SCOTTISH EXECUTIVE

Health Department

Dear Colleague

CHANGE IN NAMES OF CERTAIN MEDICINAL SUBSTANCES

Summary

We are writing to notify you of a programme of action, in the interests of patient safety, to achieve consistency in the naming of medicinal substances. Currently both British Approved Names (BANs) and recommended International Non-Proprietary Names (rINN) are in use in the UK and for some substances these names differ, giving rise to confusion and the risk of medication error. Since 1 December 2003, where the names differ the rINN is the correct name. The key actions needed are:

- prescribers and dispensers are asked, where BANs and rINNs differ, to use rINNs by 30 June 2004. This date has been agreed in consultation with stakeholder groups and should provide sufficient time for medical and pharmacy software systems to be updated;

- all healthcare professionals who prescribe, dispense or administer medicines are asked to take particular care to avoid the risk of medication errors during the transition period;

- Directors of Public Health, Medical Directors of NHS Boards and Trusts, Scottish Specialists in Pharmaceutical Public Health, Trust Chief Pharmacists, Directors of Nursing, Consultants in Dental Public Health and General Practitioners are asked to consider whether any additional local action may be necessary to minimise the risk of medication error during the transition period, including issuing briefing material about the name changes to staff;

- prescribers and dispensers are asked to inform their patients (and where appropriate their carers) when the names of the medicine on their prescription and dispensed medicine charges.

From the Chief Medical Officer, Chief Nursing Officer, Chief Pharmaceutical Officer and Chief Dental Officer

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For action

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Background

There is a requirement in both European and UK legislation to use rINNs for active substances in medicinal products. Until now this requirement has not been fully applied as there had been concerns about the possibility of medication errors that might result from a switch to the use of rINNs. However, it is clear from our discussions with professional bodies and from the independent advice we have received from the Medicines Commission (the Government's principal independent advisory body on medicines) that the greater risk would be to remain with the current confused situation. The consensus is that we now need a planned move to the use of rINNs in the interests of patient safety.

The change in names

The British Pharmacopoeia 2003 has published the name changes and they became effective on 1 December 2003. In most cases the differences between BANs and rINNs are very minor, for example *amoxycillin* (BAN) and *amoxicillin* (rINN), and are unlikely to cause confusion. However, some differences are more substantial, for example *bendrofluazide* and *bendroflumethiazide* and in some instances, the name changes completely, for example *benzhexol* and *trihexphenidyl*. A list of affected substances in common use, including those with significant differences in the names, is attached**.** Laminated copies of this list will be distributed to doctors and pharmacists through the professional journals in April and May. The full list of substances affected can be found on the website of the Medicines and Healthcare products Regulatory Agency (MHRA) at www.mhra.gov.uk.

There are two exceptions to the policy. These are *adrenaline* (rINN *epinephrine*) and *noradrenaline* (rINN *norepinephrine*). Based on the advice of the Medicines Commission, the MHRA will be encouraging manufacturers to use both names on product packaging and information literature. This reflects the wide usage of these substances under both the BAN and the rINN in emergency medicine.

Discussions with stakeholder groups have shown that dual labelling with both the BAN and rINN would not generally be practical for prescriptions and dispensing labels. Therefore, for these two substances, we recommend that prescribers and dispensers should retain the BANs *adrenaline* and *noradrenaline* on public health grounds and in line with the advice of the Medicines Commission.

Changes in naming of licensed medicines

The MHRA is asking industry to amend product labelling and literature during the year starting from December 2003 to show the rINN in cases where the BANs and rINNs differ. In cases where the rINN is not the active substance of the product (for example where it is referred to in information about interactions with other medicines) two years from December 2003 will be allowed for industry to make the change. Existing stock already in the supply chain at the change will continue to be used. In view of the shelf life of medicines it is likely to be a number of years before the changeover is complete.

Use of rINN by prescribers and dispensers

Health professionals who prescribe and dispense medicines should:

- familiarise themselves, as appropriate to their circumstances, with the changes and in particular those rINNs that differ significantly from the BAN;
- by 30 June 2004, use only rINNs; and
- continue to use the BANs only for *adrenaline* and *noradrenaline*.

