



**REPORT OF WORKSHOP ON
RECLASSIFICATION AND GOOD GOVERNANCE
OF NON-PRESCRIPTION MEDICINES**

June 2014

CONTENTS PAGE

1. EXECUTIVE SUMMARY
2. THE WORKSHOP'S CONTEXT
3. EUROPEAN BACKGROUND
4. MOVING FORWARD IN UK
5. STAKEHOLDER ENGAGEMENT
6. OVERALL WORKSHOP FINDINGS
7. CONCLUSIONS
8. NEXT STEPS
9. ATTACHEMENTS

Executive Summary

An EU Project Group, part of the European Commission's Platform on access to medicines, identified that a key success factor for access to non-prescription medicines is engagement of all stakeholders. To this end the MHRA organised a multi-stakeholder workshop to identify how best to involve all stakeholders in the process of reclassifying medicines in the UK from Prescription Only (POM) to Non-prescription and in ensuring access and appropriate use of medicines after reclassification. The workshop also explored the scope in principle for increasing access to medicines through reclassification within two therapeutic areas – one in which there were already a number of medicines available to treat some of the conditions within therapeutic area, and the other which was a completely new therapeutic area for treatment with non-prescription medicines.

There was clear support from workshop participants for establishing an overarching Strategic Platform for Reclassification comprising skilled and experienced individuals from stakeholder representative bodies, meeting as needed to consider high-level issues related to reclassification and good governance of non-prescription medicines, and to oversee the governance of reclassification submission, methods of work and outputs. A number of issues raised in discussion were identified as areas that could be addressed by the Platform.

Workshop participants also agreed that there was a need for ad hoc “task and finish” Reclassification Stakeholder Groups to consider specific reclassification applications and that the MHRA should facilitate wider engagement of stakeholders in reclassification using social media. The remit of the Reclassification Stakeholder Groups will be to consider the professional and practical aspects of a proposed reclassification. Membership of each group would depend on the reclassification application under consideration. It would include not only stakeholder representatives but also healthcare professionals and patients with a special interest in the therapeutic area in question.

It was clear from the workshop findings that, to enable effective engagement, stakeholders needed more understanding of the reclassification process and the regulation of non-prescription medicines, and better knowledge and understanding of the perspectives, of all stakeholders. There was also scope for improving the patient “journey” between prescription and non-prescription supply especially immediately after reclassification. These would be amongst the issues that would be considered by the stakeholder platform.

Overall the pilot group discussions on the principle of widening access to medicines within specific therapeutic areas gave valuable insight into what would be needed to prepare a Reclassification Stakeholder Group to look at a specific application.

Work will now be taken forward by the MHRA with a view to establishing a stakeholder platform which will have its first meeting in November 2014.

The Workshop's Context

For many years the MHRA has been at the forefront of moves to reclassify medicines from prescription only (POM) to non-prescription use when it is acceptably safe to do so. Non-prescription medicines can be 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.

A number of regulatory and policy initiatives have been undertaken by the MHRA to encourage and facilitate innovation in reclassification in the UK including:

- Legislative amendment in 2002 to enable product-specific reclassification by amendment of the Marketing Authorisation rather than a formal update of an Order
- The formation and report of the Ministerial Industry Strategy Group (MISG) Forum on widening access to medicines via reclassification, set up to explore how to increase the pipeline of medicines available in the UK without prescription.
- A new streamlined [reclassification guideline](#), published in December 2012, as part of the Government's red tape challenge, and through the Better Regulation of Medicines Initiative (BROMI), to speed the process within the legislative framework of moving medicines from POM to P or GSL.

Over the years there has been a significant number of innovative POM to P reclassifications in the UK, not only for the treatment of acute, short term, self-limiting conditions, but also for more chronic or recurrent disease management. However, over the recent few years, despite the launch of the new UK reclassification guideline there have been very few applications in the UK for innovative reclassifications. Moreover, it has become clear that a successful regulatory process does not always result in a successful reclassification for patients, healthcare professionals and companies. While some POM to P reclassifications have provided benefit both to individuals and to the public's health, others have not reached their anticipated potential or resulted in an increase in access to those medicines. This could indicate that factors other than the regulatory process alone can have a significant effect on improving access to a medicine without prescription.

