CHANGING THE LEGAL CLASSIFICATION
IN THE UNITED KINGDOM
OF A MEDICINE FOR HUMAN USE

INTRODUCTION

1. A new medicine, when first authorised, is usually restricted to use under medical supervision and made available only on a prescription; a medicine restricted in this way is classified as a Prescription Only Medicine (POM). If, following experience gained during use, it can be demonstrated that the medicine is safe for use with pharmacist supervision, reclassification as a Pharmacy Medicine (P) may be undertaken by removing the prescription requirements to allow sale or supply from a pharmacy. If experience demonstrates that access to professional advice is not required for safe use of the medicine, suitable presentations may then be reclassified as General Sale List (GSL) medicines to allow sale from a wider range of retail outlets.

2. Procedures for changing the legal classification of a medicine have been revised with a view to simplifying and speeding up the process wherever possible and providing greater transparency. This booklet replaces earlier advice on legal and administrative requirements for reclassification. It should be treated as general advice and not as a complete and authoritative statement of the law.

3. Requests for change of legal classification of products/substances and associated policy matters are dealt with by the Post-Licensing Division of Medicines Control Agency.
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BACKGROUND

4. The sale and supply of medicines is controlled by the Medicines Act 1968 and Council Directive 92/26/EEC (classification for the supply of medicinal products for human use). All medicines are classified according one of the three following categories, which will not change:

- Prescription Only Medicines (POM) – available only on a prescription
- Pharmacy (P) – available under the supervision of a pharmacist
- General Sale List (GSL) – available in general retail outlets such as supermarkets.

The presumption under law is that all medicines are P unless they meet the criteria for POM or GSL status. Pack size restrictions for GSL products are listed in the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980.

5. Since (insert date) changes in legislation mean that for all licensed medicines, legal status is determined by the Marketing Authorisation (MA).

6. The reclassification procedures are outlined below. If the guidance does not appear to describe adequately any particular circumstance relevant to an application, please contact Post-Licensing Division at the contact points listed on page 1. (admin contact and MCA Info Centre) Applicants who are considering making a reclassification application are encouraged to discuss their proposals and prospective timetable with MCA prior to submission. Contact numbers for discussion of professional aspects are listed in the MAIL bulletin, supplied to all MA holders, or may be obtained from the contact points listed on page 1.

PROCEDURES FOR RECLASSIFICATION

7. Following receipt in MCA, applications are validated and sifted on a triage basis. The reclassification process depends on the type of application. The Complex procedure is used for the first reclassification of a substance from POM to P or P to GSL, involving new indications, new routes of administration, new patient groups, new strengths or new doses and other applications with significant public health implications.
The Standard procedure is for changes in pack size, the extension of an existing indication within authorised use and additional strengths and forms of existing products unless there are significant public health implications.

Follow on “me too” reclassifications (not supported by full data) for products with exactly the same active ingredient and the same indications as one which has already been reclassified are dealt with as a Standard Type II variation.

Consultation and advice

8. Public consultation with interested parties for a 12-week period in line with Cabinet Office guidelines will take place at different points in the two procedures. Consultation will take place immediately in the Standard procedure and will be based on the applicant's 'Reclassification Summary' (see section 29 below). In the Complex procedure, public consultation will only take place after the advice of the committee has been sought and they have recommended that reclassification should take place. A flow-chart showing the steps involved in reclassification is provided in Appendix 2.

9. The advisory committee is invited to comment on straightforward applications during the public consultation period. Complex applications are submitted for advice in the first instance and released for consultation following positive advice. Standard applications on which issues have been raised in consultation will also be submitted for advice following consultation.

There is a right of appeal to the Medicines Commission on applications that are refused.

Standard Procedure

10. This process will generally take up to 120 calendar days, not including the consultation. Valid applications will be submitted immediately for consultation, via the MCA website on a rolling cycle with interested parties notified in writing at the start of each exercise.
11. Applications will only be submitted for formal review by the advisory committee if issues are raised as a result of the consultation process or of the review of the supporting data by the MCA Secretariat. Members of the relevant committee may also request that the full application be referred to another committee or to MC. Such committee referral will, of necessity, lengthen the time to final determination. The applicant may also be approached for additional information in relation to specific concerns and any such action would again increase the time required to determine the application.

