks of abuse or misuse the option to mitigate safety concerns is usually to upschedule to a prescription medicine. This can impact access for those consumers who are using the medicines appropriately. In NZ the restricted medicine model allow pharmacists who have been subject to additional training and have capabilties to monitor and record supply to continue to supply a product over the counter even though it has a prescription status. The development of Project Stop and the MedsASSIST programmes by the Pharmacy Guild in collaboration with industry stakeholders and the Australian Self Medication Industry Association should be considered as potential models that could facilitate this type of approach in Australia, in conjunction with other measures. This pathway should thus be part of the considerations for changes to the SPF. |
| **Recommendations**<br>**Policy Recommendation 5** | **New controls for certain medicines that have been down-scheduled to pharmacist only classification (S 3)**<br>Create a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for certain Schedule 3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4 (prescription only). This new appendix will function in a similar manner to Appendix D, which specifies additional controls for particular Schedule 4 or 8 substances. | MA agree in principal with the option for additional controls for select Schedule 3 substances where this is warranted to support classification as an OTC medicine. The additional controls should be open for public consultation and agreed prior to implementation.<br>It should be possible to remove additional controls based on evidence as is the case for prescription medicines with approved RMP. Tthe procedural aspects for this need to be included and clarification of whether this decision would need to be made by the ACMS or TGA as part of the marketing application. |

| Parallel Processes and Other Incentives (Medicines) | Recommendation/Topic | Response / Comments |
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| Red tape reduction | Simplification of registration and rescheduling processes | Significant inefficiency and red tape that stifles innovation is the inability to prepare a single application to support Rx to OTC rescheduling applications that meets the needs of both the rescheduling and registration processes and is reviewed in parallel. This could be achieved by creating a specific CTD Module 1 section for rescheduling applications that incorporates the elements required to address the scheduling factors criteria. The CTD format already has an existing section for Risk Management activities that will allow applicant to propose additional risk mitigation approaches that would be part of any additional controls reflected in the SUSMP. The CTD format already offers a logical presentation of quality, nonclinical and clinical information and an electronic format facilitates navigation of information. A single navigable presentation of information would allow both TGA evaluators and members of the ACMS easy access to data relevant to their responsibilities and reduce the time to prepare applications, which would facilitate access to more OTC medicines. |
| **Recommendations**<br>**Ongoing Improvements 4** | **Down-scheduling - alignment with OTC product submission and incentives?**<br>a) Develop a mechanism to better align applications to reschedule an active substance from Schedule 4 to Schedule 3 with the marketing authorisation applications for newly rescheduled Schedule 3 medicines. | We fully support the relaxation or removal of this requirement to allow submission of the associated marketing authorisation application to the TGA at the same time as the scheduling application. We propose that the marketing authorization applications and down-scheduling applications are submitted and evaluated in parallel, allowing the TGA to consider the applicant's submission within one review and eliminating additional timeframes. It is noted that this could lead to additional workload for applicants should the rescheduling application be unsuccessful and this is considered acceptable.<br>As part of alignment with the EU Brass model benefit risk assessment: the dossier content should be part of reschedulingconsiderations (especially risk management aspects and conditions of registration). |

| Parallel Processes and Other Incentives (Medicines) | Recommendation/Topic | Response / Comments |
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| | b) Consider options for market incentives for down scheduling, for example similar to the UK system, and whether development of a similar mechanism for the Australian context would be in the interests of public health. | MA agree that incentives should be available for the applicant that initiates a rescheduling application, as occurs in other jurisdications. A significant amount of time and resource is involved in preparing rescheduling applications and we believe that availability of incentives will encourage innovation to support new OTC medicines. The option of an incentive for the initiator of a rescheduling application would not amend the net public health benefit, as the consumer will continue to be able to access remaining Schedule 4 brands with a prescription.<br>MA recommend that a more detailed consultation is needed to properly consider what these 'incentives' might look like and their market impacts. For the option of market exclusivity, the date of SUSMP implementation for the active substance should drive the market exclusivity period applied to the first branded product to have initiated a rescheduling application.<br>Incentives based on market exclusivity periods should be a minimum of 1 year as in the UK, noting the US has a 3 year period of exclusivity. |

