To Interested Organisations

15 June 2001

Dear Sir or Madam

CONSULTATION LETTER MLX 272

Proposed amendments to:

THE MEDICINES (PRODUCTS OTHER THAN VETERINARY DRUGS) (GENERAL SALE LIST) ORDER 1984 (SI 1984/769) and

THE MEDICINES (SALE OR SUPPLY)(MISCELLANEOUS PROVISIONS) REGULATIONS 1980 (SI 1980/1923)

INTRODUCTION

1. I am writing to consult you, under section 129(6) of the Medicines Act 1968 ("the Act"), on proposed amendments to: The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 (SI 1984/769)² ("the GSL Order") and the Medicines (Sale or Supply) (Miscellaneous Provisions).Regulations 1980 (SI 1980/1923)³ ("the Sale or Supply Regs").

BACKGROUND

2. Under Section 51 of the Act (see Appendix 1) a medicine can be classified as suitable for general sale if it can, with reasonable safety, be sold or supplied without the supervision of a pharmacist. The GSL Order, made under that section, lists medicines that can be made available on general sale. The Sale or Supply Regulations set out pack size limits for certain GSL medicines at section 8. The proposed amendments to the Order and Regulations are set out below.

PROPOSED AMENDMENTS TO THE GSL ORDER & SALE OR SUPPLY REGULATIONS

3. two antihistamine substances - cetirizine dihydrochloride and loratadine

Both substances have been available without prescription since 1993, with a maximum dose of 10mg, in packs of 10 tablets. They are used for the symptomatic relief of perennial rhinitis (persistent sneezing), seasonal allergic rhinitis (hayfever) and idiopathic chronic urticaria (itchy rashes) in adults and children aged 12 years and over. Both substances are classified as non-sedating antihistamines and there are no safety concerns with regard to diagnosis or misdiagnosis of the condition, or precautions for use (interactions or side-effects).

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¹ See Appendix 2
The Committee on Safety of Medicines (CSM) has advised that both cetirizine dihydrochloride and loratadine could safely be on general sale provided that:

- They are supplied in tablet form;
- They are for the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis and idiopathic chronic urticaria in adults and children aged 12 years and over;
- The maximum strength is 10mg; and
- They are supplied in packs containing not more than 7 tablets.

We propose to amend the GSL Order and Sale or Supply Regulations accordingly.

4. **aspirin 75mg**

Low dose aspirin is used in the prevention of further heart attack or stroke. The Sale or Supply Regulations currently limit the maximum pack size of aspirin tablets or capsules on general sale to 16. The CSM has advised that enteric-coated aspirin 75mg may be on general sale in packs of up to 28 tablets (i.e. a month’s supply). We propose to amend the Sale or Supply Regulations accordingly.

5. **ibuprofen (liquid preparations)**

Ibuprofen is currently available on general sale for use in adults and children over the age of 12 years. The maximum strength is 200mg, the maximum dose is 400mg and the maximum daily dose is 1200mg. It is to be used only for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, or symptoms of colds and influenza. It is available in the form of tablets, capsules, powder and granules, in a pack of no more than 16 tablets or capsules, or 12 sachets of powder or granules.

CSM has advised that a liquid preparation of ibuprofen 100mg/5ml for use in children under the age of 12 years could safely be made available on general sale provided that:

- It is for internal use;
- It is for the treatment of rheumatic or muscular pain, headache, dental pain, feverishness, or symptoms of colds and influenza;
- The maximum dose is 200mg;
- The maximum daily dose is 800mg; and
- It is supplied in individual unit doses of not more than 5ml each, in a pack containing not more than 20 doses.

We propose to amend the GSL Order and Sale or Supply Regulations accordingly.

6. **ibuprofen lysine**

Ibuprofen lysine is a water-soluble salt of ibuprofen, a well-established analgesic, anti-inflammatory and antipyretic. It is more rapidly absorbed than ibuprofen but is used for the same indications. It has been available without prescription since 1996 and has been shown to be comparable to ibuprofen with respect to safety and efficacy.

CSM has advised that it would be safe to allow ibuprofen lysine to be available on general sale when it is used internally for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, or symptoms of colds and influenza, in adults and children over 12 years of age, when the maximum strength is equivalent to 200mg ibuprofen, the maximum dose is equivalent to 400mg ibuprofen, and the maximum daily dose is equivalent to 1200mg ibuprofen, and when it is supplied in a pack containing no
more than 16 tablets. We propose to amend the GSL Order and Sale or Supply Regulations accordingly.

7. **paracetamol (liquid preparations)**
Some liquid preparations of paracetamol are available on general sale. Preparations with a maximum strength of 2.5% are for use by adults and children aged 12 years and over and have a maximum pack size of 160ml, while preparations with a maximum strength of 2.4% are for use in children aged less than 12 years and must be presented in individual unit doses of not more than 5ml each, to a maximum of 20 unit doses.

