



Medicines & Healthcare products
Regulatory Agency



MHRA
Regulating Medicines and Medical Devices

RECLASSIFICATION STAKEHOLDER PLATFORM – FINAL REPORT

Autumn 2017



EXECUTIVE SUMMARY

This report outlines the work of the UK Stakeholder Platform on Reclassification of Medicines (hereafter called the “Group”) that was set up in November 2014 to consider how to maximise the input from stakeholders in the process of reclassifying medicines. A medicine is reclassified when it is acceptably safe to change it from a Prescription Only Medicine (POM) to non-prescription (NP) medicine. The over-riding principle of reclassification of a product is that its safety in use is well established. This is decided after a robust evaluation of the evidence of safety and seeking advice, as appropriate, from the Commission on Human Medicines and, its Expert Groups. The work of the Stakeholder Platform focuses on the additional considerations in the reclassification process: the management of risk of supply, and acceptability to patients and health professionals. These are the parts of the process that stakeholders can add most value to.

The Group met 6 times between November 2014 and March 2017 and analysed all aspects of the reclassification process, identifying where and how stakeholders could give their views. The report details the recommendations of the Group, the work carried out so far by the MHRA to implement these recommendations and plans for further work.

A clear message from the Group is that stakeholders need to have a better understanding of the reclassification process to enable them to provide meaningful input into those parts of the process where they can add value. As a result, the MHRA has redesigned its [reclassification webpage](#) to provide more accessible information on the way in which medicines can be obtained without prescription by patients within the UK. The MHRA has also worked with the industry to revise the regulatory assessment process and timelines to provide greater clarity and transparency of the process for industry stakeholders. This also provides predictability for applicants when the MHRA is processing a reclassification application. The new [process and timelines](#) now available on the reclassification webpages.

The Group analysed some reclassification case histories. They agreed that applications that were regarded as being more successful (and supported by stakeholders) were those that had had minimal changes to the authorised use of the medicine compared to the corresponding prescription medicine. Applications for products that had significantly different conditions of use for the pharmacy product were less supported by stakeholders as they appeared to cause confusion for healthcare professionals and patients. The MHRA’s assessment process now considers more widely the learnings from the case studies which were reviewed and greater emphasis is placed on proportionate risk minimisation measures.

The MHRA’s ARM (Application to Reclassify a Medicine) public consultation process was reviewed in detail by the Group and they identified a number of areas for change in order to improve stakeholder engagement in the consultation process. These included a revision of the ARM consultation document to make it easier to understand and to provide the background information needed to enable stakeholders to provide informed comments on the reclassification proposal. The revised consultation prepared by the MHRA contains an overview of what is being proposed by way of reclassification, and a clear, high level

summary of the conclusions of the assessment as well as any consultation which may already have been undertaken with stakeholders and/or any advice from the Commission on Human Medicines (CHM) – the independent expert advisory body to the MHRA. It also contains focussed questions on specific information that the MHRA is seeking on the reclassification proposal. The revised ARM process will be reviewed and a 'lessons learned' exercise will be undertaken in the next year with further refinements added thereafter to optimise the process. Further work will also be undertaken on how the MHRA can get wide ranging views on a proposed reclassification, including by using digital and social media.

The Group reviewed the measures currently used to manage the risk of reclassifying a medicine from POM to Pharmacy (P), sold only from pharmacies by or under the supervision of a pharmacist. These risk minimisation measures (RMMs) include: the content and design of labels and leaflets; pharmacy support material (training, questionnaires and protocols); and Post Authorisation Safety Studies (PASS) conducted by companies. Some key learnings were identified for the content and approach to this element of the reclassification process such as: the need to address both first-time sales and on-going sales of the product; the need to ensure RMMs are not complicated and do not result in patients being referred to the doctor unnecessarily; and the need to use pack size as a RMM more selectively. The Group also agreed that the provision of educational materials, protocols and questionnaires should not be mandatory for all reclassification applications but considered as part of a reclassification application where appropriate. The Group was enthusiastic about the use of "Active Packs", as a RMM. These are specially designed labels, containing all the information needed to decide on whether a non-prescription medicine was suitable for an individual as well as the usual information about what the medicine is for, how to take it and any special warnings about using it.

The Group stressed the importance of seeking views on RMMs from doctors, pharmacists and patients early during the reclassification process and of ensuring a proportionate approach to managing risk so that the patient benefit is not lost, doctors' workloads are not increased unnecessarily and 'over-medicalisation' of the condition is avoided. As a result, for specific innovative reclassification applications, the MHRA now ensures RMMs are considered by stakeholders early in the reclassification process through the use of Ad Hoc Stakeholder groups (see below). Going forward the MHRA will develop further guidance to ensure RMMs are proportionate and maximise patient benefit and public health outcomes.

The Group advised on the membership, governance and procedures for setting up and running Ad Hoc Stakeholder Groups to consider specific innovative POM to P reclassification applications. Ad Hoc Groups are set up by CHM to provide the opportunity for stakeholders to provide input early in the assessment process. The Group considered the experience of the Ad Hoc Groups that had been set up so far and agreed that they have added significant value to the reclassification process. As a result, the MHRA has now integrated the use of Ad Hoc Stakeholder Groups into the assessment process for innovative reclassification applications, incorporating the recommendations of the Group.

Recognising the importance of ensuring that healthcare professionals as well as patients are aware when a medicine is made available without prescription, the Group advised on methods to inform stakeholders about new reclassifications. These include using publications used by healthcare professionals, such as the British National Formulary (BNF), and websites directed at patients and the public, such as NHS Choices, as well as the MHRA's own website. Considering the views of the Group the MHRA will develop a best practice model for communicating new reclassifications. The Group also advised on an overarching Reclassification Communications and Stakeholder Engagement Plan which will be implemented over the next year.