12. Upon determination, the applicant will be informed of the outcome. Favourable decisions on applications will be implemented depending on what type of application was submitted, by including the new legal classification in the grant of the new MA, the renewed MA or the variation to the existing MA. Reclassified products will then be listed in the next available Medicines Act Information Letter (MAIL) and on the MCA website.

13. In the case of applications not approved, the reasons for the decision will be notified to the applicant who will also receive the assessment report. Applicants will be given the opportunity to appeal by written representation to the MC against the decision.

Complex Procedure

14. This process will generally take up to 180 calendar days, not including the consultation. Applications will be assessed by the MCA Secretariat, and submitted to the relevant committee for consideration.

15. If reclassification is recommended, consultation will take place with interested parties via the MCA website on a rolling cycle as and when applications are made, with interested parties being notified at the start of each exercise. Provided that no outstanding issues remain following the consultation procedure, action as in the Standard procedure (see 17 and 18 above) will be instigated. Notification
and opportunity for appeal will be given, as before, if reclassification is not recommended (see 19 above).

Applications not supported by data

16. Follow on “me too” reclassifications (not supported by full data) for products with exactly the same active ingredient and the same indications as one which has already been reclassified are dealt with by the variation procedure. There is no public consultation or referral to the advisory committee.

Timetables

17. Applications may be made at any time during the year. There are certain constraints on the process imposed by the timing of meetings of the relevant committee and any other committee involved; MCA will strive to meet the time-scales indicated but these cannot be guaranteed.

Form of application

18. Applications from MA holders should be made as part of a new MA application, a renewal application or a variation application made in the usual way. It should be noted that, as classification is determined on a national basis, the position of MAs determined via the Mutual Recognition (MR) procedure may require special consideration and applicants are advised to discuss with MCA at an early stage.

19. If an applicant wishes to retain a POM product without some of the restrictions proposed for the P product, a new MA application rather than a variation must be made for the P product. The applicant will than have separate licenses for the POM and P products. MA holders are reminded that where products of identical composition exist as a POM and P, with different indications, the two products must be distinguishable by name since it would give rise to safety concerns for the two products to exist under identical names.
20. For any one product, reclassification from POM to P is normally considered first. Following a suitable period of marketing as a P product a subsequent P to GSL application may be submitted if considered appropriate.

21. The criteria for classification and the data requirements for reclassification applications are detailed in the following sections of this booklet. Only those applications that fulfil the criteria listed will be accepted as valid.
EC CLASSIFICATION DIRECTIVE

22. The EC Directive on the Classification for Supply of Medicinal Products for Human Use (92/26/EEC) specifies the criteria by which Member States should classify medicines into those subject to medical prescription and those not subject to prescription control. The criteria to be applied are set out in Appendix 3. In summary, prescription control is required for medicines where -

- a direct or indirect danger exists to human health, even when used correctly, if used without medical supervision; or
- there is frequently incorrect use which could lead a direct or indirect danger to human health; or
- further investigation of activity and/or side-effects is required; or
- they are normally prescribed by a doctor to be administered parenterally.

CONTENT OF RECLASSIFICATION APPLICATION

23. In all cases, the covering letter should clearly state that the application contains a reclassification request. The content of the reclassification application should consist of the following elements which are addressed in more detail in the sections which follow: -

- **Reclassification Summary** - a comprehensive summary in set format which will form part of the information provided for the public consultation.
- **Safety/Efficacy Summary** - supporting safety and where necessary efficacy data.
- **Patient Information** - full details of leaflets and labels and an indication of the support to be provided for pharmacists and of the advertising plans.
- **Training and Education** – a summary of what provision has been made for appropriate education and training.
- **Clinical Expert Report** - a critical evaluation of the proposed pharmacy product demonstrating that none of the prescription criteria apply.