A range of action has been taken or is planned to support health professionals in this change:

- information and reference sources, including the British National Formulary (BNF), the Monthly Index of Medical Specialities (MIMS) have been updated;
- providers of IT software systems that support prescribing and dispensing which do not already use rINNs are working to a timetable to make the necessary changes by 30 April 2004;
- advertisements and articles will appear shortly in a number of professional journals to alert health professionals to the changes; and
- the Royal Pharmaceutical Society and the British National Formulary produced a poster detailing the name changes in the 6 September 2003 issue of the *Pharmaceutical Journal*.

Risk management

All healthcare professionals who prescribe, dispense or administer medicines should:

- familiarise themselves with the rINNs and be vigilant against the risk of medication errors during the changeover period.

Directors of Public Health, Medical Directors of NHS Boards and Trusts, Scottish Specialists in Pharmaceutical Public Health, Trust Chief Pharmacists, Directors of Nursing, Consultants in Dental Public Health and General Practitioners are in a position to influence local clinical practice and procedures and should:

- undertake a risk assessment of how and where the affected medicine products are used locally and consider whether any additional local action, is required to further minimise risk. This may be of particular importance in areas where hand-written prescriptions are used, and where medicines are held in stock in clinical areas e.g. in hospitals, nursing homes and out of hours in primary care. For example, placing information concerning name changes on the front of medicine cupboard doors and next to prescription forms, and additional briefing for staff would help minimise risk. Also while dual labelling of medicines is not generally encouraged, there may exceptionally be local circumstances, if a risk cannot effectively be addressed in other ways, where it may be appropriate to ask a pharmacy to label specific medicines with both the rINN and the BAN during the changeover period.

The main areas of risk during the changeover period include the possibility of the wrong medicine or a duplicate of the correct medicine being prescribed, dispensed or administered; and the patient delaying or not taking the correct medicine as a result of uncertainty over whether the correct medicine has been supplied or taking a double dose. These risks are of course all ones which already apply in the present situation whereby different BANs and rINNs coexist for the same substance and clinicians may well be able to draw from experience in identifying and addressing any specific areas of risk in the local context.

BNF 47, published in March 2004, includes advice from the National Patient Safety Agency on how healthcare professionals can minimise the risks.

Informing the public

Healthcare professionals should ensure that they are well informed about the changes and able to advise and reassure patients. In particular:

- *prescribers* should explain the change to patients (or where appropriate, the patient's carer) when they start prescribing by rINN during the course of a treatment;
- *dispensers* should explain the position to patients where there is a discrepancy between the rINN on the dispensing label and a BAN that may be used in product information, for example.

Perceptions of risks or concerns held by patients may be different from those held by healthcare professionals. It is important that as well as alerting patients and carers to the change of name of their medicine, healthcare professionals try to tailor additional information to the specific needs of individual patients.

To help pharmacists and doctors to brief patients or answer queries, a laminated card will be distributed through the professional journals during April and May 2004. The text of this information can also be downloaded from the MHRA website and reproduced as necessary.

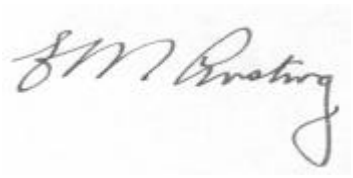
NHS 24 has been briefed to deal with patient queries. Posters about the name changes will be circulated to General Practitioners surgeries, community and hospital pharmacies, residential and nursing homes and other clinical environments where it would be helpful to advise patients and carer's concerning the change in the name of their medicine.

Further information

Further information, including Q&A briefing, can be found on the MHRA website.

Our counterparts in England, Wales and Northern Ireland will also be writing in similar terms to professional colleagues there.