European Background

In 2011 the EU Commission (DG Enterprise) established the Platform on Access to Medicines in Europe. This aimed to enhance collaboration among Member States and all relevant stakeholders, in order to find common, non-regulatory approaches to timely and equitable access to medicines, which can be addressed within the current European legal framework.

The UK was invited to co-chair with the Commission one of the Project Groups of the Platform on Access to Medicines - Promoting a Good Governance of Non-Prescription Medicines in the EU. The objective of the Project Group was to identify the necessary elements to ensure availability, uptake, and informed use and choice of non-prescription medicines, including medicines after a change of classification. The project in particular investigated the role of competent authorities, pharmaceutical companies, consumers and patients, and healthcare professionals in facilitating such uptake and proper use. The [working group's report](#) was published in June 2013.

The findings of the group were that there is great diversity throughout the EU in relation to access to non-prescription medicines. Influencing factors included differences in healthcare policy and systems and national cultures. However common views were found in relation to success factors for reclassification and barriers to access to non-prescription medicines:

Factors making a successful reclassification:

- Safety, ease of use and appropriate monitoring for switched products
- A clear beneficial impact on public health
- Responding to the needs/demands of citizens and health professionals, in particular, in terms of patient empowerment, timely access, access to improved treatments and improved quality of life
- Fulfilling unmet needs and addressing conditions that would otherwise remain untreated
- Embraced by health professionals

Barriers to access to non-prescription medicines:

- Focus on risk without consideration of benefit
- Attitudes and knowledge of stakeholders
- Differing views between stakeholders
- Lack of awareness of the product
- Lack of availability of information for patients
- Reimbursement

Considering a key success factor for access to non-prescription medicines is engagement of all stakeholders two of the final recommendations of the project group were that:

- Stakeholders should be involved early in the reclassification process so that concerns can be addressed and training prepared.
- Stakeholder platforms 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

Moving forward in UK

In September and October 2013, the MHRA held bilateral meetings with key stakeholder organisations (the Royal Pharmaceutical Society, the General Pharmaceutical Council, Pharmacy Voice and the Proprietary Association of

Great Britain) to discuss plans for setting up a stakeholder platform and seek views on its format and aims.

Taking into consideration the views expressed at the bilateral meetings a pilot stakeholder platform was held in the form of a workshop on 2nd June 2014. The main objective of the workshop was to identify the best way of getting stakeholders involved in reclassification of medicines and of ensuring access and appropriate use after reclassification. The workshop also piloted the concept of stakeholder engagement in specific reclassifications by exploring in principle the scope for increasing access to medicines through reclassification within two therapeutic areas; one in which there were already a number of medicines available to treat some of the conditions within therapeutic area and the other which was a completely new therapeutic area for treatment with non-prescription medicines. The Agenda is at **ANNEX 1**.

The workshop was attended by a range of stakeholders including patients, doctors and pharmacists in primary and secondary care, representatives from Public Health England and the Chief Pharmaceutical Officer for Wales. A List of participants is at **ANNEX 2**.

Participants were given background material to read and some questions to consider in preparation for the meeting.

Discussions began by focussing in general on stakeholder engagement. Attendees were asked to consider in breakout groups who should be involved in a stakeholder platform, how it should function and what it should deliver.

The afternoon workshops focussed on the two therapeutic areas. The skin was an example of a therapeutic area that includes a number of conditions for which there are already OTC medicines available to treat them in the community pharmacy. It provided the opportunity to explore whether more medicines could be made available to treat existing non-prescription skin conditions and whether the types of conditions suitable for treatment with non-prescription medicines could be extended. Erectile dysfunction was used as an example of a potentially new therapeutic area for treatment with non-prescription medicines.

A report of the breakout sessions on exploring the scope for increasing access to medicines through reclassification within specific therapeutic areas is at **ANNEX 3**.