All cited references must be provided in full with translations where applicable.
Reclassification Summary

24. The data requirements for the reclassification summary are set out below. This summary should rarely extend beyond two sides of A4 paper but should provide sufficient non-confidential information to allow an informed decision to be made in relation to safe usage of the product as a P medicine. It will be used for the consultation procedure to provide interested parties with a comprehensive overview of both the essential aspects of the reclassification request and the public health impact of the change. A sample form for completion is provided in Appendix 4.

Applicant detail:

25. The name of the applicant and the name and address of the person to contact in relation to the application should be provided.

Product Details

26. Details should be provided of the proposed P product including name (both existing POM and proposed P names if different), the MA number of POM to be reclassified, composition, indications, dosage, age-limits and pack size.

Rationale for the Reclassification

27. In addition to a concise explanation of the rationale for the switch, the place of the product in the management of the disease in question, in line with current clinical guidelines, should be briefly outlined. Particular attention should be paid to the revised role of the pharmacist and any essential equipment/facilities required to perform this role.
Support for Reclassification

28. A brief indication is required of experts or organisations providing written endorsement of the proposal which can be made available by the applicant on request. Specific OTC Requirements

29. Details should be provided of measures incorporated to ensure correct self-diagnosis/self-treatment together with any essential safeguards required in order to prevent incorrect usage. This information will include changes such as additional advice or warning statements, any restrictions on indications, contraindications, dose, pack, length of treatment etc and clear statements about circumstances requiring physician intervention and the action needed if symptoms do not respond or if an adverse reaction occurs.

Safety Profile

30. An outline is required of the safety profile including product utilisation / patient exposure details. The major risk factors associated with the product should be summarised and risk-benefit briefly analysed paying particular attention to 'at risk' groups and to known drug interactions. Hazards arising from therapeutic misuse, whether accidental or deliberate, should be indicated including those arising from misdiagnosis, overdose or delay in receiving medical attention.

Safety/Efficacy Summary

31. The extent of the supporting safety data required will depend on experience with the product and the availability to the applicant of recent Product Safety Update Reports (PSURs). Where available, summaries from PSURs already submitted to MCA should be provided with full bridging data for the intervening period. If the application is made within 5 years of marketing, the PSUR summaries should be drawn together ahead of the 5-year date. It is not necessary to resubmit the complete PSUR.

32. Experience in terms of patient exposure to the product needs to be considerable allowing the safety profile to be fully established. Full details of availability,
classification for sale and patient exposure should be provided for all countries where marketed.

33. A safety profile should be drawn up based on the following data:
   - Spontaneous reports of adverse reactions
   - Post-marketing surveillance studies
   - Clinical trials
   - Published literature
   - Safety reviews

Data obtained in the UK should be distinguished from that obtained from other countries and, for non-UK data, details must be provided in relation to differences in product or usage characteristics. All cited references must be provided in full with translations where applicable.

34. Adverse drug reactions to the proposed P product should normally be minor and should cease on discontinuing therapy. Information concerning serious type A and type B reactions experienced should be given and discussed. The problems of extrapolating data from a 'prescription only' population to a 'non-prescription' population should be addressed. Comparison of safety with other drugs available in the UK without prescription may be helpful.

35. Where pharmaceutical forms or doses to be used have received only limited use, it may be possible to extrapolate from data relating to other presentations and full justification for this approach must be given when used.

36. Reports of therapeutic overdose, misuse or abuse, whether deliberate or accidental, should be reviewed. In the case of misuse, the consequence of delay in seeking medical attention should be addressed.

37. Drug interactions may have additional consequence for P products and these should be reviewed in the light of the reclassification proposal. Attention should
be paid to any OTC products the patient may already be using including herbal remedies and nutritional supplements.

38. Efficacy data is only required when indications, dosages or age ranges differ from the authorised product. Pharmacokinetic or pharmacodynamic data are required if a different pharmaceutical form is used.

39. A suitable time period for treatment should be given, with justification, and should be reflected in the pack size proposed for the P product.

