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Chief Executives of Boards and Trusts
Drug and Therapeutics Committees of Boards and Trusts (or equivalent)
Medical Directors of Trusts
All Consultants
Directors of Pharmaceutical Services in Boards and Trusts
Directors of Public Health in Boards
GP and Prescribing Advisers in Boards
Directors of Nursing in Boards & Trusts

2 April 2003

Dear Colleague

THE REGIONAL GROUP ON SPECIALIST DRUGS – IMPLEMENTATION OF RED/AMBER LISTS – 1 MAY 2003

1.0 INTRODUCTION

The Regional Group on Specialist Drugs, chaired by Professor Denis Johnston, has made recommendations regarding the introduction of a categorisation system (Red/Amber lists) for specialist medicines. This system provides professional guidance on where prescribing responsibility should lie in respect of a small number of specialist medicines. It was developed to enhance patient care and promote safety in the prescribing, supply and administration of specialist medicines.

It should be emphasised that these lists are advisory, and appearance of a medicine on a red/amber list does not imply endorsement of use, but rather a recommendation on prescribing responsibilities and whether or not the supply of a medicine should be organised through the hospital pharmacy network. Its primary function relates to patient safety and enhancement of services for patients on specialist medicines; it does not take account of the cost implications of use of a particular medicine. Appendix A contains the definition of a specialist medicine and the criteria used by the Group for development of the red/amber list. In summary:

Red List Drug: Prescribing responsibility should remain with the consultant. It is recommended that the supply of these medicines should be organised via the hospital pharmacy.

Amber List Drug: Responsibility for prescribing may be transferred from secondary to primary care with the agreement of an individual GP and when agreed shared care arrangements have been established.

2.0 HPSS RED/AMBER LIST PROCESS

The purpose of this letter is to outline the HPSS process for changes to be made to the red/amber lists. This process builds on the work already undertaken in the Northern Health and Social Services Board and in other areas of the United Kingdom. There is a need to have a sustainable process for change, which reflects:

i. the introduction of new specialist medicines;

ii. the changes in established clinical practice where it might be appropriate to change the status of a medicine on the red/amber list; and

iii. the changes in licensed indications for specialist medicines already in use.

Appendix B contains a diagrammatic over view of the process. The process for maintaining the red/amber lists will have two components:

a. horizon scanning; and

b. a biannual trawl through the HPSS on proposals for change.

2.1 Horizon Scanning

There will be an ongoing commitment to horizon scanning on new developments from a variety of sources at local, national and international level. This preliminary horizon scan will be contributed to by HPSS professionals, the new interface pharmacy network, the Regional Medicines Information Service and the Department informed by the UK Medicines Information Network. These arrangements will take account of any future links with national standard setting bodies. The local interface pharmacist will bring the evidence to the 4 Area Drug and Therapeutic Committees (or equivalent) for preliminary assessment on a specific medicine. It will be the responsibility of the Area Drug and Therapeutic Committee (or equivalent) to ensure that there is sufficient professional input from GPs, consultants, pharmacists and nursing colleagues through existing committee structures. Where a medicine is considered to be of a highly specialist nature, there may also be a need to seek wider views from those with specialist expertise.

The evidence which might be considered would not be in relation to the clinical efficacy of the medicine, but rather evidence on:

- where prescribing responsibilities might lie;
- the specialist nature of the medicine; and
- the complexity of the assessment and monitoring arrangements required for the care of the patient.

The result of the preliminary assessment will be documented on Form 1 (Appendix C) and then submitted to the Regional Group on Specialist Drugs for a recommendation against agreed criteria.

2.2 Biannual Trawl

There will be a biannual trawl on behalf of the Regional Group on Specialist Drugs to Trusts, Boards and Local Health and Social Care Groups. It is recommended that organisations bring the trawl notice to the attention of relevant committees and professionals.

A suggested pro forma is set out in Appendix D. The pro forma should be returned to the interface pharmacist coordinator with the supporting evidence, who, together with colleagues in the interface pharmacy network will put the proposal forward to the relevant Area D&T Committee (or equivalent).

The recommendation of the Area Drug and Therapeutics Committee, together with the reason for recommendation, will be sent to the secretariat of the Regional Group on Specialist Drugs. It will be the responsibility of the Regional Group, having adjudicated on submissions, to communicate its decisions to the service. This will include feedback to individual practitioners who have requested changes to existing lists.