A number of issues were discussed by the Group that fall outside the scope of the MHRA's medicines regulatory function. These are captured in this report for others to consider.

CHAPTER 1: INTRODUCTION

- 1.1 The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. Part of its role is to ensure that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy.
- 1.2 For many years, the (MHRA) has been at the forefront of moves to reclassify medicines from Prescription Only Medicines (POM) to non-prescription (NP) use when it is acceptably safe to do so. Non-prescription medicines can be legally classified in the UK as either Pharmacy (P) medicines, sold only from pharmacies by or under the supervision of a pharmacist, or General Sales List (GSL) medicines, sold also in general retail outlets and without the supervision of a pharmacist. P and GSL medicines are collectively also called Over-The-Counter (OTC) medicines. More information about the reclassification process can be found [here](#).
- 1.3 The over-riding principle of reclassification of a product is that its safety in use is well established. This is decided after a robust evaluation of the evidence of safety and after seeking advice, as appropriate, from the [Commission on Human Medicines](#) – (CHM) the independent expert advisory body to the MHRA – and, its Expert Groups. An application to [reclassify](#) a medicine also involves identifying the risks associated with reclassification and considering whether and how those risks can be managed in the non-prescription setting.
- 1.3 At the end of 2012, the MHRA launched revised [Guidance on how to change the legal classification of a medicine in the UK](#). The guidance aimed to streamline the reclassification process. This process involves a company or other person or body applying to make a POM medicine available without prescription from pharmacies as a P medicine. They can also apply to make a P medicine available more widely outside of pharmacies as a General Sales List (GSL) medicine. The guidance was developed with the industry through the Better Regulation of Medicines Initiative (BROMI) and in response to the Government's Red Tape Challenge. The BROMI and Red Tape Challenge initiatives aimed to reduce unnecessary red tape to ensure regulation was proportionate and not over burdensome. One of the features of the reclassification guideline was that for innovative new reclassification applications advice would be sought from stakeholder groups. Generally, applications are regarded as being innovative if they are for medicines that will treat conditions that have not previously been able to be treated with non-prescription or OTC medicines.
- 1.4 In addition, work undertaken by a European Union (EU) Project Group on Promoting a Good Governance of Non-Prescription Medicines in EU highlighted the importance of early involvement of stakeholders in the reclassification process. The EU Project Group was an initiative organised by the European Commission. It was made up of representatives from national regulators within the EU, such as the MHRA, and representatives of European groups representing: health professionals, patients, industry and health insurance groups. The EU Project Group looked at how to increase availability, uptake and informed use and choice OTC medicines in Europe. The group also concluded that involving stakeholders after reclassification was important to ensure people have the support and information needed to be able to access non-prescription medicines and make best use of them. The EU project Group recommended that stakeholder platforms/groups should be established at national level to share views and develop strategies to reach a common approach to supporting patient access to non-prescription medicines.

1.5 In 2013 the MHRA held individual meetings with key pharmacy bodies and industry groups to explore what a national stakeholder platform might consist of, and to consider aims for such a group and what it could deliver. A wider pilot meeting of all stakeholders together was conducted. This involved: patients, doctors and pharmacists in both primary and secondary care settings, public health policy officials from across the UK and industry observers. There was clear support for an overarching national stakeholder platform which would meet as needed to consider strategic issues related to reclassification and good governance (access, uptake and informed choice and use) of non-prescription medicines. The MHRA created the UK Stakeholder Platform for Reclassification of Medicines (hereafter called the “Group”) to help inform assessment decisions and to ensure that the voice of the healthcare professionals and patients was heard and able to influence outcomes. The work of the Stakeholder Platform focuses on the parts of the reclassification process that stakeholders can add most value to: the management of risk of supply, and acceptability to patients and health professionals. This report outlines the work of the Group, what the Group has already delivered and the Group’s recommendations. It also describes work already completed by MHRA and ongoing work being undertaken in response to those recommendations.

CHAPTER 2: BACKGROUND

- 2.1 In 2014 MHRA governance recognised the importance of stakeholder engagement in regulatory decision-making and supported the establishment of the Group to help inform assessment decisions and ensure that the voice of the healthcare professionals and patients was heard and able to influence outcomes also noting that some reclassifications were less successful than others.
- 2.2 The Group met six times between November 2014 and March 2017. Its overall remit was to consider how to maximise input from all those affected when a medicine is reclassified from POM to P. This was done by analysing all aspects of the reclassification process other than the evaluation of safety, and identifying where and how stakeholders could give their views. Further details of the remit for the Group are at Annex 1 and membership is at Annex 2. Membership of the Group included: practising healthcare professionals, patients, Government representatives and observers from industry trades associations. Minutes and other papers from these meetings have been posted on the MHRA website and can be found [here](#).
- 2.3 At its first meeting the Group discussed a work plan and the outcomes which would be delivered in the life of the Group. The work plan is at Annex 3. The next sections in this report discuss the way in which work on these topics has been carried out.
- 2.4 During the Group’s discussions some issues were raised that did not fall within the responsibility of the MHRA as they were not about the medicines regulatory process. However, points raised that are outside the scope of the MHRA, and therefore of the Group, are captured in Chapter 9 for others to consider.