**Patient Information**

40. Mock-ups of Patient Information Leaflets (PILs) and packs should be submitted. Those used for the POM product will normally require amendment to ensure safe use as a P Product. Clear instructions to aid correct diagnosis and prevent misdiagnosis will be needed. Additional precautions and warnings may be necessary due to the absence of medical supervision, e.g. the action to be taken if no response is obtained and the circumstances requiring pharmacist and/or medical advice.

41. Promotional material should comply with legislation and with self-regulatory procedures in operation. It is helpful for advertising plans to be briefly outlined and MCA may further require pre-submission, before issue, of all such material. It should be noted that pharmacodynamic claims based on pharmacokinetic data alone are not acceptable.

**Clinical Expert Report**

42. Current CPMP guidelines on completion of expert reports should be followed. The Expert is expected to make an objective and impartial assessment of the application in the light of current scientific knowledge and to confirm that the safety data provided is adequate to support reclassification.
43. The Expert should critically evaluate the proposed P product in the light of the criteria for prescription control and demonstrate why none of the criteria apply. In considering the criteria the factors outlined below should be addressed.

**First POM Criterion: Likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision**

**Direct danger**

44. A direct danger may be present if the product causes adverse reactions that are important because of their seriousness, severity or frequency or because the reaction is one for which there is no suitable preventative action such as the exclusion of a clearly identifiable risk group. In addition to the product's safety profile, it may be helpful to consider the benefit-to-risk in relation to that for similar products already available as Pharmacy medicines for the same indication. One member of a class that causes adverse reactions more frequently than other members of the class, may be unsuitable for reclassification for the same indication.

45. Consideration should also be given to the danger arising from drug interactions with commonly used medicines and how these may be prevented.

**Indirect danger**

46. An important example of an indirect danger is when symptomatic treatment might mask an underlying condition requiring medical attention, for example cancer or heart disease. Consideration should be given to whether an indirect danger might exist and if so, whether the risk, its frequency and the seriousness of the consequences would make reclassification unacceptable. Additional warnings such as a recommendation to seek medical advice if symptoms persist beyond a stated time period may be necessary in such instances.

47. Another important example of an indirect danger would be the increased risk of development of bacterial resistance in the community as a result of wider use of antibiotics without medical supervision.
48. Treatments may also present an indirect danger when particular symptoms are outward manifestations of a diverse range of underlying pathologies. If the patient cannot easily self-diagnose the cause of such symptoms it may be inappropriate to provide symptomatic treatment without management of the underlying disease. Special attention should be paid to the possibility of serious asymptomatic damage in chronic conditions.

**Self-diagnosis**

49. It is important that the conditions or symptoms for which the product is indicated can be correctly diagnosed without medical supervision or can be easily recognised following initial medical diagnosis. The problem of excluding conditions with similar symptoms but unsuitable for treatment with the product in question may need to be addressed. Appropriate patient information and/or pharmacist advice may be able to influence the ability to correctly self-diagnose.

50. Patients should be able to understand the natural course of the disease and the possibility and consequences of reoccurrence. They should also be able to recognise contraindications and understand essential precautions and warnings. Experience in such issues in relation to other medicines may provide important supplementary information.

**Risk of misuse**

51. A high incidence of conditions listed as contraindications, extensive precautions and warnings or a high rate of usage of interacting drugs in the population of patients likely to use the drug may increase the incidence and risk of misuse.

52. It is important that the danger to health is small if the patient uses the product when it is not indicated, exceeds the recommended dose or recommended length of treatment or fails to heed the contraindications or warnings. Consideration of the consequences of misuse is an important component of the overall safety profile of the product. Concerns over the risk of misuse are lessened where the product causes only few, non-serious side-effects. In this situation, while the risk-
to-benefit may be unfavourable to the patient who uses the product incorrectly, the overall risk-to-benefit for availability of the medicine in the community without prescription may be favourable.

