1. Introduction

The purpose of this paper is to collate the responses to the consultation exercise on proposed amendments to the General Sale List Order and the Sale or Supply Regulations and to seek Medicines Commission's advice.

2. Background

Consultation letter MLX 272 (copied at Annex A) was issued on 15 June 2001, with a deadline for comments by 3 August 2001. It was sent to 162 interested organisations (see Annex B) some of which copied it to their members; to the Department of Health and the Devolved Administrations and to members of the Committee on Safety of Medicines and the Medicines Commission.

The consultation letter contained proposals to amend the General Sale List Order so that the products could be sold without the supervision of a pharmacist. The proposals are summarised in section 3 below.

3. Summary of proposed amendments

Additions and amendments to the GSL Order:

- aspirin 75mg – See paper MC01/40
- cetirizine hydrochloride – See paper MC01/41
- ibuprofen (liquid preparations) - See paper MC01/42
- ibuprofen lysine - See paper MC01/43
- loratadine – See paper MC01/44
- paracetamol (liquid preparations) - See paper MC01/45
- potassium chloride – paragraph 4 below
- sodium fluoride – paragraph 5 below

4. 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.

The proposal was welcomed by the Royal College of GPs, the Royal College of Physicians in Glasgow and the Scottish Pharmaceutical General Council who welcomed this "very sensible clarification"
5. Sodium fluoride
Following an earlier consultation, this issue was submitted to the Commission (Paper MC 01/07) for discussion at the meeting on 1 March 2001. A request was made for further information. This was presented to the Commission at the meeting on 3 May 2001 (Paper MC 01/19) when it was agreed that the "GSL Order could be amended to permit the general sale of mouthwashes for daily use containing sodium fluoride at a maximum strength of 0.05% and mouthwashes other than those for daily use containing sodium fluoride at a maximum strength of 0.2%.”

This recommendation was included in consultation letter MLX 272. The British Dental Association, the Royal College of GPs and the Royal College of Physicians all fully supported the proposal. The Scottish Pharmaceutical General Council considered it “A very reasonable addition which will help the fight against dental caries, an important Government priority.”

The Royal Pharmaceutical Society of Great Britain expressed concern that "pharmacists receive many enquiries from intending purchasers about the amounts of fluoride containing products that can be used safely in combination, particularly in areas where the water supply is fluorinated."

MCA comment
Sodium fluoride mouthwashes, marketed under the cosmetics regulations, are freely available and we are not aware of any safety issues.

6. General Responses to consultation
The 35 responses are collated at Annex C and copies are attached.

Responses predominantly welcomed the proposals. The BMA considered them “safe for and helpful to patients” and the Royal College of Physicians and surgeons in Glasgow believe they will “facilitate appropriate and safe use of the relevant medicines.”

The National Pharmaceutical Association cited the added value of sales in pharmacies as a reason not to reclassify to GSL “Pharmacists are available for consultation without an appointment and provide not only information on choosing and using medicines safely and effectively, but also advise people seeking help on treating common ailments when it is more appropriate to see a doctor.”

The Royal College of Physicians of Edinburgh is concerned that greater availability of GSL medicines “is likely to make more precarious the financial viability of community pharmacies who currently provide a valuable health care resource.”

MCA comment
These comments highlight the role of the pharmacist in informing patients about suitability of medicines, warning about possible interactions, ensuring proper use and advising referral to a doctor. However, medicines are only suitable for GSL status when the hazard to health is small and the medicine can be safely used without professional supervision. Medicines must be marketed with comprehensive information for the patient, on the label or in a patient
information leaflet, which advises patients on proper use and any drug interactions or contraindications.