It should be noted that the workshop focussed on reclassification in the context of UK clinical and pharmacy practice. The scientific analysis of reclassification applications and the regulatory challenges associated with the possible reclassification of medicines authorised through European procedures were not considered.

Stakeholder engagement

An overview of the regulatory reclassification process and some questions were presented to the workshop:

- How can stakeholders be more involved in the reclassification process?
- What should be the composition of the stakeholder groups that will be set up under the streamlined reclassification process?
- How much knowledge of the reclassification process do stakeholders need to be able to fully engage in stakeholder consultation?
- Are doctors sufficiently informed of new reclassifications and the conditions/restrictions for non-prescription supply?
- How best can pharmacists be supported to ensure they are able to provide advice on use of a newly reclassified medicine?
- How can the label and patient information leaflet be optimised to ensure the patient can decide if a non-prescription medicine is suitable for them and to help them to use newly classified non-prescription medicines safely and effectively?

At the workshop attendees were also asked to consider the following questions:

1. What would you want a stakeholder platform to achieve? What will the platform deliver?
2. Who do you think needs to be involved?
3. How should it function?

Outcome of discussion

1. An overarching Strategic Platform for Reclassification

There was clear support for the idea of an overarching Strategic Platform which would meet as needed to consider strategic issues related to reclassification and good governance of medicines.

The platform should comprise a core group made up of skilled and experienced individuals from bodies representing all stakeholder groups including patient support groups and representatives from the devolved administrations. Experts would need to be brought in depending on the agenda. For example, pharmacists and GPs with specialist interest, doctors in secondary care specific patients/patient support groups, those involved in the education and training of pharmacists and doctors, and there should be transparency with regards to the members of the group. There was divided opinion on whether manufacturers should be part of the platform as they had other opportunities to influence the reclassification process, including through their applications. Some participants indicated that they were not able to talk frankly in front of industry representatives.

It was also suggested that there should be a wider EU network as there were different drivers for reclassification and access to non-prescription medicines across Member States.

A number of general issues related to reclassification and access to non-prescription medicines were raised. There was a perception by some that the consultation process with pharmacists when people were seeking to purchase P medicines was seen as a barrier, but on the other hand the implications were raised of the possibility that P medicines, which are currently mostly available behind pharmacy counters may become available on self-selection from open shelves. Some healthcare professionals and patient representatives were concerned that non-prescription availability could actually reduce access if, for example, Clinical Commissioning Groups in England stopped GPs from prescribing these medicines to save costs. The issue of costs of non-prescription medicines versus free availability on prescription was also identified and it was suggested that this could be more significant in some devolved administrations, for example, where all prescriptions were free. It was clarified that cost is outwith the MHRA's remit.

Patients' other perspectives of non-prescription medicines were also discussed, including the view that a medicine which is obtained without prescription may not be as effective or 'as good' as a medicine received on prescription, and questions were raised about why there was a pack size restriction on some non-prescription medicines or restrictions on dose and length of treatment.

More specific issues were also discussed including concerns where conflicting messages from healthcare professionals and from the product information can cause confusion to patients.

Questions were also raised about how it was known that a reclassified medicine was used safely and correctly under the conditions of the P or GSL licence and what steps could be taken if it was found not to be.

Many members of the workshop had not appreciated that in most cases a reclassification will result from an application being submitted from the marketing authorisation holder and it was suggested that the MHRA could be more proactive in identifying possible candidates for reclassification that would be of benefit to public health and in extending the terms of authorisation of a non-prescription medicine in the light of experience in use or the emergence of new clinical treatment guidelines.