Medicines Commission have advised that public consultation may take place on a proposal to amend the GSL Order and Sale or Supply Regulations to permit the general sale of 5% strength liquid preparations of paracetamol, under the following conditions:

- for use in children aged 6 to 12 years
- presented in unit doses of not more than 5ml, in packs of not more than 10 unit doses.

Medicines Commission have recommended that if the 5% preparations in unit doses become available on general sale, they should be in packaging that is sufficiently distinct from that of the lower strength (2.4%) preparations, to prevent confusion between the two.

8. **potassium chloride**
Potassium chloride is listed in both Table A (substances for internal and external use) and Table B (substances for external use only) of schedule 1 to the GSL Order. This duplication is confusing and we propose to remove the surplus entry in Table B and clarify the entry in Table A to specify both internal (maximum strength of 0.15% for treatment of acute diarrhoea) and external use.

9. **sodium fluoride**
Medicines containing sodium fluoride are used in the prevention of dental caries (tooth decay). Mouthwashes containing up to 0.2% sodium fluoride are available without a prescription but supply is restricted to pharmacies. However, the Cosmetic Products (Safety) Regulations permit the use of fluoride compounds in oral hygiene products up to a maximum total fluorine content of 0.15% fluorine (which is equivalent to 0.33% sodium fluoride). Toothpastes and mouthwashes containing sodium fluoride are marketed under these regulations and are freely available and there are no apparent safety issues.

We therefore propose to amend the GSL Order to permit the general sale of products containing sodium fluoride for use in the prevention of dental caries, in the form of daily-use mouthwashes with a maximum strength of 0.05% sodium fluoride, and mouthwashes for other than daily use with a maximum strength of 0.2%.

**COMMENTS**
10. You are invited to comment on these proposals and a form is attached for your reply.

11. You are also invited to comment on the possible impact on business of the proposed changes and draft Regulatory Impact Assessment which is attached.
Copies of the final version will be made available to Ministers, Parliament and to the public. It would therefore be helpful if you could identify and quantify any direct or indirect costs (recurring or non-recurring) or any profits which would be likely to arise for business in your sector if these changes are made.

12. Comments should be addressed to Tricia Griffiths, in room 14-110 at the above address, to arrive by 3 August 2001.

13. The Medicines Commission will be asked to consider the proposals in the light of comments received and their advice will be conveyed to Ministers. Subject to the agreement of Ministers, we plan to implement the changes by Statutory Instrument coming into force in October 2001. This will be available from Stationary Office Books and may be viewed on their website http://www.hmso.gov.uk/stat.htm

MAKING COPIES OF REPLIES AVAILABLE TO THE PUBLIC

14. To help informed debate on the issues raised by this consultation exercise, and within the terms of the Code of Practice on Access to Government Information ("Open Government"), the Agency intends to make copies of replies received publicly available. Copies will be available shortly after the public consultation has ended.

15. The Agency’s Information Centre at Market Towers will supply copies upon request. Copies may be further reproduced. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect the replies at the Information Centre by prior appointment. To make an appointment, telephone 020 7273 0351.

16. It will be assumed that your reply can be made publicly available in this way unless you indicate that you wish all, or part of it, to be treated as confidential and excluded from this arrangement. Under the Code of Practice on Access to Government Information, the Agency will not release confidential replies or replies containing personal confidential information.

Yours faithfully,

JAMES COPPING
POST-LICENSING DIVISION
14-111 Market Towers
REGULATORY IMPACT ASSESSMENT

THE MEDICINES (PRODUCTS OTHER THAN VETERINARY DRUGS) (GENERAL SALE LIST) AMENDMENT ORDER 2001 and
THE MEDICINES (SALE OR SUPPLY)(MISCELLANEOUS PROVISIONS) AMENDMENT REGULATIONS 2001

1. PURPOSE AND INTENDED EFFECT OF THE MEASURES

The Issue

1.1 The Medicines Act 1968 requires all medicinal products to be licensed, to ensure that they are safe, effective and of good quality. It also sets out criteria for the control of their supply.
• Those which meet the criteria for prescription control are listed in The Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830.
• Those which meet the criterion for general sale are listed in The Medicines (Products Other Than Veterinary Drugs)(General Sale List) Order 1984 SI 1984/769.
The criteria for classifying medicinal products are set out at Appendix 1.