2.3 Amber List

The amber list is an advisory list where it is considered by the Regional Group that responsibility for prescribing may be transferred from secondary to primary care when agreed shared care arrangements have been established. It is recommended that shared care agreements should be drawn up following local discussion and agreement by prescribing parties. Appendix E provides an example of a template for development of a shared care guideline for amber listed medicines.

The shared care guideline will make recommendations on the respective clinical responsibilities of both parties. It is recommended that the development of a regional guideline for specific medicines or therapeutic group of medicines be facilitated by the interface pharmacy network and developed in collaboration with consultants, GPs and others. The Regional Group will then endorse the guideline. Following endorsement by the Regional Group, the guideline could be adapted for local use with implementation being brought forward at local level through the Area Drug and Therapeutic Committees (or equivalent) in liaison with the interface pharmacy network. A repository of regional guidelines and accompanying patient information will be held on the departmental website and on the website of each of the HSS Boards.

3.0 IMPLEMENTATION – to commence May 2003

Appendix F contains the current red/amber list. The implementation of this red/amber list will be phased. From 1 May 2003 there will be a phased programme to:

- **put in place a system where new patients, who are prescribed the small number of "red listed" medicines, will receive their supply via the hospital system**. This is an extension of current practice where many patients are already receiving specialist medicines via this route.

- **accommodate the transfer of prescribing and supply of existing red listed medicines from the community to the hospital sector**. Given the specialist nature of medical conditions for which these drugs are prescribed, most of these patients will already be attending hospital out-patient clinics.

- **develop shared care guidelines in collaboration with GPs and consultants for amber listed medicines**. These will make recommendations on the respective responsibilities of general practitioners and consultants. Each will be formulated and endorsed as a common regional guideline with capacity for local adaptation.

Commencement of implementation of the red/amber lists is being facilitated by recurrent funding by the Department to accommodate the transfer of existing red listed medicines from primary to the secondary sector and the funding of 7 interface pharmacists, including a coordinator, to provide cohesive care for patients in relation to specialist medicines, particularly at the interface between primary and secondary care. The coordinator will be based at the Royal Group of Hospitals.

4.0 CONCLUSION

We believe that this is the most effective way of providing high quality consistent care for patients who receive specialist medicines in Northern Ireland. It will take some time to complete implementation of this work and we would be grateful for your support during the implementation phase.

Yours sincerely

HENRIETTA CAMPBELL (DR)	**NORMAN MORROW (DR)**	**JUDITH HILL (MISS)**
Chief Medical Officer	Chief Pharmaceutical Officer	Chief Nursing Officer

APPENDIX A

Criteria for Red/Amber Listed Adjudication

The "Red" list contains the recommendations of the Regional Group on Specialist Drugs on products, which should remain the prescribing responsibility of the consultant or specialist clinician. It is recommended that the supply of these drugs should be organised via the hospital pharmacy.

For the purposes of Red/Amber List recommendations, a specialist medicine is defined as one, which has:

> ***… significant pharmacological complexity and/or rarity of use to make the prescribing of the medicine relatively uncommon in the community.***
>
> ***Patients, for whom complex medicines are prescribed, may have particular complex monitoring requirements, which require specialist knowledge for the appropriate interpretation of results. In such circumstances, due consideration needs to be given to the settings and knowledge required by the professional to undertake the prescribing, monitoring and supply of the medicine, in order to ensure high quality patient care.***

<u>Criteria for products which would not be recommended for shared care (Red List)</u>

Drugs which meet one or more of the following criteria should remain the prescribing responsibility of the consultant or specialist clinician:

- The drug does not hold a product licence.
- The drug is being used outside the terms of the product licence to an extent that a GP would not normally be expected to accept clinical responsibility.
- The drug is being used as part of a hospital based clinical trial.
- The individual GP is unable to monitor therapy sufficiently to oversee treatment or adjust the dose where necessary to ensure safety.
- The drug is new and there may be issues around long-term safety or its appropriate place in therapy.
- The drug, dressing or appliance is only available through a hospital.