Yours sincerely



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Changing substance names from BANs to rINNs

List of commonly used names

Former BAN	rINN (new BAN)
Acrosoxacin	Rosoxacin
Amethocaine	Tetracaine
Amoxycillin	Amoxicillin
Amylobarbitone	Amobarbital
Amylobarbitone sodium	Amobarbital sodium
Beclomethasone	Beclometasone
Bendrofluazide	Bendroflumethiazide
Benorylate	Benorilate
Benzhexol	Trihexyphenidyl
Benztropine	Benzatropine
Busulphan	Busulfan
Butobarbitone	Butobarbital
Carticaine	Articaine
Cephalexin	Cefalexin
Cephamandole Nafate	Cefamandole Nafate
Cephazolin	Cefazolin
Cephradine	Cefradine
Chloral betaine	Cloral betaine
Chlorbutol	Chlorobutanol
Chlormethiazole	Clomethiazole
Chlorpheniramine	Chlorphenamine
Chlorthalidone	Chlortalidone
Cholecalciferol	Colecalciferol
Cholestyramine	Colestyramine
Clomiphene	Clomifene
Colistin Sulphomethate Sodium	Colistimethate Sodium
Corticotrophin	Corticotropin
Cyclosporin	Ciclosporin
Cysteamine	Mercaptamine
Danthron	Dantron
Desoxymethasone	Desoximetasone
Dexamphetamine	Dexamfetamine
Dibromopropamidine	Dibrompropamidine
Dicyclomine	Dicycloverine
Dienoestrol	Dienestrol
Dimethicone (s)	Dimeticone
Dimethyl sulphoxide	Dimethyl sulfoxide
Dothiepin	Dosulepin
Doxycycline Hydrochloride (Hemihydrate Hemiethanolate)	Doxycycline Hyclate
Eformoterol	Formoterol
Ethamsylate	Etamsylate
Ethinyloestradiol	Ethinylestradiol
Ethynodiol	Etynodiol
Flumethasone	Flumetasone
Flupenthixol	Flupentixol
Flurandrenolone	Fludroxycortide
Frusemide	Furosemide
Gestronol	Gestonorone
Guaiphenesin	Guaifenesin

Former BAN	rINN (new BAN)
Hexachlorophane	Hexachlorophene
Hexamine Hippurate	Methenamine Hippurate
Hydroxyurea	Hydroxycarbamide
Indomethacin	Indometacin
Lignocaine	Lidocaine
Lysuride	Lisuride
Methimazole	Thiamazole
Methotrimeprazine	Levomepromazine
Methyl Cysteine	Mecysteine
Methylene Blue	Methylthioninium Chloride
Mitozantrone	Mitoxantrone
Mustine	Chlormethine
Nicoumalone	Acenocoumarol
Oestradiol	Estradiol
Oestriol	Estriol
Oestrone	Estrone
Oxpentifylline	Pentoxifylline
Phenobarbitone	Phenobarbital
Pipothiazine	Pipotiazine
Polyhexanide	Polihexanide
Potassium Clorazepate	Dipotassium Clorazepate
Pramoxine	Pramocaine
Procaine Penicillin	Procaine Benzylpenicillin
Prothionamide	Protionamide
Quinalbarbitone	Secobarbital
Riboflavine	Riboflavin
Salcatonin	Calcitonin (salmon)
Sodium Calciumedetate	Sodium Calcium Edetate
Sodium Cromoglycate	Sodium Cromoglicate
Sodium Ironedetate	Sodium Feredetate
Sodium Picosulphate	Sodium Picosulfate
Sorbitan Monostearate	Sorbitan Stearate
Stibocaptate	Sodium Stibocaptate
Stilboestrol	Diethylstilbestrol
Sulphacetamide	Sulfacetamide
Sulphadiazine	Sulfadiazine
Sulphamethoxazole	Sulfamethoxazole
Sulphapyridine	Sulfapyridine
Sulphasalazine	Sulfasalazine
Sulphathiazole	Sulfathiazole
Sulphinpyrazone	Sulfinpyrazone
Tetracosactrin	Tetracosactide
Thiabendazole	Tiabendazole
Thioguanine	Tioguanine
Thiopentone	Thiopental
Thymoxamine	Moxisylyte
Thyroxine Sodium	Levothyroxine Sodium
Tribavirin	Ribavirin
Trimeprazine	Alimemazine
Urofollitrophin	Urofollitropin