1.2 Procedures for reclassification are published as MAL 77 and MAL 82, available from the MCA Information Centre, Market Towers, telephone 020 7273 0351. Following consultation with Trade and Professional Associations, Ministers have agreed that proposed amendments to these Orders should be considered twice yearly. Any changes are implemented by Statutory Instrument. These are available from Stationary Office Books and may be viewed on their website http://www.hmso.gov.uk/stat.htm

Objectives

1.3 These amendments are intended to allow medicines containing cetirizine, and loratadine (for relief of rhinitis and urticaria), ibuprofen lysine, liquid preparations of ibuprofen, and liquid preparations of paracetamol at the higher strength of 5%, and mouthwashes containing sodium fluoride (to prevent dental caries) to be on general sale. They would also allow medicines containing aspirin 75mg (for the prevention of further heart attack or stroke), which are already available on general sale, to be supplied in a larger pack.

2. BENEFITS IDENTIFIED AND QUANTIFIED

The additions to the General Sale List Order are being proposed largely at industry's request. They will benefit the public by making these medicines for common ailments more readily available.

3. COMPLIANCE COSTS FOR BUSINESS

3.1 Business sector affected

3.2 Actual cost of the proposal on an annual basis
The proposal would require an amended label and leaflet for each of these products which we estimate would cost £5,000. There are eight products involved, so the total initial cost of the proposal would be £40,000. These amendments have been proposed at the request of the manufacturers because general sale list status provides a wider market and the potential for greater sales.
It is therefore unlikely that they will pass this cost on to the public. We estimate that there will be no further cost arising from the proposal.

4. RESULTS OF CONSULTATION

Consultation letter MLX 272 will be sent to 162 interested organisations and to the companies involved. The trade associations (the Association of British Pharmaceutical Industry, and the Proprietary Association of Great Britain) copy it to their members. The letter will also be sent to all interested divisions of the Department of Health and to the Health Departments of the Scottish Executive, the National Assembly for Wales and the Northern Ireland Executive. Copies will be sent to the Veterinary Medicines Directorate, and to the Department of Agriculture in Northern Ireland. Comments are also invited on the likely impact on business costs of the proposed changes. We will allow six weeks for replies, with a deadline of 3 August 2001. Copies of the responses may be obtained from the Medicines Control Agency's Information Centre (phone 020 7273 0000) when the consultation is completed. The responses to consultation will be submitted to the Medicines Commission for advice.

5. SUMMARY AND RECOMMENDATIONS

We recommend that the GSL Order and the Sale or Supply Regulations be amended to allow medicines containing cetirizine, and loratadine (for relief of rhinitis and urticaria), ibuprofen lysine, liquid preparations of ibuprofen, liquid preparations of 5% paracetamol, and mouthwashes containing sodium fluoride to be on general sale; and medicines containing aspirin 75mg, already available on general sale, (for the prevention of further heart attack or stroke) to be supplied in a larger pack.

Contact point and date

For further information please contact:

Tricia Griffiths
POST-LICENSING DIVISION
Medicines Control Agency
14-110 Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ
020 7273 0366  020 7273 0293  27 June, 2001
CRITERIA FOR CLASSIFYING MEDICINAL PRODUCTS

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 1967 White Paper Forthcoming Legislation on the Safety, Quality and Description of Drugs and Medicines (Cmnd 3395) which preceded the introduction of the Medicines Bill into parliament contemplated that in the field of human medicines the General Sale List would comprise products "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."

The Medicines Commission's Report on a General Sale List of Medicinal Products for Human Use, published in April 1973, which advised Ministers on the introduction of the General Sales List, noted that they accepted this as an appropriate elaboration of the expression "with reasonable safety".
MLX CONSULTATION LIST : MLX 272