The Guild of Healthcare Pharmacists expressed concern that the medicines would be made available to the public where there was no availability of professional advice. They also commented: “We are particularly concerned about the proposal to increase the GSL pack size for Aspirin 75mg. This product was previously available as “Children’s aspirin” or “Junior Aspirin”, but its use in children under 12 years was discontinued because of the link with Reyes syndrome. Some years after this change, packs labelled with directions for administration to children were still available in general sale outlets. This illustrates the dangers of allowing the supply of medicines from outlets where there is no professionals supervision of the activity. It also demonstrates that “Drug recalls cannot be actioned effectively in these circumstances.” Tesco also commented along similar lines.

MCA comment:
Products are only considered for GSL classification where there are less safety concerns than with other products. In the event of there being serious public health concerns with regard to a product, manufacturers and distributors are required to have in place effective systems to enable its recall. GSL products are no exception and recall would be actioned through the wholesale distribution network, supplemented with appropriate publicity such as press releases. Specific concerns relating to aspirin 75mg are considered in paper MC 01/40.

7. Medicines Commission consideration
The Commission is asked to consider and advise on the responses to consultation letter MLX 267 on the proposed amendments to the GSL Order.

ATTACHMENTS
Annex A  MLX 272
Annex B  Consultation list
Annex C  Summary of Responses

MCA – Post-Licensing Division  August 2001
To Interested Organisations
date: 24 August, 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

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).
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%.

GSL-MC 24/08/01
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
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GSL-MC 24/08/01
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
RESPONSES TO CONSULTATION LETTER MLX 272

Proposals to amend the
General Sale List Order

1. GENERAL RESPONSES

British Medical Association “We have considered the proposals and would support them as safe for, and helpful to patients.”

Guild of Healthcare Pharmacists “......we are concerned at the proposal that the medicines listed should be made available to the public in circumstances where there is no availability of professional advice on their use.”

National Pharmaceutical Association “......current policies on reclassification are at odds with the Government’s policy of promoting safe, effective, responsible self-care.”

Royal College of Physicians and Surgeons of Glasgow “College is happy to welcome the proposed changes which they believe will facilitate appropriate and safe use of the relevant medicines.”

2. SPECIFIC RESPONSES
cetirizine hydrochloride and loratadine

The Boots Company “We propose that the MCA gives consideration to making concurrent change to the POM Order allowing an increase in the pharmacy pack size for both loratadine and cetirizine to a maximum of one month supply (30 x 10mg tablets = 300mg). It is entirely appropriate that patients should be able to buy OTC a one month supply of medication in the setting of a pharmacy – where professional advice on the condition and self-medication is readily available.”

Crookes Healthcare “We strongly support the proposal to allow these two non-sedating anti-histamines to be put on general sale at a strength of 10mg in packs of 7 tablets......However, we would like to propose that consideration is given to a simultaneous increase in pack size, from 10 to 30 tablets, for these anti-histamines when sold as Pharmacy products.”

Galpharm “Suggest that the amendment to the GSL Order should refer to the active as cetirizine dihydrochloride and cetirizine hydrochloride, so as to avoid any misunderstanding, even though both are descriptions for the same molecule......Making larger pack sizes of the non-sedating antihistamines available in Pharmacy will clearly differentiate pharmacy only from GSL medicines and bring the number of days treatment contained in a pack more in line with sedating antihistamines.”

The National Pharmaceutical Association “The proposal to make cetirizine dihydrochloride and loratadine available on general sale and to restrict the pack sizes obtainable from non-pharmacy outlets is nonsensical. If restriction of the pack size of these products is deemed necessary, then there must, by definition, be some concerns over one or two more aspects of their safety......We cannot see the logic in allowing a medicine to be reclassified as GSL providing it is sold in a small pack size, when consumers can easily obtain larger quantities than they need because of sales promotions.”