| Improving the Clarity of the SPF | Recommendation/Topic | Response / Comments |
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| Medicines Classification | Unscheduled medicines | The current medicine schedules do not include a 'Schedule 1' classification, which would logically be the schedule that would apply if a medicine were deemed not to require restriction to access from Pharmacy channels only under Schedule 2. This can create uncertainty over what medicines are 'unscheduled' particularly when the Schedule is dependent on pack size or strength. |

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| **Recommendations**<br>**Business Improvement Measures 6** | **Improving the clarity of the SPF**<br>1. Amend section 3.2 to provide the delegate with greater discretion when deciding to refer (or to not refer) particular substances to the relevant advisory committee(s) for advice, particularly for<br><br>a) rescheduling considerations of "second in class" medicinal substances (where the committee has already considered and the delegate already determined that a substance in the same pharmacological / medicinal class be rescheduled, based on similar considerations | In principle enabling a Delegate to make a decision without referral to the ACMS where the benefit/risk is clearly established is acceptable.<br><br>However, clarification is sought as to whether if a 'second in class molecule' with a comparable benefit risk to a 'first in class' is not referred to ACMS it will have potentially a quicker regulatory pathway. If market exclusivity applies to the first time an **active** is downscheduled on the ARTG rather than a pharmacological class, it could thus gain additional benefits compared with the first in class compound. |
| | d) and consideration of Appendix E, F and K entries of the SUSMP. | MA agrees with this proposal. |
| | 3. Decisions to include a substance in Appendix K can be a delegate-only decision and not require referral to the Advisory Committee for Medicines Scheduling. | MA agrees with this proposal. |
| | 4. Amendment to the description of the Cascading Principle and the details for inclusion in Appendix B. | MA agrees with this proposal. |

| Advertising of Schedule 3 (Pharmacist Only) Medicines | Recommendation/Topic | Response / Comments |
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| Schedule 3 medicine advertising | Advertising to the public | The current advertising restrictions for many S3 medicines mean that consumers may be unaware of the availability of treatment options that may be an effective means of managing a self-limiting condition without the need to visit a GP. As a consequence they may spend additional time and incur costs prior to gaining relief, without realising that a pharmacist, who is typically more accessible to the community, could have advised on an appropriate treatment choice. Ultimately this defeats the object of having approved over the counter medicines and the benefits of freeing up GP resources to focus on more serious conditions that require medical intervention.<br>Restrictions should remain for those products where there are concerns of abuse or misuse or other specific risk mitigation needs that requires a more extensive interaction with a pharmacist to ensure the right choice of product based on benefit risk considering any specific individual circumstances. |
| **Recommendations** | **Advertising of Schedule 3 (Pharmacist only) medicines**<br>We wish to obtain stakeholder feedback to support the development of options for government to consider around the reform of advertising requirements for pharmacist-only (Schedule 3) medicines. Some considerations include:<br>• Criteria for allowing advertising of medicines containing Schedule 3 substances under the TGA Advertising Framework.<br>• Possible retention of some form of "list" similar to Appendix H. We seek feedback on the alternatives of whether this would be a positive list | Medicines Australia supports initiatives that facilitate greater health literacy amongst the community. Therefore MA support creation of a 'negative' list of Schedule 3 substances which cannot be advertised to the public, where there is likelihood of misuse or abuse of the medicine of concern. All other substances should be allowed to advertised by default. The 'negative' list should be agreed following a public consultation process. This will better align the approach to advertising OTC medicines in Australia with the rest of the world. |