CHAPTER 3. UNDERSTANDING OF THE RECLASSIFICATION PROCESS

- 3.1 A clear message coming out of the work is that stakeholders do not have enough understanding of the reclassification process. It is not clear how potential risks of reclassification are managed. If this was better understood it would help stakeholders to provide meaningful input into a reclassification application and to take better advantage of a medicine when it has been reclassified. There is a need to explain more clearly the reclassification process if stakeholders are to be fully engaged in those parts of the process where they can add value. These include the ad hoc stakeholder groups and the public consultations. There is also a need for improved transparency about how an assessment is undertaken and about the outcome of the reclassification process, including when the Commission on Human Medicines (CHM) – the independent expert advisory body to the MHRA – advises against an application.
- 3.2. Some common misunderstandings about the process are related to cost. The MHRA does not take the proposed cost of a medicine into consideration when assessing a reclassification application or ‘encourage’ POM to P reclassification to save NHS money. Prescribing policy is not within the remit of the MHRA and this is not considered in the overall reclassification assessment.
- 3.3 The Group felt that there was a lack of understanding or transparency for key stakeholders about the evidence the MHRA considered in coming to a decision that a medicine may be reclassified. Members of the Group were reassured that the company applying for a reclassification was under a legal obligation to submit all relevant safety data and other information to the MHRA, and that, in addition to considering all data supplied by the company applying for the reclassification (the applicant), where a specific issue arises which is not addressed by the applicant, assessors to seek further data.
- 3.4 Many members of the Group were aware of the MHRA’s public ARM (Applications to Reclassify Medicines) consultations, which seek stakeholders’ views on proposals to reclassify specific medicines. However, they considered that many people were reluctant to engage in the process as they felt that the decision to reclassify had already been made before the consultations took place. Greater clarity was needed on helping those responding to these consultations to understand what issues had been considered by the MHRA and the CHM before stakeholders’ views were sought through public consultation.
- 3.5 It was also not clear to the Group how responses to ARM consultations were assessed; for example, how they were considered in relation to numbers of responses and who they were from. The Group learnt that all responses were carefully considered but a decision was not made based just on the number of respondents in favour or against a proposal. Consideration was taken of whether the response was submitted by an individual or a national representative body and of whether new evidence was presented that had not previously been considered. Issues raised in consultation that were related to a safety concern would be treated with high priority and given greater weight.
- 3.6 The Group also questioned whether public consultation is the best way to obtain feedback and suggested another form of ‘engagement’ may be worth considering. It might be unrealistic to involve large numbers of the public nationally and a patient consultative group may be a more effective way to obtain suitable input to a proposed reclassification.

- 3.7 Some Group members also felt that if a product was reclassified to Pharmacy supply, it was only a matter of time before it became GSL, which is not necessarily the case. The Group agreed that additional information on this in the public domain would be beneficial.

RECOMMENDATIONS

- 3A *Develop a range of on-line resources, written in plain English and addressing findings in this chapter. This would increase healthcare professionals' and patients' understanding of the reclassification process.*
- 3B *Deliver a communications plan that would raise awareness among patients, public and healthcare professionals of which medicines were available over-the-counter and the medical conditions for which they were suitable.*
- 3C *Revise the regulatory assessment process and timelines, and provide greater clarity of the process for industry stakeholders. This would be helpful in providing predictability for applicants when the MHRA is processing a reclassification application.*

CHAPTER 4. FACTORS FOR AN IMPACTFUL RECLASSIFICATION

- 4.1 The Group considered the factors for a successful reclassification that had been identified in the work undertaken by the EU Project Group on Promoting a Good Governance of non-prescription medicines in Europe:
- a. Safety, ease of use and appropriate monitoring for the reclassified product
 - b. A clear beneficial impact on people's health
 - c. Responding to the needs/demand of the public and health professionals, in particular, in terms of patient empowerment, timely access, access to improved treatments and improved quality of life
 - d. Fulfilling unmet needs and addressing conditions that would otherwise remain untreated
 - e. Embraced by health professionals
- 4.2 The Group considered some reclassification case histories against these 5 success criteria. There was a clear message that applications that were regarded as being more successful (and supported by stakeholders) were those that had had minimal changes to a medicine's Summary of Product Characteristics (SmPC). The SmPC is a summary of the conditions under which a product is proposed to be authorised. Examples of products that have been reclassified in this way are, levonorgestrel, the emergency hormonal contraceptive, and chloramphenicol eye drops.
- 4.3 Applications for products which had a significantly different SmPC for the pharmacy product compared to the corresponding prescription medicine, such as simvastatin and tamsulosin, were less supported by stakeholders as they appeared to cause confusion for healthcare professionals and patients. Differences in SmPC could be related to different patient populations, different dosage or contraindications for example. Group members considered that often there was a lack of clarity around the conditions under which these products were authorised for non-prescription supply. Also, the detailed risk minimisation measures, involving complicated supply

protocols which were needed to ensure appropriate supply and use without prescription were considered to be a barrier to access. These products also had complicated indications that were either difficult to self-diagnose, or which required referral to the GP at some stage for confirmation of the diagnosis.

RECOMMENDATIONS

- 4A *Risk management measures should be appropriate, practical, acceptable to patients and health professionals and proportionate.*
- 4B *To ensure simplification of the supply model in the OTC setting, care should be taken not to significantly amend the SmPC.*
- 4C *Lessons learned from the case studies considered by the Group should be published.*

CHAPTER 5: THE PUBLIC CONSULTATION PROCESS

- 5.1 Engagement through the ARM public consultation process is an important aspect in communicating the wider availability of medicines to a more diverse audience. The Group reviewed the current public consultation process and identified some areas for change. In particular, they proposed a new format for the documents used in the consultation.
- 5.2 Previous ARM documents had used a regulatory summary prepared by the company submitting the reclassification application. On detailed review Group members considered that the document did not provide the public and healthcare professionals with the background needed to enable them to provide informed comments on the reclassification proposal. They advised that, as well as providing an overview of what was being proposed by way of reclassification, the ARM consultation document should also present a clear, high level summary of the conclusions of the MHRA's assessment of the application. To provide context this would include the MHRA's assessment, information about any consultation which may already have been undertaken with stakeholders through an ad hoc group (see Chapter 7) and/or any advice from CHM. In addition, there should be a response document written with specific reader groups in mind. The response document should include focussed questions and be divided into sections aimed at the different stakeholder groups. For example, members of the public could be asked, in particular, for comments on the proposed label and leaflet, and healthcare professionals, could also be asked for comments on the proposed SmPC and the Risk Management Plan (See Chapter 6).
- 5.3 More generally, the Group discussed the value of the ARM public consultation. They suggested that with only 21 days for stakeholders to respond it might not be a true public consultation but rather an engagement exercise. They questioned whether this was the best way of obtaining feedback from patients and suggested that a patient consultative group may be a more effective way of engagement to obtain suitable input to a proposed reclassification.
- 5.4 In terms of healthcare professional engagement, the Group considered that involvement in an ad hoc stakeholder group (see Chapter 7) for a specific reclassification may be preferable to using the ARM public consultation arrangements. The stakeholder group would give healthcare professionals and their

professional organisations, as well as patients the opportunity for greater involvement and to influence at an earlier stage in the process.