AMBER LIST

It is recommended that amber list drugs are appropriate for shared care, responsibility for prescribing may be transferred from secondary to primary care when agreed shared care arrangements have been established. The GP would normally undertake prescribing responsibility provided he/she was content that sufficient information was available to do so. Concern about the prescribing/monitoring of a specific product should be discussed between parties. It is recommended that shared care agreements should be drawn up following local discussion and agreement by prescribing parties.

<u>Criteria for products which may become part of shared care agreements (Amber List):</u>

Circumstances which meet all of the following criteria may allow a product to be used as part of a shared care arrangement, following agreement by both prescribing parties involved.

1. A shared care proposal has been drawn up following joint discussions of the parties.

2. The shared care agreement:

    - provides a comprehensive summary of treatment.
    - defines the responsibility of the consultant and GP for monitoring and adjusting treatment.

    - defines the referral procedure from hospital to GP.

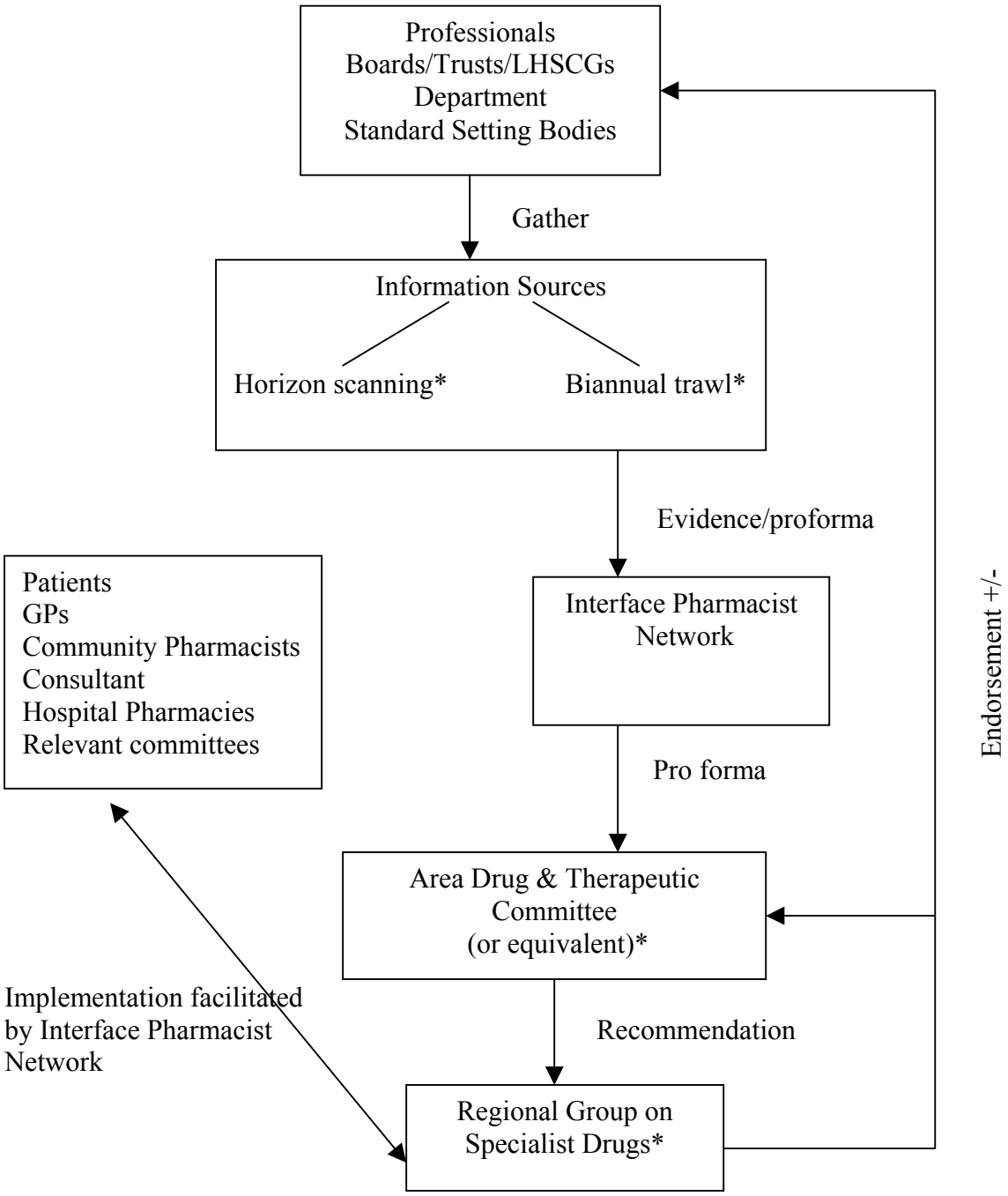
    - defines the back-up facilities available to the GP from the hospital with which the agreement is made.