Advertising Association
Advertising Standards Authority
Advisory Committee on Misuse of Drugs
Age Concern
All-Party Pharmacy Group
Arthritis Care
Association of Anaesthetists of Great Britain and Northern Ireland
Association of British Cardiac Nurses
Association of British Health Care Industries
Association of British Pharmaceutical Industries
Association of Community Health Councils of England & Wales
Association of Pharmaceutical Importers
Association of Surgeons of Great Britain and Ireland
Asthma & Allergy Research
British Association of Dermatologists
British Association of European Pharmaceutical Distributors
British Association of Pharmaceutical Physicians
British Association of Pharmaceutical Wholesalers
British Cardiac Patients Association
British Contact Dermatitis Group
British Dental Association
British Dental Association (Northern Ireland)
British Dental Association (Wales)
British Dental Trade Association
British Diabetic Association
British Epilepsy Association
British Generic Manufacturers Association
British Heart Foundation
British Institute of Regulatory Affairs
British Medical Association
British Medical Association (Northern Ireland)
British Medical Association (Scottish Branch)
British Medical Association (Welsh Office)
British Oncological Association
British Pharmacological Society
British Retail Consortium
British Society for Allergy and Clinical Immunology
British Society for Rheumatology
British Society of Gastroenterology
British Toxicology Society
Central Medical Advisory Committee
Chemist & Druggist
College of Health
College of Optometrists
College of Pharmacy Practice
Committee of Practitioners & Health Visitors Association (NI)
Community Pharmacy Magazine
Community Services Pharmacists Group
Company Chemist Association Ltd
Consolidated Communications
Consumers Association
Co-operative Pharmacy Technical Panel
CWS Ltd (Trade Liaison Department)
Department of Agriculture & Rural Development [N Ireland]
Department of Health, Social Services & Public Safety - Public Health Branch [N Ireland]
Dispensing Doctors Association
Doctor Magazine
Drug & Therapeutics Bulletin
Drug Information Pharmacists Group
English Board for Nursing, Midwifery & Health Visiting
European Association of Hospital Pharmacists
FDC Reports (Elsevier Science)
General Medical Council
General Medical Services Committee
General Medical Services Committee (Wales)
General Practitioners Association (NI)
Genetic Interest Group
Guild of Healthcare Pharmacists
Health & Safety Executive
Health Service Commissioner
Health Which?
Help the Aged
Home Office - Action Against Drugs Unit
Imperial Cancer Research Fund
IMS Health Division IDRAC
Independent Healthcare Association
Independent Television Commission
Insulin-Dependent Diabetics Trust
International Research Consultants
Joint Consultants Committee
Local Authority Central Office of Trading Standards (LACOTS)
Long-Term Medical Conditions Alliance
Medical Defence Union
Medical Protection Society Ltd
Medical Research Council
Medical Women's Federation
MIMS (Haymarket Medical Publishing Ltd)
National AIDS Trust
National Assembly for Wales, Health Department
National Association of GP Co-operatives
National Association of Women Pharmacists
National Back Pain Association
National Board for Nursing, Midwifery & Health Visiting (NI)
National Consumer Council
National Eczema Society
National Federation of Retail Newsagents
National Pharmaceutical Association
Neonatal and Paediatric Pharmacists Group
Neurological Alliance
NHS Information Authority (Coding & Classification)
Northern Ireland Consumer Council
Ophthalmic Group Committee
OTC Bulletin
OTC Business News (Informa Publishing Group Ltd)
OTC News & Market Report
Overseas Doctors Association in the UK Ltd
Paediatric Chief Pharmacists Group
Patients Association
Pharmaceutical Contractors Committee (Northern Ireland)
Pharmaceutical Journal
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society for Northern Ireland
PharMAG
Prescription Pricing Authority
Proprietary Association of Great Britain
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Midwives
Royal College of Nursing
Royal College of Nursing (Northern Ireland)
Royal College of Nursing (Wales)
Royal College of Obstetricians & Gynaecologists
Royal College of Ophthalmologists
Royal College of Paediatricians and Child Health
Royal College of Pathologists
Royal College of Physicians & Surgeons (Glasgow)
Royal College of Physicians (Edinburgh)
Royal College of Physicians (London)
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons (Edinburgh)
Royal College of Surgeons (England)
Royal College of Surgeons (Faculty of Dental Surgery)
Royal Colleges of Physicians : Faculty of Pharmaceutical Medicine
Royal Colleges of Physicians : Faculty of Public Health Medicine
Royal Pharmaceutical Society of Great Britain
Royal Pharmaceutical Society of Great Britain (Scotland)
Royal Pharmaceutical Society of Great Britain (Welsh Executive)
Royal Society for the Promotion of Health
Scottish Consumer Council
Scottish Executive, Department of Health
Scottish General Medical Services Committee
Scottish Pharmaceutical General Council
Scottish Wholesale Druggists Association
Scrip Ltd
Social Audit Unit
Society of Pharmaceutical Medicine
St Andrew’s Ambulance
St John Ambulance
St John Ambulance (NI)
Switch
Terrance Higgins Trust
Tic-Tac Administration
Tutsells Enterprise IG (The Brand Union Limited)
UK Committee for Nursing, Midwifery & Health Visiting
UK Clinical Pharmacy Association
UK Homoeopathic Medical Association
UK Inter-Professional Group
University of Aberdeen : Department of General Practice & Primary Care
Veterinary Medicines Directorate (VMD)
Welsh Consumer Council
Women in Medicine
CONSULTATION LETTER MLX 272

Proposed amendments to
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* 1. We have no comment to make on the proposals in MLX 272.

* 2. Our comments on the proposals in MLX 272 are below/attached.
   * My reply may be made freely available.
   * My reply is confidential.
   * My reply is partially confidential (indicate clearly in the text any confidential elements)

Signed : _____________________________________________

* Delete as appropriate