RECOMMENDATIONS

- 5A *Develop an accessible ARM consultation document which is written with the specific reader groups in mind.*
- 5B *Consider the need for focussed questions within the consultation document aimed at different stakeholder groups.*
- 5C *Ensure that the consultation includes details of how the decisions have been made and the data that have been considered in coming to these views.*
- 5D *Consider the additional measures which could be used to get wide ranging views on a proposed reclassification, including the use of digital and social media.*
- 5E *Ensure healthcare professionals and patients are engaged early in the assessment process.*

CHAPTER 6: THE RISK MANAGEMENT PLAN

- 6.1 The Risk Management Plan (RMP) is a document that describes the current knowledge about the safety and efficacy of a medicinal product and key information on plans and actions needed to gain more knowledge about the product's safety and efficacy. Within the RMP Risk Minimisation Measures (RMMs) are also specified which address how the risks identified are managed. Reclassification of a medicine can change the RMP and introduce new risk minimisation measures.
- 6.2 When the Group reviewed the RMMs currently used in the reclassification process, the discussions revealed some key learnings for the content and approach to this element of the reclassification application. Risk minimisation measures often include revisions to the product information to address how any perceived risks should be managed to enable the medicine to be used without the need for a doctor to oversee treatment. Often additional support materials for pharmacists and their staff to assist with supply of the product are considered to ensure that only suitable patients are identified and supplied with the medicine.
- 6.3 The Group noted that in developing a RMP to support an innovative POM to P reclassification, it was important to reflect that the pharmacist's role and pharmacy professional development in the UK are evolving. Reclassification is not seen in isolation but as part of a bigger picture of people having more responsibility for taking care of themselves through self-care, which moves people into pharmacies and out of other NHS facilities. Pharmacists have a professional obligation to ensure they are competent to undertake any role or professional intervention, so the responsibility is theirs to ensure they have the knowledge and skills to safely and appropriately supply a P medicine. Pharmacists also now have access to NHS summary care records, so they can verify medicines that a patient has been prescribed, as well as details of allergies and adverse drug reactions. The Group agreed that access by pharmacists to summary care records is valuable when advising on choice and use of P medicines.
- 6.4 The Group agreed that, overall, it was important to consider RMMs to manage the risk of both sales in pharmacies and online sales. Whilst pharmacy supervision of a

P medicine sale was required for online sales in the same way as for face-to-face transactions, it was felt that there were different needs for different methods of supply. The Group also recommended that any RMMs being developed should be tested with patients prior to launch.

- 6.5 The Group agreed that a lot of consideration was given to the RMMs which were essential the first time a product was requested by a patient or suggested by the pharmacist in response to treatment advice sought by the patient. However, attention also needed to be given to providing support on how repeat supplies should be managed by the pharmacist.
- 6.6 It was agreed that evidence of established safety in use was critical. The content of the SmPC should be reviewed during a reclassification procedure to address safety in use. Clear and easy to read labelling and patient information, and supplementary materials such as training materials would flow from this. The SmPC, and the labelling and package leaflet were the essential RMMs needed at the point of supply to enable safe and effective use of the medicine. Any educational materials or patient support documents had to be based on the SmPC and should be reviewed and considered as part of the application.
- 6.7 It was agreed that the RMP should not be too complicated and that steps should be taken not to refer patients to the doctor unnecessarily. The Group agreed that management of risk by limiting pack size was not generally understood or supported by patients and healthcare professionals. It was noted that the regulator considered pack size logically, aligning it with RMMs such as maximum length of treatment before referral to a doctor was needed, and risk of harm if a full pack was taken. However, pack size restriction was not seen as helpful by the public in terms of value for money and convenience. Members advised that use of pack size as a risk minimisation measure should be considered more selectively, for example, when there was a potential risk of misuse or other risk to public health.
- 6.8 Pharmacists confirmed that they did find other risk minimisation materials useful, such as protocols and questionnaires to use with patients when deciding on whether a product was suitable for an individual. But largely, they used these when a product was first reclassified to become familiar with supply in the OTC setting. Pharmacists explained that, once familiar with a product and the materials, they were more likely to use only their professional judgement to decide on the most appropriate questions to ask a patient to communicate in a more natural manner.
- 6.9 It was important to note that whilst protocols and questionnaires were used, these could be cumbersome and not very user friendly. When followed literally by pharmacists and their staff they could be regarded by both pharmacists and patients as a barrier to conversation. This disempowered pharmacists and sometimes frustrated patients. Therefore, the provision of educational materials, protocols and questionnaires should not be mandatory for all reclassification applications. But they should still be considered as a RMM as part of a reclassification application where appropriate.
- 6.10 The Group was enthusiastic about using 'active packs' as a RMM. These are packs with specially designed labels containing all the information needed to decide on whether a non-prescription medicine was suitable for an individual as well as the usual information about: what the medicine is for, how to take it and any special warnings about using it. It was felt that well designed and clear 'active packs' were a good aide memoire for the pharmacist when discussing whether a product was suitable for an individual and explaining how to use it correctly. They enabled

pharmacists and their staff to use their consultation skills to discuss the suitability of the product with the patient in a less formal way than when working through questionnaires and protocols. A well designed 'active pack' was also a useful summary for the patient after purchase including when the product remained in the home for future use.