Royal College of General Practitioners “Antihistamines can take several days before they reach their maximum effectiveness against the condition so therefore short interrupted courses of antihistamines are not optimum treatment. We would therefore suggest they should consider pack sizes of at least 14 and maybe even 28 tablets.”
Royal Pharmaceutical Society of Great Britain “The Council believes that an individual with hay fever is more likely to have other, possibly more serious, allergy-related conditions. The involvement of a pharmacist in the sale or supply can help ensure that these do not go unrecognised and untreated. The pack size limit, considered to be an essential component of the reclassification from prescription only status, is accepted within pharmacy but the Council is concerned that such controls can be readily circumvented by the sale of multiple packs from non-pharmacy retail outlets.

Scottish Pharmaceutical General Council “SPGC wishes to record its opposition to the proposal to amend to GSL the 2 antihistamine substances cetirizine dihydrochloride and loratadine. There is, at this time, substantive evidence emerging which shows that these substances are being taken inappropriately as they appear to be less effective this hay fever season. In many rural areas patients are being found to overdose by taking 2 or even 3 doses per day.”

aspirin 75mg

British Medical Association “Aspirin 75mg is usually prescribed as the soluble formulation. The enteric coated formulation is far more expensive and confers little, if any, benefit. We would suggest that aspirin 75mg is made available in soluble formulation in larger packs for those patients who purchase them.”

Faculty of Dental Surgeons of England “....need for clear labelling as being unsuitable for children”

Galpharm “Since this is prophylaxis and long-term treatment, the enteric coating is critical so as to prevent the gastro-intestinal irritation associated with aspirin.”

The National Pharmaceutical Association “Wider availability of lower strengths of aspirin could encourage increased use in young children and may lead to further increases in the incidence of Reye’s syndrome in the UK.”

Prescription Pricing Authority “…the increase in allowed pack size for Aspirin 75mg E/C from 16 to 28 may lead to a proliferation of pack sizes.”

Royal College of General Practitioners “Could they consider increasing the availability to two months supply per pack (ie 56 tablets), this would reduce the number of buying trips from 12 to 6 per annum.”

Royal College of Physicians of Edinburgh “…this dose of aspirin is generally used for the prevention of heart attack or stroke, and medical assessment should be advised before this drug is taken long-term as the risk of gastrointestinal haemorrhage may outweigh cardiovascular benefit for patients at low risk of vascular disease.”

Royal Pharmaceutical Society of Great Britain “The provision of large quantities, in the event of the sale of multiple packs from non-pharmacy retail outlets, may suggest to the patient that self-treatment is inherently safe. Whilst the safety of the product itself is not in dispute, the lack of long-term professional advice may be prejudicial to patient safety.”

Scottish Pharmaceutical General Council “Our only comment is that aspirin is not a panacea, therefore its purchase for stroke prevention should always be accompanied by advice on appropriateness which will not be done in the garage or supermarket setting.”

ibuprofen (liquid preparations)

The Boots Company “We concur with the proposal for the wider availability of liquid ibuprofen liquid preparations

Crookes Healthcare “We wholeheartedly endorse the proposal to make ibuprofen liquid preparations for paediatric use more widely available. We do however, have a concern about the maximum dose (200mg) and the maximum daily dose (800mg) quoted. Our concern is that these older children will receive a sub-
therapeutic dose. We suggest that a 30ml multi-dose bottle be added to the proposed 5ml unit dose containers which we believe would not compromise patient safety in any way. We also suggest that it would be useful to word the Sale or Supply Regulations such that other non-liquid formulations of ibuprofen, containing not more than 100mg of the drug, which might be designed specifically for children could be covered."

_Mentholatum Company_ "We are in support of the proposal to allow liquid preparations of ibuprofen 100mg/5ml for use by children under the age of 12 years to be made available on general sale. However, we believe that if a liquid preparation of ibuprofen for children under 12 can safely be made available on general sale, ibuprofen for external use for children under 12 should equally be considered to be available on general sale."

_Royal College of General Practitioners_ "We fully support this medication becoming available on general sale."