53. It may also be necessary to consider whether incorrect use might lead to an indirect risk, e.g. a delay in seeking medical treatment, and if so, whether the consequences to the patient would be important.

Second POM Criterion: Frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health

54. When a product or substance is known to be used frequently incorrectly, pharmacy status is not appropriate. Recognised widespread misuse of a product or substance classified as a pharmacy medicine could lead to its reclassification as a prescription medicine.

Third POM Criterion: Contain substances or preparations thereof the activity and/or side-effects of which require further investigation

Limited experience

55. Further investigation is likely to be necessary where the number of patients exposed is relatively small, for example when a medicine has only recently been authorised, because there is limited experience of the product under normal conditions of use. Even if clinical trial data are extensive and reassuring, it is important to have evidence of safety where the product is being used without the exclusion of certain groups of patients imposed by the design of clinical trials (e.g. the elderly, children and those with certain medical conditions.)

New strength, dose, route of administration, age group or indication

56. Further investigation is also necessary where it is proposed that the substance will be available without prescription as follows: -

• in a new strength,
• at a new dose,
• using a new route of administration,
• exposing a different patient age group, or
• for a new indication, particularly when the indication has not been previously authorised for a non-prescription product.

Even though the safety profile of the medicinal product as it is presently marketed, is relevant, re-evaluation of risk-to-benefit according to the proposed use is necessary. This may be difficult because the product will not have been widely available for the new indication or new dosage. It may nevertheless be possible to extrapolate from the known safety of the existing prescription product, particularly if there are few side-effects and/or where doses proposed for non-prescription supply are lower and the population is a sub-group of the patient group treated on prescription.

**Fourth POM Criterion: Are normally prescribed by a doctor or dentist to be administered parenterally**

57. Parenteral administration involves breaching the skin or mucosa. Products for parenteral administration are not appropriate for availability without medical supervision because of the additional risks and complexity of this route of administration.

**Additional considerations**

58. The Expert may need to take account of the other factors that influence legal status as outlined in Directive 92/26/EEC (see paragraph 2 & 3 of Appendix 1). This includes whether the substance is a narcotic or a psychotropic substance or might be abused leading to addiction or misused for illegal purposes. Supply without a medical prescription may be acceptable if additional restrictions are introduced. e.g. limiting the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, the circumstances of use, the type of packaging and/or pack size.

59. If restrictions to the maximum dose or maximum daily dose are introduced in order to protect against a danger when the medicine is used either correctly or
incorrectly, it is necessary to confirm that the restricted dose retains the efficacy and the favourable benefit-to-risk of the full dose.

60. Consideration should also be given to the need for restrictions on the strength, pharmaceutical form, circumstances of use, pack size, or a combination of these in order to provide a safeguard against incorrect use including overuse or overdose or against a delay in seeking medical attention. When pack size is restricted, the proposed pack must be compatible with the intended duration of use.

Label and Patient Information Leaflet

61. In all cases labelling and patient information leaflets must be supplied which are compliant with Council Directive 92/27/EEC on the labelling of medicines for human use and on package leaflets.

62. The proposed product label and patient information are important elements of the application and should be reviewed by the Expert to confirm that clear and comprehensive information has been provided which will effectively protect patients from any safety hazards.

63. The patient information leaflet should take full account of the circumstances of use and should provide warnings, as appropriate for use without medical supervision. eg. limiting duration of treatment, when to seek medical advice etc.

64. The written information should effectively minimise the risk of use where a product is contraindicated or where problems could occur. The Expert should ensure that adequate instructions are included and that all contraindications, precautions and warnings are clearly described in lay terms and prominently printed in the leaflet. In order to minimise risk and maximise benefit, situations where the product must not be used should be given equal prominence on the label and in the leaflet to those in which it may be used.