- 6.11 The Group agreed that the patient leaflet was also an important RMM and noted that healthcare professionals and patients might not be aware that improvements had been made to the design and presentation of information in these statutory elements of a product's Marketing Authorisation (the terms under which a product is authorised to be marketed, sold or supplied.) Ordinarily a patient would not be able to read the leaflet until after purchase although all statutory documents are available on-line and more use could be made of this resource in the consultation process.
- 6.12 The group agreed it was important that the views of doctors, pharmacists and patients were sought on the RMMs that were proposed in a reclassification application. This would ensure that the documents developed were acceptable and practical. Companies should be encouraged to consult with stakeholders but in addition and independently, in the case of innovative reclassifications, these issues could also be considered by an Ad Hoc Stakeholder Group (see Chapter 7 below).
- 6.13 The Group advised that there should be a proportionate approach to risk management so that: the patient benefit is not lost, doctors' workloads are not increased unnecessarily and 'over-medicalisation' of the condition is avoided.
- 6.14 The Group discussed the value of Post Authorisation Safety Studies (PASS) as a RMM. These are studies undertaken by the company after the product has been reclassified to measure whether its safety profile has changed. They agreed that this was a valuable tool in some cases provided the study is designed well and will provide meaningful statistics to confirm the safety of the product in the non-prescription setting. PASS could also be a way of testing that protocols are in place and/or whether they are acceptable to pharmacists and patients in practice, and that their use ensures the pharmacist correctly identifies those people who should and who should not be using the product.

RECOMMENDATIONS

- 6A *The approach to risk management should be proportionate to the risk of use of the product. This will ensure that the potential benefit to patients of availability of the product without prescription is maximised and that the appropriate level of healthcare professional input is available within the wider context of encouraging people to look after themselves when it is safe to do so, enabling them to treat conditions themselves without the need for a prescription.*
- 6B *Materials used to manage risk should be subject to testing, review and comment by stakeholders to ensure that these add value to the supply and use of the P medicine.*
- 6C *Risk minimisation measures should be designed so that they are applicable to both face-to-face and online consultations.*
- 6D *Measures put in place to manage risks should be acceptable to healthcare professionals and patients, and encourage communication between them rather than acting as a barrier to access.*

- 6E *Where possible the use of 'active-packs' (including the key risk minimisation information) should be considered and encouraged.*
- 6F *Risk minimisation measures should cover the management of both first-time supply and repeat requests for the medicine.*
- 6G *Risk minimisation measures should be submitted as part of the application as the effectiveness and acceptability of these materials will be an important consideration when making a decision on reclassification.*

CHAPTER 7: AD HOC STAKEHOLDER GROUPS

- 7.1 The use of Ad Hoc Stakeholder Groups to consider specific reclassification applications is a key element of the revised reclassification process, particularly for innovative POM to P reclassification applications. They are set up by CHM and chaired by a CHM Member. Their purpose is to provide the opportunity for stakeholders to provide input early in the assessment process. Specifically, they are asked to consider the clinical, professional and practical aspects of a proposed reclassification application as well as patients' views of the proposed reclassification. The decision about whether an Ad Hoc Stakeholder Group should be set up is made by the CHM.
- 7.2 An Ad Hoc Group will meet on one occasion after the application has been assessed by the MHRA and the key issues that need to be addressed by stakeholders have been identified. The views of the Ad Hoc Group will be included in the MHRA's assessment report prepared for the CHM when the Commission's advice is sought on a reclassification application.
- 7.3 The Group advised on the membership, governance and procedures for setting up and running Ad Hoc Stakeholder Group.
- 7.4 The Group considered it to be critically important that the healthcare professional membership of an Ad Hoc Group included practising healthcare professionals who had regular patient contact as well as representatives of professional organisations.
- 7.5 The Group also agreed that all members of an Ad Hoc Group should be confident in expressing their opinion within a diverse group of people with different knowledge, skills and experience. This needed to be reflected in: the recruitment process; the way members were briefed and prepared in advance of the meeting; and the way in which meetings were chaired and conducted.
- 7.6 The Group discussed feedback from the Ad Hoc Groups that had been run so far and noted that, overall, they have helped to shape the content of the marketing authorisation and the RMMs for the proposed P products.
- 7.7 The Group agreed that, based on the experiences from Ad Hoc Groups set up so far, they have added significant value to the reclassification assessment process. Positive feedback had been received from the stakeholders who took part. Patient members had reported their view was valued. Healthcare professional members remarked that the meetings were focused on patients, whose views were, at times, surprising and challenging. It was also noted that contributions from patients could not have been captured through a public consultation because in a meeting they could discuss and interact with each other and with the healthcare professionals.