A number of issues raised in discussion could be addressed by the platform and could be identified as key outputs:

- Establishing and reviewing the process for stakeholder input into reclassification applications
- Identifying the information needs for all stakeholders to ensure consistency of information, in line with a product's Summary of Product Characteristics (SPC), which are a description of a medicinal product's

properties and the conditions attached to its use, and full engagement with the reclassification process (including consideration of IT solutions)

- Tackling issues related to reclassification in general that are raised by stakeholders, such as pack size and length of treatment, limitation of indications for non-prescription medicines
- Considering what approaches to reclassification need to be addressed to prevent conflicting messages
- Developing a process to support appropriate access after reclassification, including signposting to patient groups
- Reviewing the outcome of reclassification applications, including through the use of post marketing studies
- Developing a mechanism to deal with changes in clinical guidance that could conflict with the conditions of non-prescription licences
- Developing a mechanism for a proactive approach (from patients and healthcare professionals) to identifying for consideration within the legislative process possible reclassifications or for extending the conditions for existing non-prescription medicines that will meet patient needs and benefit public health
- Considering the extension of, or other changes to, existing non-prescription licences – to reflect new clinical guidance practice and developments in practice

It was agreed that there was a need for all stakeholders and especially those involved in an overarching Stakeholder Platform or in a Reclassification Stakeholder Group to have a greater understanding of the regulatory process and enough information to enable meaningful stakeholder engagement.

2. Ad Hoc Reclassification Stakeholder Groups

There was a clear view that ad hoc “task and finish” Reclassification Stakeholder Groups would also be of benefit to consider specific reclassification applications as part of the MHRA’s new process for assessing reclassification applications.

The membership of an ad hoc Reclassification Stakeholder Group would depend on the application that was under consideration; they would include not only stakeholder representatives but also healthcare professionals and patients with a special interest in the therapeutic area in question.

3. Wider stakeholder engagement

In addition to the establishment of an overarching Strategic Platform and ad hoc Reclassification Stakeholder Groups, it was suggested that the MHRA should facilitate wider engagement of ‘ordinary’ stakeholders in reclassification proposals by setting up a forum via social media or through Facebook.

Overall Workshop findings

The findings of the workshop indicated that there was clear support for an overarching Platform that would meet as needed to consider strategic issues related to reclassification and good governance of non-prescription medicines. A number of areas were identified, which could form the terms of reference and the initial programme of work.

It was clear from the discussions that, to enable effective engagement, more understanding is needed by stakeholders of the reclassification process, including its scientific rigour, the regulation of non-prescription medicines in general and the implications for NHS supply of reclassification. The difference between P and GSL classification was not clearly understood and concerns that a medicine may be made less available on the NHS if reclassified need to be addressed. The link between cost and pack size was raised. Measures to keep the pack size small to manage the risk of P or GSL availability might become barriers to access/uptake because of the cost of these medicines.

There appears to be scope for improving the “patient journey” between prescription and non-prescription supply especially immediately after reclassification, for example by ensuring doctors as well as pharmacists are aware that a medicine has been reclassified and under what conditions. Patients currently do not understand why, when a medicine is reclassified, it can only be obtained without prescription under certain circumstances and mixed messages from pharmacists and doctors can cause more confusion.

There is also benefit in exploring how to gain evidence of usage of a new non-prescription medicine and of the outcome of the reclassification in the most practical way and with the minimum of burden for all stakeholders.

There was also a clear view that ‘ad hoc’ Reclassification Stakeholder Groups would be of benefit for considering specific reclassification applications. The group discussions about widening access in principle to medicines through reclassification within two specific therapeutic areas gave valuable insight into what would be needed to prepare a group to look at a specific application. For instance, participants will need a better understanding of how the MHRA has assessed a reclassification application they are being asked to consider and what the key issues are in the case of the application that need to be addressed. The MHRA’s streamlined reclassification guideline published in December 2012 incorporates a step in the assessment of reclassification applications that involves consideration by stakeholders. Consideration by a Strategic Stakeholder Platform of how that process should be conducted and how its outcome could be measured would be valuable.

The strategic platform could also consider how best to reach out to individual stakeholders - healthcare professionals and patients - to ensure as wide engagement as possible. Better opportunities need to be given to allow individuals, not just those involved in the ad hoc Reclassification Stakeholder Groups, to feed in their views about reclassification applications, and about

regulation and good governance of non-prescription medicines in general. This doesn't prevent participation at the Reclassification Stakeholder Groups, but further strengthens the patient voice and ensures the issues are better understood. Clearly better use needs to be made of the social media to enable debates to take place.