3. The GP is satisfied that he/she has all the information and support needed to prescribe and to monitor the patient.

4. If a product is not licensed for the proposed indication, full justification for its use is given by the consultant to the GP.

APPENDIX B

PROCESS FOR ADJUDICATION ON RED/AMBER LIST



*See notes 1-4

Notes

1) For new specialist medicines, recommended for use at Trust level, the default position should be "red list" until a recommendation can be made by the Regional Group on Specialist Drugs.

2) The biannual trawl and preliminary horizon scanning is co-ordinated by the interface pharmacist network.

3) The collated results (from 2 above) are presented to the local Area Drug and Therapeutics Committees or equivalent for preliminary assessment.

4) The Regional Group will feedback the recommendation to the proposer. Communication to patients and professionals, and implementation, will be led by the interface pharmacy network, working in close collaboration with local professionals.

APPENDIX C

FORM 1
HORIZON SCANNING ASSESSMENT AND REFERRAL TO AREA DRUG AND THERAPEUTICS COMMITTEE (OR EQUIVALENT) FOR PRELIMINARY ASSESSMENT

Medicine----------

Supporting papers ---------- y/n? If yes, please document.

<u>Rationale for proposal (against agreed criteria and evidence base)</u>

Signature of Interface Pharmacist ----------

Date----------

Recommendation to Regional Group on Specialist Drugs by the Area D & T Committee of the XXXX Board

Recommendation – Red/Green/Amber (please circle)

Reason

Evidence considered

Signature ---------- Date----------

(PTO) if necessary

APPENDIX D

FORM 2

PROPOSAL FROM PRESCRIBERS IN RELATION TO ATTACHED RED/AMBER LIST

Attached are copies of:

a. the current recommendations relating to where prescribing responsibilities might lie for certain specialist drugs; and

b. the criteria upon which a recommendation is made for inclusion of a medicine in the Red/Amber List.

This form is to allow consideration of proposals for adjudication by the Regional Group on Specialist Drugs against the agreed criteria.

In considering a proposal prescribers should take account of new medicines, and new licensed indications of medicines. They should also consider the removal of medicines from either the red or amber list where regulation, clinical practice or experience of use makes it inappropriate to continue with the current designation.

Proposal from
(e.g. GP/Consultant/pharmacist)----------

Medicine---------- Supporting papers ---------- y/n?

<u>Rationale for proposal (against agreed criteria and evidence base)</u>

Signature of professional ---------- Date----------

Recommendation to Regional Group on Specialist Drugs

This proposal was considered by the Area Drug and Therapeutic Committee of the XXXX Board

Recommendation – Red/Amber/Green (please circle)

Reason (against agreed criteria)

Evidence considered

Signature ---------- Date----------

(PTO) if necessary

Appendix E

Shared Care Guideline Format.

	Drug Name Shared Care Guidelines (Indication)
Introduction	Background Treatment Aims Pharmacology of the drug Dosage and administration
Hospital Specialist Responsibilities	Summary Disease Monitoring Drug monitoring criteria
GP Responsibilities	Summary Disease Monitoring Drug monitoring criteria
Adverse Effects and Contraindications	Adverse effects and contraindications
Drug Interactions	Drug interactions
Communication	Contact details Information the Hospital Specialist is required to provide to the GP Information the GP is required to provide to the Hospital Specialist
Footnotes	Date prepared Date of review Reference to full prescribing information e.g. SPC.

RED LIST

The following "Red" list contains the recommendations of the Regional Group on Specialist Drugs on products, which should remain the prescribing responsibility of the consultant or specialist clinician[*]. It is recommended that the supply of these drugs should be organised via the hospital pharmacy.