RECOMMENDATIONS

- 7A *Views from Ad Hoc Stakeholder Groups are likely to be required for POM to P reclassification applications under the following circumstances:*
- *New therapeutic area (condition to be treated) for a P medicine*
 - *Addition to an existing therapeutic area for a long-term condition*
 - *Potential for shared NHS and OTC care for the treatment of a chronic condition*
- 7B *A set core group of representatives should be recruited to make up the membership of Ad Hoc Stakeholder Groups, and recruitment should follow an established process.*
- 7C
- 7C *As part of its communications plan the MHRA should seek to increase exposure for the reclassification work via its website to try to get more stakeholders interested in taking part in an ad hoc group.*

CHAPTER 8: COMMUNICATING DECISIONS ON RECLASSIFICATION

- 8.1 The Group noted that for the benefits of a reclassified medicine to be realised, healthcare professionals as well as patients, needed to be aware that the medicine was now available from pharmacies. Both healthcare professionals and patients needed to understand the circumstances under which a product was now available without prescription. There was a particularly low awareness among doctors of new innovative reclassifications and how these products can be supplied without prescription. There was also a low awareness among doctors of the range of OTC medicines and the conditions that could be treated with them.
- 8.2 The Group considered and advised on the preferred and most effective methods of informing stakeholders about new reclassifications.
- 8.3 The Group advised that the practicalities of publishing information about medicines reclassifications and about the illnesses and conditions on which pharmacists can provide treatment advice should be considered. Publications to consider include the British National Formulary (BNF) or Monthly Index of Medical Supplies (MIMS) as the messages were likely to be picked up by both pharmacists and doctors. Prescribers needed to know, for example, the limitations of the circumstances under which the new P medicine can be supplied by the pharmacist and the contents of the RMP, particularly if the reclassification could have an impact on their practice. Their practice could be affected, for example, if a pharmacist could not supply a P product without an initial diagnosis by the doctor or if the product could only be used for a defined period after which the patient would need to seek advice or a diagnosis from their doctor. For applications that include supply protocols that refer patients to the doctor after a certain time, GPs needed to be fully engaged with their role in that supply model.
- 8.4 Patients usually find out about new medicines through advertising, which is regulated by MHRA under the Human Medicines Regulations. The Proprietary Association of Great Britain (PAGB) also pre-vets the advertising of products for their member companies. Where a new medicine is made available OTC the MHRA will review the advertising materials and any educational materials being developed prior to launch.

The Group agreed that advertising should not be the only way patients heard about new products and that the MHRA should communicate new reclassifications directly. Possible ways to do this included the development of a digital platform, combined with social media.

- 8.5 The Group suggested that as well as announcing individual reclassified products, the MHRA should include the self-care message more generally in their communications, highlighting which conditions pharmacists could provide advice on rather than which substances are available in P medicines.
- 8.6 The Group agreed that more use could be made of the NHS Choices website to inform patients about new reclassifications and their correct use. This should also be an important source of information about medicines that have been reclassified from non-prescription to prescription only for safety reasons.

RECOMMENDATIONS

- 8A *Develop a best practice model for communicating new reclassifications considering the views of all stakeholders.*
- 8B *Work with other information providers such as NHS Choices and other patient-focussed providers, BNF and MIMS to ensure wide dissemination of information about newly reclassified medicines.*
- 8C *Consider the need for MHRA to communicate which therapeutic areas can be managed with OTC medicines in addition to providing a list of medicines which are available through pharmacies and more widely.*

CHAPTER 9: WIDENING THE SCOPE OF THE MHRA

Issues discussed by the Group that fell outside the scope of the MHRA's medicines regulatory function are detailed below along with recommendations. These will not be taken forward by the MHRA but are captured for others to consider.

9.1 MEASURING OUTCOMES

- 9.1.1 From a regulatory perspective the output of a reclassification application is the final decision to either refuse, or approve the application. If the application is approved the product is subsequently introduced into the market by the company making it. Outcomes, such as increases or decreases in number of patients seeking advice from a doctor, are dependent upon the use and uptake of a reclassified medicine. These are not part of the regulatory process, unless they have been specifically requested as part of a post-authorisation safety study. From an industry perspective, a commercial outcome is relatively simple to quantify.
- 9.1.2 The Group agreed that measuring outcomes was important following a reclassification and that the most important outcome would be that the product would benefit the health and wellbeing of the public. However, this was a difficult outcome to measure. Useful markers could be: awareness; use and perceived benefits of a reclassified product (determined from a stakeholder survey); and potential financial savings to the NHS. The table below summarises possible outcome measurements and methods to measure them.

Table 1: Potential reclassification outcomes

Outcome	How to measure
Measuring compliance with the supply model for the reclassified medicine to ensure the risk minimisation measures are robust to support the pharmacy supply	Post-authorisation study
Ease of use	Patient surveys
Appropriate monitoring	Yellow card reporting; reviewing other outcomes (e.g. safety).
Clear beneficial impact on people's health	Post-authorisation study to review clinical outcomes in patients buying a reclassified medicine.
Patient empowerment	Patient surveys
Timely access	Patient/Pharmacist surveys
Access to improved treatments	Not practical to measure
Improved quality of life	Patient surveys
Addressing conditions that would otherwise remain untreated	Not practical to measure
Embraced by health professionals	Surveys of healthcare professionals; sales and prescription data
Primary route of supply switched from prescription to non-prescription	Sales and prescription data

- 9.1.3 The Group agreed that time points for measuring outcomes would be specific for each product but to get meaningful results, it is more likely that these will be set over a long period (up to five years), rather than in the short term.
- 9.1.4 The Group also agreed that, whilst outcomes measurement was seen as an important part of increasing access to medicine through reclassification, it was not within the remit of the MHRA to undertake this work so it needed to be taken forward by others such as the manufacturer and community pharmacy organisations. The Group acknowledged that a major barrier to measuring outcomes would be cost and who would pay for it.
- 9.1.5 The Group noted that whilst the MHRA cannot measure success, it does monitor safety and will take regulatory action if necessary. It might, for example, in the light of new safety information, reconsider the terms under which a product can be authorised as a non-prescription medicine. This could be done by changing the patient information or the population for which the product can be used.
- 9.1.6 The Group agreed that further work was needed on identifying:
- The types of reclassification applications that would benefit from outcomes measurement
 - What action should be taken in the event of the outcomes measured being negative or positive
 - How work on outcomes measurement would be funded

9.2 ROUTES TO RECLASSIFICATION

- 9.2.1 The Group commented that the current regulatory system for reclassification was largely industry led. This is because reclassification is on a product basis with the

product's classification being part of its Marketing Authorisation. The Marketing Authorisation Holder will have available the data and evidence needed to support an application to reclassify their product. While a case for reclassification could be made by any interested party, including for example: a patient group, a professional body or a government body, cooperation would be needed from the Marketing Authorisation Holder to put a reclassified product on the market so it was available to the public. It was therefore difficult for stakeholders to take a unilateral approach to reclassification.