Conclusions

Overall this Workshop provided valuable insight into how the MHRA can better engage stakeholders in the reclassification process. It identified the need for the establishment of a small strategic UK Platform to oversee the governance of reclassification submission, methods of work and outputs. The membership would comprise skilled and experienced individuals from stakeholder representative bodies to meet as needed to consider specific strategic issues related to reclassification and good governance of non-prescription medicines as identified by the Platform.

The workshop also gave some insight into how best to engage stakeholders early in the consideration of specific reclassification applications – through ad hoc Reclassification Stakeholder Groups, the governance of which could be overseen by the Strategic Platform. The feedback from the workshop and ongoing consideration by the Strategic Platform will ensure that these groups are run effectively and result in better engagement in reclassification applications.

In general there is a need for greater understanding of the reclassification process and regulation of non-prescription medicines in order for stakeholders to have meaningful engagement in the process – especially those involved in Reclassification Stakeholder Groups.

Next steps

Work will now be taken forward to establish a strategic UK stakeholder platform for reclassification of non-prescription medicines with a view to holding the first meeting in November 2014.

Healthcare professional members of the platform will be invited to participate based on their knowledge and experience and the experience and standing of the organisations they are employed by or are elected to represent.

Individuals will be selected to promote the patient voice based on their knowledge, interest and skills in patient and public engagement and/or involvement.

Membership will be reviewed after one year, including the requirements for a more formal selection process.

Attachments

ANNEX 1 Agenda

ANNEX 2 List of participants

ANNEX 3 Report of the breakout sessions on exploring the scope for increasing access to medicines through reclassification within specific therapeutic areas

Pilot Workshop
UK Stakeholder Platform for Good Governance of Non-Prescription Medicines

Monday 2nd June, MHRA, 151 Buckingham Palace Road

Programme

10.30 – 11.00

Coffee

11.00 – 11.15

Welcome and introduction

Morning Session

11.15 – 11.45

Introduction: A New UK Platform for Stakeholder Engagement in Reclassification and Good Governance OTC medicines

11.45 – 12.00

Introduction to first breakout session:
Exploration of what the platform will deliver in terms of stakeholder input, information and support needed in relation to the reclassification process

12.00 – 12.05

Coffee

12.05 – 12.35

Breakout group discussions

12.35 – 12.50

Feedback from breakout session

12.50 – 13.00

Summary from breakout session

13.00 – 13.30

LUNCH

Afternoon Session

13.30 – 14.00

Introductions to second breakout session:
Exploring the scope for increasing access to medicines through reclassification:
– Skin conditions
– Erectile dysfunction

14.00 – 15.00

Breakout group discussions

15.00 – 15.30

Feedback from breakout session

15.30 – 15.55

Summary and closing remarks

ANNEX 2

WORKSHOP ON RECLASSIFICATION AND GOOD GOVERNANCE OF NON- PRESCRIPTION MEDICINES

List of Participants

Participant	Organisation
Phil Adams	McCann Healthcare
Miriam Adamson	Leo
Dr Elizabeth Allen	British Association of Skin Camouflage
Joseph Anokam	Health Watch Camden
Martin Astbury	RPS - Royal Pharmaceutical Society
Johanne Barry	Pharmacy Forum NI (PSNI)
Rachel Bowes	Leo
Christine Clark	UK Clinical Pharmacy Association (UKCPA)
David Chandler	MHRA EAG member
Helen Darracott	PAGB
James Davies	Company Chemists Association (CCA)
Dr Martin Duerden	RCGP - Royal College of GPs
Dr Paul Goggin	Pfizer
Andrew Green	BMA - British Medical Association
Gill Hawksworth	UK Clinical Pharmacy Association (UKCPA)
Ray Jobling	Psoriasis Association
Anne Joshua	MHRA EAG member
Dr Stephen Kownacki	Primary Care Dermatology Society
Priya Patel	GSK
Martha Pawluczyk	GPHC - General Pharmaceutical Council
Carla Renton – (sent via Ray Jobling)	Psoriasis Association
Amanda Roberts	Patient representative (NICE)
Gul Root	Public Health England (PHE)
Dr Kate Stockman	Pfizer / PAGB
Ruth Wakeman	RPS - Royal Pharmaceutical Society
Prof. Roger Walker	Chief Pharmaceutical Officer, Wales
Carole Crumb (sp)	Industry