65. The patient is likely to need guidance on action to take if the medicine does not have the desired effect or causes adverse effects. The Expert should ensure that
appropriate action by the patient is recommended to provide for the absence of medical supervision.
RECLASSIFICATION FROM P TO GSL

CRITERIA FOR GENERAL SALE LIST CLASSIFICATION

66. Under the provisions of Part III of the Medicines Act 1968, GSL is appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist. The following classes of products are excluded from GSL:

- Anthelmintics
- Parenterals
- Eye drops
- Eye ointments
- Enemas
- Irrigations used wholly or mainly for wounds, bladder, vagina or rectum
- Aspirin or Aloxiprin for administration wholly or mainly to children

67. When considering the safety of a product for GSL, it is necessary to confirm firstly that the hazard to health and the risk of misuse is small and that significant special precautions in handling are not required.

68. If there are no safety impediments, it is then necessary to justify the need for wider sale with the reasons why the convenience to the purchaser outweighs the benefit of availability of professional advice at the point of sale.

CONTENT OF RECLASSIFICATION APPLICATION

69. The content of the reclassification application should consist of the following elements which are addressed in more detail in the sections which follow:

- **Reclassification Summary** - a comprehensive summary in set format which will form part of the information provided for the public consultation.
- **Safety/Efficacy Summary** - supporting safety and where necessary efficacy data.
• **Patient Information** - full details of leaflets and labels and an indication of the advertising plans.

• **Clinical Expert Report** - a critical evaluation of the proposed GSL product demonstrating that reclassification is both safe and necessary.

All cited references must be provided in full with translations where appropriate.

**Reclassification Summary**

70. The data requirements for the reclassification summary are set out below. A sample form for use is included in Appendix 5. This summary should rarely extend beyond two sides of A4 paper but should provide sufficient non-confidential information to allow an informed decision to be made in relation to safe usage of the product as a GSL medicine. It is designed to provide interested parties with a comprehensive overview of both the essential aspects of the reclassification request and the public health impact of the change.

**Applicant details:**

71. The name of the applicant and the name and address of the person to contact in relation to the application should be provided.

**Product details:**

72. Details should be provided of the proposed GSL product including name, the MA number of product to be reclassified (MA holders only), composition, indications, dosage, age-limits and pack size.

**Rationale for the reclassification:**

73. In addition to a concise explanation of the rationale for the switch including why pharmacist supervision is not required, the place of the product in the management of the disease in question should be briefly outlined.
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Support for reclassification:

74. A brief indication is required of experts or organisations providing written endorsement of the proposal which can be made available by the applicant on request. If the applicant is not the MA holder, the position of the MA holder(s) in relation to the application should be specified.

Specific GSL Requirements

75. Details should be provided of measures incorporated to ensure safety when available by general sale.

Safety Profile

76. An outline is required of the safety profile including support for use without professional advice.

Safety/Efficacy Summary

77. The extent of the supporting safety data required will depend on experience with the product and the availability to the applicant of recent Product Safety Update Reports (PSURs). PSURs already submitted to MCA need not be resubmitted but should be updated for the intervening period and this data provided together with the PSUR summary.

78. Experience in terms of patient exposure to the product needs to be considerable and should be outlined. Normally, substances suitable for GSL classification will have been in widespread use in P products for many years. Comparison of safety with other drugs having GSL availability in the UK for similar indications may be helpful.

79. The safety profile should be described. Particular reference should be made to experience relevant to reclassification. eg. The adverse drug reaction (ADR) profile from countries other than the UK where this or a similar product is available without access to professional advice or with data from post-marketing
surveillance studies or from clinical trials involving use without access to professional advice.

80. Reports of therapeutic overdose, misuse or abuse, whether deliberate or accidental, should be reviewed. Symptoms and hazards of overdose and other misuse should be clearly described and recommended treatments given, where appropriate.

81. New pharmacokinetic, pharmacodynamic or efficacy data are not usually required as it would be unusual to consider a formulation or use as being appropriate for GSL supply where it had not been available previously as a P medicine.

Patient Information

82. Mock-ups of Patient Information Leaflets (PILs) and packs should be submitted in the usual way. Any additional safety measures required should be reflected in the patient information.

83. Promotional material should comply with legislation and with self-regulatory procedures in operation. It is helpful for advertising plans to be briefly outlined and MCA may further require pre-submission, before issue, of all such material.