| Advertising of Schedule 3 (Pharmacist Only) Medicines | Recommendation/Topic | Response / Comments |
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| | (substances considered and permitted to be advertised, status quo) or a negative list (list of substances not permitted to be advertised to consumers, with anything off the list authorised to be advertised by default) from this public consultation. | |
| | • Any restrictions or requirements that should be applied to advertisements or other form of information provided for medicines containing these substances, e.g. mandatory and repeated mention that the product should be selected with the advice of a pharmacist, requirement to describe possible adverse events, requirement to emphasise that the particular OTC products containing the substance in question are only for short-term use. | MA agrees with the proposal that the advertisements should contain a repeated and mandatory statement that a pharmacist consultation is required to determine if the product is suitable. Any additional disclaimers should be product specific and aligned with any risk mitigation plans.<br>MA supports the proposals of ASMI which defines a structured approach to advertisements that has equal prominence for the brand information, disease state and role of the pharmacist to ensure quality use of medicines by consumers. |
| | • An exploration of what regulatory enforcement/compliance powers would be required in the event that restrictions for the advertising of S3 substances were changed, noting that the Government has agreed that advertising pre-approval processes should be removed once appropriate compliance and enforcement powers are in place (MMDR Recommendation 55). | MA agrees with this proposal and notes the need for additional consultation on this aspect, recognising final proposals to address the MMDR recommendations have yet to be confirmed. |
| | • Relationship with possible additional requirements for pharmacist education and provision of information by patients (e.g. to declare that they do not have certain pre-existing conditions for which the OTC medicine would be | Enabling an enhanced risk management approach to support availability of an increased number of S3 products will have a number of benefits across the community such as reduced burden on doctors, more timely access to medicines, raise |

| Advertising of Schedule 3 (Pharmacist Only) Medicines | Recommendation/Topic | Response / Comments |
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| | contra-indicated) at the point of sale, for particular medicines that have been down scheduled from S4 to S3. | patient awareness, and an increased ability for consumers to self-manage minor ailments.<br>Models implemented overseas such as in the UK and NZ have demonstrated the effectiveness of schemes involving additional pharmacist intervention to manage risks. Additional tools such as questionnaires that would be completed at the time of consultation to help determine treatment suitability together with optimum pack labelling are all appropriate options where pharmacists could be provided with additional specific training to ensure quality use of medicines. |
| | • Consideration of a potential mechanism to allow sponsors to seek approval to advertise to the public products containing Schedule 3 substances as part of a market authorisation application for the medicine(s) in question. | MA agrees with this proposal, in particular for new S3 medicines. |

**List of reclassified products 1991 – 2016**

The tables below contain the information for UK medicines reclassified from prescription only medicine (POM) to Pharmacy (P) medicine and P medicine to general sales list (GSL) Medicine from 1991 - 2016. Where relevant, brand names have been included in brackets.

The lists represent the first reclassification either from POM to P or P to GSL of the product and further extensions such as wider indications, additional pack sizes or higher strengths have not been included.

Not all products listed are currently available, for various reasons, including both commercial and regulatory.

**POM to P**

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| **1991** | |
| Hyoscine Butyl Bromide | *Indication not recorded* |
| **1992** | |
| Carbenoxolone sodium granules | Mouthwash treatment for adults and children not less than 12 |
| **1993** | |
| Acrivastine 24mg tablets | For treatment of seasonal allergic rhinitis |
| Cetirizine hydrochloride 10mg tablets | For treatment of seasonal allergic rhinitis |
| Ketoprofen | For rheumatic and muscular pain, in adults and children aged 12 and over |
| Loratadine 10mg tablets | For treatment of seasonal allergic rhinitis |
| Zovirax Cold Sore Cream (aciclovir) | Treatment of herpes simplex virus infections of the lips and face (herpes labialis) |
| **1994** | |
| Beclometasone dipropionate Non aerosol Nasal Spray | For treatment of seasonal allergic rhinitis in adults and children over 12 |
| Cimetidine 200mg tablets | Short-term symptomatic relief of heartburn, dyspepsia & hyperacidity<br>Prophylactic management of nocturnal heartburn |
| Famotidine 10mg tablets | Short-term symptomatic relief of heartburn, dyspepsia & hyperacidity |
| Mebendazole 100mg sachet | For enterobiasis in adults and children over 2 |