ANNEX 3

WORKSHOP ON RECLASSIFICATION AND GOOD GOVERNANCE OF NON- PRESCRIPTION MEDICINES

Report of the breakout sessions on exploring the scope for increasing access to medicines through reclassification within specific therapeutic areas

1. Exploring the Scope for Reclassification of Treatments for Skin Disorders

For this session the background material included brief outlines of the long term skin conditions currently mainly treated with prescription only medicines (POM) and the main POMs used in their treatment.

At the workshop attendees were provided with a table with details of the prescription only and non-prescription availability of the major topical skin preparations and an overview of how self-care of skin conditions has developed through reclassification with the major dermatological POM to Pharmacy only (P) reclassifications that have occurred over the last 30 years. Attendees were asked to consider the following questions:

- Is there scope to add to the currently available non-prescription topical skin preparations?
- What are the barriers that prevent current POM treatments becoming non-prescription and how can these be overcome?
- What disease entities currently mainly treated with POM products could be managed in the non-prescription setting?
- What conditions would need to be put in place?

Results

From the discussions within 2 breakout groups it was found that there might be scope for increasing the range of topical medicines available without prescription for the treatment of skin conditions although there were different views on the types of skin conditions that were suitable and the circumstances for use.

There were opposing views on increasing the availability without prescription of products for the treatment of long term skin conditions in general. Some members of the workshop felt that it would not be appropriate for patients with a life-long condition to have only a consultation with a pharmacist or for their skin condition to be examined and assessed in a community pharmacy setting. For any reclassification of a topical medicine for a long term skin condition consideration would need to be given to national guidelines and standards, such as NICE Guidelines, which cover not only medicines use but also treatment review, on-going clinical assessment of the condition and, in some cases, non-medical treatment, such as psychological support. There

was concern that if long term skin conditions were managed in the pharmacy there would be no link back to the doctor.

However, other members of the workshop considered the pharmacy setting to be appropriate for the management of long term conditions with non-prescription medicines and commented that this was already recognised as a role for pharmacists within the NHS. The NHS Medicines Use Review service provided by pharmacists in England and similar services in the devolved countries was a formal process which included consultation with the pharmacist about regularly prescribed medicines for the treatment of long term conditions and the provision of feedback to the GP. It was suggested that this type of model could be developed for the treatment of long term conditions with non-prescription medicines. Consideration could also be given to people registering with a particular pharmacy in order to provide an established relationship between patient and pharmacist and to enable feedback to the GP. In any case consideration would need to be given to people moving between prescription and non-prescription treatment to ensure continuity of care.

Some participants of the workshop felt that people should be given a choice about where they sought advice and obtained their medicines. Reclassification of a medicine from POM to P would not mean a patient could not continue to go to their GP for it if they preferred to. Also, an advantage in making medicines for the treatment of long term conditions available without prescription would be easier and convenient access for people who were managing their conditions well but had run out of their medicine and were not in a position to obtain easily a prescription straight away.

Views were mixed about which skin conditions could possibly be managed in the pharmacy with non-prescription medicines without a previous doctor's diagnosis, which could be managed provided there was an initial diagnosis by the doctor, and which were inappropriate for management with OTC medicines in any circumstances.

While some felt that conditions such as psoriasis and atopic dermatitis were inappropriate for management with non-prescription medicines, others thought this could be possible, in principle, but only if the condition had been previously diagnosed by a doctor. Some considered conditions such rosacea to be suitable for treatment with non-prescription medicines without a previous diagnosis and that the range of non-prescription treatments for the treatment of acne, without a doctor's diagnosis could be extended.