Clinical Expert Report

84. Current CPMP guidelines on completion of expert reports should be followed. The Expert is expected to take and defend a clear position on the proposal in the light of current scientific knowledge and to confirm that the safety data provided is adequate to support reclassification, including justification of the use without access to pharmacist advice.

85. The expert should discuss the indications, maximum dose and maximum daily dose considered suitable for GSL sale and should confirm that the proposed treatment length is justified and is reflected in the pack size. In addition,
compliance with relevant clinical guidelines, where appropriate, should also be confirmed.

86. The significance of the contraindications, warnings, ADRs, interactions, problems of overdose and other misuse should be discussed in the context of use without access to professional advice. Confirmation should also be provided that significant special handling precautions are not required.

87. The need for GSL classification should be reviewed focusing on the advantages arising from the convenience of general sale and why these are considered to outweigh the disadvantages arising from lack of access to professional advice at the time of purchase.
Appendix 1

LEGISLATION IN THE UNITED KINGDOM
ON SALE OR SUPPLY OF MEDICINES FOR HUMAN USE

- The Medicines Act 1968
- The Prescription Only Medicines (Human Use) Order 1997 (The POM Order)
- The Medicines (Products other than Veterinary Drugs) (General Sale List) Order 1984 (the GSL Order)
- The Medicines (Pharmacy and General Sale – Exemption) Order
- The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations
PROPOSED RECLASSIFICATION PROCEDURE

Applications received, and triage

1. Standard
   Consultation (clock stops)
   Grant PL with new legal status
   Approve
   Issues Raised
   Upheld

2. Complex
   Committee consideration
   Approve
   Upheld
   Reject
   Right of Appeal to Medicines Commission

Total
1. 120 Days (not including consultation) for straight forward case
2. 180 days (not including consultation) for more complex cases

Note: This is an indicative process chart, which does not necessarily cover all scenarios of routing.
CRITERIA FOR CLASSIFYING MEDICINAL PRODUCTS AS PRESCRIPTION ONLY MEDICINES

PRESCRIPTION-ONLY MEDICINES

Directive 92/26/EEC and the Medicines Act 1968 Section 58A provides that:

1. Prescription control is applied to any product which:
   (a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or
   (b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or
   (c) contains substances or presentations of substances of which the activity requires, or the side effects require, further investigation; or
   (d) is normally prescribed by a doctor or dentist for parenteral administration.

2. Exemptions from prescription control may be made having regard to:
   (a) the maximum single dose;
   (b) the maximum daily dose;
   (c) the strength of the product;
   (d) its pharmaceutical form;
   (e) its packaging; or
   (f) such other circumstances relating to its use as may be specified in the determination.

GENERAL SALE LIST

Section 51 of the Medicines Act 1968 provides that:

"Ministers may by order specify descriptions or classes of medicinal products, as being products which in their opinion can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist."

The term “with reasonable safety” has been defined as: “where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser."
Appendix 4

RECLASSIFICATION SUMMARY for POM to P APPLICATIONS

1. Applicant details:
Name of the applicant

Name & address of contact for provision of statements of support (see paragraph 33)

2. Product Details:
Name and where applicable MA number
(give both existing POM and proposed P names if different)

Active ingredients

Indications

Dosage including age-limits and restrictions on length of treatment

Pack size.

3. Rationale for the Reclassification

4. Support for Reclassification
5. Specific OTC Requirements

6. Safety Profile
Appendix 5

RECLASSIFICATION SUMMARY for P to GSL APPLICATIONS

1. Applicant details:
   Name of the applicant

   Name & address of contact for provision of statements of support (see paragraph 78)

2. Product Details:
   Name and where applicable MA number
   *(give both existing P and proposed GSL names if different)*

   Active ingredients

   Indications

   Dosage including age-limits and restrictions on length of treatment

   Pack size.

3. Rationale for the Reclassification

4. Support for Reclassification
5. Specific GSL Requirements

6. Safety Profile