_Royal Pharmaceutical Society of Great Britain_ "The Council has no objection to the proposals, but notes that, unusually, the proposal does not specify a lower age below which the product will not be available for GSL use. The Council would wish to be assured that a lower age is specified in the Order, so that products are not sold inappropriately for treatment of very young babies."

**ibuprofen lysine**

_Royal College of General Practitioners_ "...less than 3 days supply at the maximum dose has been recommended for general sales. We would suggest at least a week and preferably 2 weeks supply should be available."

_Royal Pharmaceutical Society of Great Britain_ "The Council has no objection to the proposal"

_Scottish Pharmaceutical General Council_ "Ibuprofen Lysine is a poor selling analgesic but perhaps has potentially more risk than Ibuprofen because it is more rapidly absorbed into the bloodstream. We are surprised to see its inclusion in addition to ibuprofen, which is safer and effective."

**paracetamol (liquid preparation)**

_The National Pharmaceutical Association_ "The NPA believes that it is important that all presentations of paracetamol liquid for children should remain as Pharmacy Medicines and that supply should be restricted to pharmacies. In 1998 changes to the Prescription Only Medicines Order, regarding the sale of paracetamol, highlighted the Government’s views on the safety of Paracetamol. It was felt that reducing the pack sizes available for sale to the public would prevent both accidental and intentional poisoning and, indeed, this has been shown to be the case. It seems anomalous to us therefore, that the Government now intends to increase the availability of paracetamol for use in children."

_Paediatric Trust Chief Pharmacist Group_ "It is absolutely imperative that the packaging for the 5% preparation is sufficiently distinct from that of the 2.4% preparation to prevent confusion."

_Royal College of Physicians of Edinburgh_ "Limiting the pack size to 50ml would mitigate against the danger of overdose somewhat, but recent reductions in pack size have resulted in at best a 20% reduction in overdose, and acute liver failure due to paracetamol toxicity still accounts for 80% of urgent liver transplants in Scotland. We would prefer that paracetamol be sold in a pharmacy where the sale of multiple units is unlikely to be allowed by responsible pharmacist."

_Royal Pharmaceutical Society of Great Britain_ "The Council...wishes to support the sentiment of the Medicine Commission’s desire that the packaging of any GSL..."
products are clearly differentiated, and that prominent patient information is given to reduce the risk of accidental overdose." 

**Scottish Pharmaceutical General Council** "SPGC is pleased that only sachets will be allowed on safety grounds but see this as a way to allow a safe "distress" purchase by mothers with older children."

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**potassium chloride**

*Royal College of General Practitioners* "We fully support its general sales availability and changes to the table."

*Royal Pharmaceutical Society of Great Britain* "The Council has no objection to the proposal"

*Scottish Pharmaceutical General Council* "Very sensible clarification here which is welcomed."

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**sodium fluoride**

*British Dental Association* "We support the proposal to amend the GSL Order to permit the sale of products containing sodium fluoride for use in the prevention of dental caries......a distinction in packaging would also be desirable for the two different mouthwashes to minimise the possibility of accidentally overdosing on fluoride intake."

*Royal Pharmaceutical Society of Great Britain* "Whilst the Council accepts the feeling that Sodium Fluoride is sufficiently safe for GSL classification, it is concerned that pharmacists receive many enquiries from intending purchasers about the amounts of fluoride containing products that can be used safely in combination, particularly in areas where the water supply is fluorinated."

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**3. RESPONSES WITH NO COMMENT**

Advertising Standards Authority  
British Epilepsy Association  
British Association for Nursing with Cardiac Care  
British Association of Dermatologists  
British Heart Foundation  
British Oncology Association  
British Pharmacological Society  
British Society for Rheumatology  
Health and Safety Executive  
Hope Hospital, Salford  
Imperial Cancer Research Fund  
Independent Healthcare Association  
Royal College of Pathologists  
Royal College of Physicians  
Scottish Consumer Council  
Scottish Executive Chief Pharmaceutical Officer  
UCB Pharma