9.3 EFFECTS OF NHS POLICIES ON RECLASSIFICATION

- 9.3.1 During their discussions about the regulatory reclassification process, the Group identified NHS policies that could influence different stakeholders' attitudes to reclassification. For example, in Scotland, Wales and Northern Ireland all NHS prescriptions are free of charge. Additionally, in Scotland, there is a national scheme in place whereby people could get free NHS treatment for minor illnesses from their pharmacist rather than having to go to their doctor. There are similar, locally-led schemes in England. This could make reclassification of less interest to the public in these countries. Additionally, there were developments in the field of NHS prescribing in England about possible restrictions on the prescribing of some OTC medicines which could influence stakeholders' attitudes to reclassification.
- 9.3.2 The Group noted that input from stakeholders and decisions taken by the MHRA to reclassify a product from POM to P are made based on safety. The MHRA does not take into consideration the consequences of a medicine's availability on the NHS if it is reclassified.

RECOMMENDATIONS

- 9A *Develop Guidance on outcome measurement for innovative reclassifications which have the potential to impact significantly on people's health.*
- 9B *Consider the production of a guidance document which reflects the input from community pharmacy, the medical and nursing professions and industry to measure outcomes with real-world data.*
- 9C *Led by the Department of health and working with appropriate stakeholders a process should be considered that will enable other interested parties, apart from the industry, to take a unilateral approach to reclassification.*

CHAPTER 10: MHRA RESPONSE AND WORK DELIVERED

MHRA has already taken forward different strands of work to deliver the recommendations in this report and some of these have already been completed.

Chapter 3 – Raising Awareness

- Working with the PAGB – the trade association for the over-the-counter medicines industry – a new reclassification process has been developed and published. The report of this work can be [located here](#)
- A [new reclassification webpage](#) has been delivered which provides more accessible information on the way in which medicines can be obtained without prescription within the UK. Further work will be undertaken to increase the information available on reclassification and implement other recommendations in this report

Chapter 4 – Factors for a Successful Reclassification

- The assessment process now considers more widely the learnings from the case studies which were reviewed and greater emphasis is placed on proportionate risk minimisation measures

Chapter 5 – Public Consultation

- The public consultation process has been overhauled and a new procedure has been put in place. Since the new process has been established seven consultations have been undertaken. Responses to these and the value added will be reviewed and a ‘lessons learned’ exercise will be undertaken in the next year with further refinements added thereafter to optimise the process

Chapter 6 – Risk Management

- Routinely the risk minimisation measures are reviewed during the application assessment
- Risk Minimisation Measures are now discussed by an Ad Hoc Stakeholder Group if it is convened
- Going forward longer term, further guidance for assessors and the industry will be developed to ensure risk management measures are proportionate and maximise patient benefit and health outcomes
- MHRA will consider with the Royal Pharmaceutical Society what guidance is needed to ensure patients can access a similar level of professional advice in both the face-to-face and on-line supply scenarios
- Guidance will be elaborated for applicants to make it clear that risk minimisation measures should be subject to testing with stakeholders where relevant and the use of active packs will be encouraged

Chapter 7 – Ad-hoc Stakeholder Groups

- The use of Ad Hoc Stakeholder Groups for innovative reclassifications has been integrated into the reclassification assessment process

- MHRA internal guidance and procedures for establishing and running an Ad Hoc Stakeholder Group have been developed incorporating the recommendations of the Group
- On the reclassification web page an invitation has been added encouraging stakeholders to express an interest in taking part in Ad Hoc Stakeholder Groups. The MHRA will collect details of all those interested so that they can be approached in the future when an Ad Hoc Group needs to be set up

Chapter 8 – Communications

- A new web presence has been launched which provides more accessible information on the availability of medicines in the UK
- The work of the UK Reclassification Stakeholder Platform has been [published on-line via the MHRA web pages](#)
- MHRA will develop a best practice model for communicating new reclassifications taking into account the views of all stakeholders
- Further work with other information providers such as NHS Choices, BNF and MIMS to ensure wide dissemination of information about newly reclassified medicines will be undertaken
- MHRA will consider how best to communicate which therapeutic areas can be managed with over-the-counter medicines in addition to providing list of medicines which are available through pharmacies and more widely
- The Reclassification Communications and Stakeholder Engagement Plan agreed by the Group will be implemented over the next year

Chapter 9 – Outcome Measures

- MHRA will work with industry and healthcare professional organisations to develop guidance around outcome measurement for innovative reclassification applications which have the potential to impact significantly on people's health

UK MEDICINES RECLASSIFICATION STAKEHOLDER PLATFORM

Terms of reference

1. To advise on strategies and processes that will ensure maximum engagement of all stakeholders in the reclassification of medicines.
2. To advise on strategies and processes that will ensure the public has the support needed, including from healthcare professionals, to benefit from increased access to medicines after reclassification.
3. To advise on:
 - the composition of ad-hoc task and finish groups set up to consider specific reclassification applications, and learning needs and support for group members to maximise their contributions to the group
 - the value of wider public consultation on reclassification applications and how to achieve maximum stakeholder engagement in the process
 - the advantages and disadvantages of risk minimisation measures used as part of the reclassification process from the perspective of healthcare professionals and medicines users and, where appropriate, to identify how these can be improved
 - the information needs of all stakeholders following the reclassification of a medicine to ensure the public is fully supported with sufficient, consistent and non-conflicting information about its safe and effective use
 - elements that should be considered, from stakeholders' perspectives, when reviewing the outcome of a reclassification
 - whether there is public benefit in taking a proactive approach to reclassification of medicines
4. To advise on any other strategic issues concerning stakeholder engagement in the reclassification process.