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| Sodium cromoglycate 2% eye drops and<br>4% eye ointment | For acute seasonal allergic conjunctivitis |
| Tioconazole 2% cream | For vaginal candidiasis |
| Anhydrol Forte (aluminium chloride hexahydrate) | Treatment of Hyperhydrosis |
| Diclofenac diethylammonium 1.16% Gel | For symptomatic relief of pain and inflammation in trauma of tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism in adults and children aged 12 years and over for not more than 7 days |
| Felbinac 3.17% Gel | For relief of symptoms associated with soft tissue injury such as strains, sprains and contusions, in adults and children aged 12 years and over for not more than 7 days |
| Flunisolide 0.02% Nasal Spray | For prevention and treatment of seasonal allergic rhinitis in adults and children aged 12 and over |
| Minoxidil 2% Lotion | For the treatment of alopecia androgenetica, in men aged 18 to 65 |
| Piroxicam 0.5% Gel | For relief of rheumatic pain and muscular aches, pains and swellings such as strains sprains and sports injury for not more than 7 days in adults and children aged 12 & over |
| Ranitidine Hydrochloride 75mg tablets | For short term symptomatic relief of heartburn, dyspepsia and hyperacidity |
| **1995** | |
| Fluconazole 150mg Tablet | For the treatment of vaginal candidiasis in persons aged not less than 16 or more than 60 years of age |
| Hydroxyzine Hydrochloride 25mg tablets | For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children |
| Ketoconazole 2% Shampoo | For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp |
| Pyrantel embonate 750mg Sachets | For the treatment of enterobiosis in adults and children aged not less than 2 years |
| Budesonide 100mcg Nasal spray | For the prevention and treatment of seasonal allergic rhinitis in adults and children not less than 12 years in non-aerosol, aqueous form |
| **1996** | |
| Azelastine hydrochloride 140mcg Nasal Spray | For the treatment of seasonal allergic rhinitis in adults and children not less than 12 years, in non-aerosol, aqueous form |

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| Nizatidine 75mg tablets | For the prevention of symptoms of food-related heartburn in persons aged not less than 16 |
| **1997** | |
| Mebeverine hydrochloride 135mg Sachets | For the symptomatic relief of irritable bowel syndrome |
| **1998** | |
| Domperidone maleate 10mg Tablets | For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn |
| Levocabastine hydrochloride 0.05% Nasal Spray<br>and 0.05% Eye Drops | For the symptomatic treatment of seasonal allergic rhinitis<br>For the symptomatic treatment of seasonal allergic conjunctivitis |
| Nedocromil sodium 2% Eye Drops | For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis |
| **2000** | |
| Terbinafine hydrochloride 1/% Cream | For the treatment of tinea pedis and tinea cruris |
| Lodoxaminde trometamol 0.1% Eye Drops | For the treatment of ocular signs and symptoms of allergic conjunctivitis, in adults and in children aged 4 years and over |
| **2001** | |
| Levonorgestrel 0.75mg Tablets | For use as an emergency contraceptive in women aged 16 years and over |
| **2002** | |
| Fluticasone Nasal Spray (Flixonase) | For the prevention and treatment of allergic rhinitis, in persons aged 18 years and over, for a maximum period of 3 months |
| Azelastine Hydrochloride 0.05% Eye Drops (Optilast Allergy) | Allergic Conjunctivitis |
| **2003** | |
| Griseofulvin 1% Spray (Grisol) | For the treatment of athlete's foot |
| Vivioptal Capsules (adenosine 750mcg with vitamins and minerals) | Supplement for vitamin and mineral deficiency |