There was a consensus that genital warts and lichen planus were not suitable conditions for treatment with non-prescription medicines and concerns were expressed about reclassifying any products containing antibiotics suggesting this could give a mixed public health message about antibiotic resistance.

Other issues discussed related to appropriate duration of use and the need to refer back to the doctor when treatment was not working. The choice of pack

size was important in relation to the expected length of treatment before review was needed.

2. Exploring the Scope for Reclassification for treatments for Erectile Dysfunction (ED)

For the session on erectile dysfunction the background material included an overview of why ED was being considered at the workshop. Factors included the prevalence of the condition, limited access to date on the NHS, the prevalence of sourcing the products through the internet and the risk to public health of obtaining counterfeits if sourced through illegitimate sites.

The material also contained some questions for consideration:

- Is ED potentially a suitable condition for treating with non-prescription medicines?
- What are the public health benefits and risks of wider availability of medicines for ED?
- What conditions would need to be put in place to ensure safe supply and safe use?
- Which medicines may be suitable for non-prescription supply?
- What stakeholder support might be needed to support safe and appropriate use (e.g. pharmacist training, monitoring tools, information for GPs, patient support)?

At the workshop attendees were provided with a table with details of the oral prescription medicines available for ED and asked to discuss the questions raised in the pre-meeting briefing material.

Results

Consensus amongst the group was that oral medications for the treatment of ED could be suitable for non-prescription supply as P medicines as long as the right framework was in place. The framework would need to ensure that the appropriate circumstances for non-prescription supply were specified in the terms of the marketing authorisation. That is that pharmacists could identify early on if non-prescription supply was not suitable for a man, in which case he should be encouraged to seek advice from a doctor and that men presenting in the pharmacy with ED also received wider health and lifestyle messages.

The current restrictions on obtaining these treatments through the NHS were noted and there were discussions around some of the routes of supply chosen by men: from pharmacies as a face-to-face service supplied via a patient group direction; on line from legitimate sites following on-line consultation with a medical practitioner or with a pharmacist (in the case of supply via a patient group direction). There was concern that men were also seeking to source products from illegitimate internet sites or in pubs leaving them vulnerable to counterfeits or adulterated products. It was felt that there

needed to be more patient friendly access to ED medicines and supply as a P medicine was one way of achieving this.

Issues were raised about the sensitivity of the condition, which may put men off going to the GP even if it was more freely available on the NHS. Some men might be embarrassed to discuss the issue or want anonymity, or they may not want ED to be put on to their medical records.

On the other hand it was also recognised that men do not see ED as serious enough to see the GP and do not appreciate that it could be an indicator of serious health problems (the main conditions mentioned were cardiovascular (CV) disease, diabetes, depression and alcoholism.)

The public health benefits and risks of wider availability of medicines for ED were discussed. It was considered that a key non-prescription benefit could be to educate and drive awareness that ED is a symptom of CV disease, or other conditions and it would encourage men to engage earlier with the healthcare system.

There would be significant benefit in reducing the risk to men who were currently obtaining medicines on-line without accessing any healthcare system and which could be counterfeit or adulterated. A good quality pharmacy supply would be better for men's health than an illegitimate supply from the internet or in a pub.

There were also discussions about online access through legitimate pharmacies. While these services gave men anonymity, access to authorised products and the opportunity to be made aware of associated health issues, some participants felt that these routes of supply were not robust enough and could be abused. Face-to-face pharmacy supply could provide the opportunity to inform and educate men about health related issues.

Regarding the risks of pharmacy supply an increased potential for abuse was highlighted and particular consideration would need to be given to the age range for non-prescription use and how a P product would be advertised and promoted.

Consideration was given to the conditions that would need to be put in place to ensure safe supply and safe use. A key issue highlighted was the need for a pharmacy protocol to identify possible health risk factors. The protocol would need to be robust but not too long and complicated so as to be a barrier to supply. The protocol needed to identify early on if non-prescription supply was not suitable to avoid wasting a man's time when requesting the product. It was suggested that consideration should be given to making the use of a protocol a condition of the authorisation of the product for non-prescription use.