UK MEDICINES RECLASSIFICATION STAKEHOLDER PLATFORM

Members

- Simon Adams, lay representative
- Johanne Barry, Pharmacy Forum, Pharmaceutical Society of Northern Ireland
- Marguerite Beard-Gould, lay representative
- Rob Darracott, Pharmacy Voice
- Martin Duerden, Royal College of General Practitioners
- Trevor Fernandes, lay representative
- Andrew Green, British Medical Association
- Alpana Mair, Scottish Government
- Bob McNabb, lay representative
- Theo Raynor, University of Leeds
- Gul Root, Department of Health
- Ash Soni, Royal Pharmaceutical Society
- Ruth Wakeman, Royal Pharmaceutical Society
- Roger Walker, Chief Pharmaceutical Officer, Welsh Government.
- Bruce Warner, NHS England

Observers

- Helen Darracott, the Proprietary Association of Great Britain
- Sunayana Shah, Association of the British Pharmaceutical Industry
- Paul Flemming, British Generic Manufacturers Association

UK MEDICINES RECLASSIFICATION STAKEHOLDER PLATFORM

Work Plan

Work stream	Methodology	Action	Date Actioned	Contribution to delivery of the TOR	OUTPUT
Increase Platform Members' understanding of the reclassification process	Overview of the UK and EU legislation and the reclassification process introduced in 2012	- Presentation from the MHRA	- February 2015	Item 1 Item 2	Platform members have a better understanding of the reclassification process and are better able to contribute to the work of the platform. The learning gained from this will also inform how ad hoc stakeholder group members will need to be briefed to enable them to contribute when their views are sought on specific applications. The learning will also inform on how wider stakeholder understanding of the reclassification process can be achieved in the comms and engagement plan

Increase Stakeholders' understanding of the reclassification process	Consideration of stakeholders' perspectives of reclassification	<ul style="list-style-type: none"> - Discussion on reclassification on "myths" raised by platform members - Explore the possibility of publishing articles in the pharmacy and medical press to address the reclassification on "myths" 	- February 2015	Item 1 Item 3	The learnings from these discussions and the actions agreed by the platform have been incorporated into the communications and engagement plan.
	Discuss reclassification case histories	- discussion on papers prepared by the MHRA	<ul style="list-style-type: none"> - Levonorgestrel and simvastatin considered February 2015 - Chloramphenicol and tamsulosin considered September 2015 		The learnings from these discussions will be used in the review of the process for assessing reclassification applications
Analysis of key elements of the reclassification process	Ad Hoc Task and Finish Groups Consideration of: <ul style="list-style-type: none"> - composition - what input/advice is needed - What groups members need to ensure they can effectively advise 	- Paper to be prepared for consideration	September 2015	Item 1 Item 3 Item 4	The learnings from these discussions will be used to prepare MHRA internal guidance on setting up and running Ad Hoc Stakeholder Groups

	<p>Public Consultation Process</p> <ul style="list-style-type: none"> - Consideration of the revised ARM public consultation process and how it can be revised to enable maximum wider stakeholder engagement and input into the reclassification process - Review of the reclassification process to ensure it is fit for purpose 	<ul style="list-style-type: none"> - Paper to be prepared for consideration - Paper to be prepared for consideration 	<p>February 2015 September 2015</p> <p>Autumn 2016</p>	<p>Item 1 Item 3 Item 4</p>	<p>The learnings from these discussions will be considered in the review of the process for public consultations and overall for assessing reclassification applications</p>
	<p>Risk minimisation measures used in reclassification</p> <ul style="list-style-type: none"> - Consideration of how the Risk minimisation measures can meet the needs of pharmacists and doctors as well as effectively manage the risks identified in a reclassification application 	<p>Analyse the risk minimisation measures used as part of the reclassification process (including pack size, length of treatment, limitation of indication and protocols) and, from a stakeholder perspective, discuss their advantages and disadvantage and how to improve</p>	<p>December 2015</p>	<p>Item 1 Item 3</p>	<p>The learnings from these discussions will be considered in the review of the reclassification process</p>

		understanding of these measures.			
Communicating decisions on reclassification and supporting appropriate use after reclassification	Analyse the current situation regarding access to, and awareness of reclassification processes and decisions. Consider current sources of information and learning for pharmacists, doctors and the public on newly reclassified medicines, identify gaps and improvements needed to ensure sufficient and consistent, non-conflicting information for all stakeholders	Paper to be prepared for consideration Paper to be prepared for consideration Paper to be prepared for consideration	December 2015 December 2015 December 2015 Autumn 2016	Item 2 Item 3	The learnings from these discussions will be considered in the review of the reclassification process Develop guidance on introducing a newly reclassified medicine onto the market
Measuring outcomes of reclassification	Identify the elements that need to be considered in order to review the outcome of a reclassification	Paper to be prepared for consideration	March 2016	Item 3	

	on (e.g. stakeholder awareness, where applicable, implementation of a pharmacy protocol, where appropriate referrals to GP, where appropriate correct choice by the user without input from a healthcare professional)				
Consider options for a proactive approach to reclassification	Organise a day to consider this with a wider group of people. Issues to consider: - analysis of the advantages and disadvantages - how could proactive approach work - how do could it be approached - who should be involved in the day	Paper to be prepared for consideration	Autumn 2016	Item 3	A day will be organised and the results published
Outcome measurement and review of the work of the Platform	Undertake a full review of the work streams and measure	Paper on outcomes measurement to be prepared for consideration	March 2016		

	outputs against delivery of the TOR		December 2015		
	Review the membership of the platform after one year including the skill mix and the requirements for a more formal selection process.				