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| **2004** | |
| Omeprazole Gastro Resistant 10mg tablets | For the relief of reflux-like symptoms such as heartburn |
| Simvastatin 10mg Tablets (Zocor Heart Pro) | To reduce the risk of a first coronary event (non fatal myocardial infarction and coronary heart disease (CHD) deaths) in individuals who are likely to be at moderate risk (approximately 10-15% 10-year risk of a first major event) of CHD. Treatment should be taken as part of a programme of actions to reduce the risk of CHD |
| **2006** | |
| Amorolfine hydrochloride 5% Nail Lacquer (Curanail) | For the treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds; treatment is limited to 2 nails |
| Sumatriptan 50mg Tablets (Imigran Recovery) | For the acute relief of migraine attacks, with or without aura, in patients who have a stable well established pattern of symptoms in adults aged 18 to 65 years |
| Penciclovir 1 % Cream (Fenistil Cold Sore Cream) | For the treatment of herpes simplex virus infections of the lips and face (*Herpes labialis*) in adults and children aged 12 years or more |
| **2007** | |
| Chloramphenicol 0.5% Eye Drops and 1% Eye Ointment | For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over; maximum length of treatment: 5 days |
| **2008** | |
| Naproxen 250mg enteric-coated tablets | For the treatment of primary dysmenorrhoea in women aged between 15 and 50 years |
| Azithromycin 500mg Tablets<br>(Clamelle) | For the treatment of confirmed asymptomatic Chlamydia trachomatis genital infection in individuals aged 16 years and over, and for the epidemiological treatment of their sexual partners |
| **2009** | |
| Orlistat 60mg Capsules (alli)<br>(via EU Centralised procedure) | For weight loss in adults who are overweight (body mass index, BMI, ≥28 kg/m2) and should be taken in conjunction with a mildly hypocaloric, lower-fat diet |
| Pantoprazole 20mg tablets<br>(via EU Centralised procedure) | For the short-term symptomatic treatment of gastro-oesophageal reflux-like symptoms (e.g. heartburn) in adults aged 18 years and over |

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| Alclometasone dipropionate 0.05% Cream (Diprolieve Eczema and Dermatitis) | For the short-term treatment and control of patches of eczema and dermatitis including atopic eczema and primary irritant and allergic dermatitis in adults and children aged 12 years and older |
| Tamsulosin 0.4mg Modified Release Tablets (Flomax Relief MR) | For the treatment of functional symptoms of benign prostatic hyperplasia (BPH) in men aged 45 to 75 years |
| **2010** | |
| Tranexamic acid 500mg Tablets (Cyclo-f) | For reduction of heavy menstrual bleeding over several cycles in women with regular, 21-35 day cycles with no more than 3 days individual variability in cycle duration; in women aged 18 to 45 years old |
| **2012** | |
| Rabeprazole 10mg gastro resistant tablets (Pariet) | For the short-term symptomatic treatment of gastro-oesophageal reflux-like symptoms (e.g. heartburn) in adults aged 18 years and over |
| **2013** | |
| Esomeprazole 20mg Gastro-resistant Tablets (Nexium Control)<br>(via EU Centralised procedure) | For the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults |
| **2014** | |
| Zolmitriptan 2.5mg Orodispersible Tablet Zomig P | For acute relief of migraine attacks with or without aura for adults aged 18 to 65 years |
| **2015** | |
| Ulipristal acetate, 30mg (ellaOne)<br>(via EU Centralised procedure) | For emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure |

**P to GSL**

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| **1994** | |
| Crotamiton Cream | For relief of itch in the skin |
| **1996** | |
| Clotrimazole 1% Cream | For athlete's foot |
| Magnesium Alginate | *Indication not recorded* |
| **1997** | |
| Benzoyl peroxide 2.5% Cream | For the treatment of spots and pimples on the face |
| Dequalinium chloride 0.25mg Lozenges | For minor infections of the mouth and throat |
| Loperamide hydrochloride 2mg Tablets | For symptomatic treatment of acute diarrhoea, in adults and children aged 12 years and over |
| Miconazole nitrate 2% Cream / Powder | Treatment of tinea pedis (athlete's foot) |
| Sodium picosulphate 1% | For adults and children aged 10 years and over |
| **1998** | |
| Potassium chloride 0.15% | Treatment of acute diarrhoea only |
| **1999** | |
| Nicotine 2mg Chewing Gum | For the relief of nicotine withdrawal symptoms as an aid to smoking cessation only |
| Ranitidine hydrochloride 75mg Tablets | For the short-term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity in patients aged 16 years and older |
| **2000** | |
| Mepyramine maleate 2% Cream | For the symptomatic relief of insect stings and bites, and nettle stings, in adults and in children aged 2 and over |
| Famotidine 10mg Tablets | For the short-term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity |
| Heparinoid 1% Gel | For the relief of bruises, sprains and soft tissue injuries, in adults and children aged 12 years and over |
| **2001** | |
| Loratadine 10mg Tablets | For the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis, and idiopathic chronic urticaria, in adults and children aged 2 years and over and weighing more than 30Kg |

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| Cetirizine hydrochloride 10mg Tablets | For the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis and idiopathic chronic urticaria, in adults and in children aged 12 years and over |
| **2002** | |
| Minoxidil 2% Solution (Regaine Regular Strength) | For the treatment of alopecia androgenetica in those aged between 18 and 65 years |
| Ketoconazole 2% Shampoo (Nizoral Dandruff Shampoo) | For the prevention and treatment of dandruff |
| Miconazole nitrate 0.16% Spray (Daktarin Dual Action) | Prevention of Athlete's foot |
| **2003** | |
| Beclometasone dipropionate Nasal Spray (Non-aerosol) | For the treatment of seasonal allergic rhinitis in persons aged 18 years and over, for a maximum period of 1 month |
| **2004** | |
| Aciclovir 5% Cream (Zovirax) | For the treatment of herpes simplex virus infections of the lips and face (*Herpes labialis*) |
| Terbinafine 1% Cream (Lamisil AT) | For the treatment of tinea pedis and tinea cruris |
| Hyoscine butyl bromide 10mg Tablets (Buscocalm) | For the relief of gastrointestinal tract spasm associated with medically confirmed irritable bowel syndrome (IBS) in adults and children aged 12 years and over |
| **2005** | |
| Acrivastine 8mg Tablets | For the symptomatic relief of allergic rhinitis, including hayfever, and chronic idiopathic urticarial, in adults and children 12 – 65 years |
| **2007** | |
| Hydrocortisone 1% Cream (Boots Hc45 Bite & Sting Relief) | For the treatment of insect bite and stings |
| Bifonazole 1% Cream | For the treatment of athlete's foot |
| **2008** | |
| Diclofenac diethylammoniuim 1.16% Gel (Voltarol Pain-eze Emulgel) | For the local symptomatic relief of pain and inflammation in: trauma of the ligaments, muscles and joints e.g. due to sprains, strains and bruises; localised forms of soft tissue rheumatism |
| Sodium cromoglicate 2% Eye Drops | For the relief and treatment of eye symptoms of hay fever |

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| **2009** | |
| Nicotinamide 4% Gel (Freederm) | For the treatment of mild to moderate inflammatory acne vulgaris |
| Dimeticone 4% Solution (Hedrin 4% cutaneous solution) | For the eradication of headlice infestations in adults and children aged six months and above |
| **2011** | |
| Colecalciferol 0.02mg (combined with calcium gluconate and nicotinic acid) (Crampex) | For the treatment of night muscle cramp |
| Griseofulvin 1% Spray (non-pressurised) | For the treatment of athlete's foot |
| **2014** | |
| Penciclovir 1% Cream (Fenistil Cold Sore Cream) | For the treatment of herpes simplex virus infections of the lips and face (*Herpes labialis*) in adults and children aged 12 years or more |
| **2015** | |
| Esomeprazole 20mg Gastro-resistant Tablets (Nexium Control) | For the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults |
| Fluticasone propionate Nasal Spray (Pirinase Hayfever Relief for Adults 0.05%) | For the treatment of allergic rhinitis, in persons aged 18 years and over, for a maximum period of 1 month |