DRUG NAME	BRAND NAME (Examples)
acitretin	Neotigason
clozapine	Clozaril
dexamfetamine (for narcolepsy and use outside of licensed indications)	Dexedrine
desferrioxamine (treatment of poisoning)	Desferal
disodium pamidronate	Aredia
dornase alpha	Pulmozyme
epoprostenol	Flolan
erythropoietin (for dialysis patients)	Eprex, NeoRecormon
etanercept	Enbrel
factor VIII	
filgrastim	Neupogen
ganciclovir	Cymevene
infliximab	Remicade
infertility drugs[**] (excluding clomifene)	various
interferon alfa	Intron-A, Roferon-A, Viraferon
drugs for MS	Betaferon, Avonex, Rebif, Copaxone
interferon gamma	Immukin
[#]drugs for impotence (severe distress category)	Viagra, Caverject, Viridal Duo, MUSE, Uprima, Cialis, Erecnos, Levitra
isotretinoin	Roaccutane
IV cytotoxics eg docetaxel, paclitaxel (also includes parenteral Methotrexate)	Various e.g. Taxotere, Taxol
IV/nebulised anti-infectives for HIV, cystic fibrosis and post chemotherapy	
eg colistin	Colomycin
tobramycin	Tobi, Nebcin
teicoplanin	Targocid
ketamine	Ketalar
lanreotide (outside of licensed indications)	Somatuline
lenograstim	Granocyte
linezolid	Zyvox
medroxyprogesterone acetate (high dose)	Farlutal / Provera
methylphenidate (outside of licensed indications)	Ritalin, Equasym, Concerta XL
molgramostim	Leucomax
levonorgestrel IUD (for menorrhagia)	Mirena
octreotide, (outside of licensed indications)	Sandostatin
palivizumab	Synagis
riluzole	Rilutek
purified immunoglobulin	
sodium clodronate (IV only)	Bonefos
Solutions for peritoneal dialysis	
TPN solutions	
tribavirin/ribavirin	Rebetol, Virazole

[*] A specialist clinician is defined as a clinician with special responsibility and expertise in the given area of care that the patient requires.

[**] see attached list of infertility drugs

[#] See Circular HSS(SC)2/99 for departmental guidance on "Treatment for Impotence – patients with severe distress". Treatment may be available from specialist services.

***RED LIST**

Examples of Red List subfertility drugs. It is recommended these drugs be prescribed via hospital subfertility clinics.

Drug name	**Brand name (examples)**
chorionic gonadotrophin	Choragon, Profasi, Pregnyl
follitropin alfa and beta	Gonal-F, Puregon
human menopausal gonadotrophins	Menogon, Menopur
cetrorelix	Cetrotide
ganirelix	Orgalutran
gonadorelin analogues	Suprecur, Suprefact, Zoladex, Synarel

AMBER LIST

The Regional Group on Specialist Drugs recommends the following "Amber" list.

It is recommended that amber list drugs are appropriate for shared care – responsibility for prescribing may be transferred from secondary to primary care when agreed shared care arrangements have been established. The GP would normally undertake prescribing responsibility provided he/she was content that sufficient information was available to do so. Concern about the prescribing/monitoring of a specific product should be discussed between parties. It is recommended that shared care agreements should be drawn up following local discussion and agreement by prescribing parties.

DRUG NAME	BRAND NAME (Examples)
anastrozole	Arimidex
apomorphine (neurological indications)	APO-go
becaplermin	Regranex
bicalutamide	Casodex
clomifene	Clomid
cyclosporin	Neoral
desferrioxamine (chronic iron overload)	Desferal
dexamfetamine	Dexedrine
donepezil	Aricept
erythropoietin (non dialysis patients)	Eprex, NeoRecormon
estramustine	Estracyt
flutamide	Drogenil
galantamine	Reminyl
gestonorone caproate	
leflunomide	Arava
lanreotide (within licensed indications)	Somatuline
Low Molecular Weight Heparins	Clexane, Fragmin
lofexidine	BritLofex
megestrol acetate	Megace
modafinil	Provigil
methylphenidate	Ritalin, Equasym, Concerta XL
mycophenolate mofetil	CellCept
naltrexone	Nalorex
octreotide, (Within licensed indications)	Sandostatin,
thioridazine	Melleril/Rideril
quetiapine	Seroquel
rivastigmine	Exelon
somatropin	Various
tacrolimus	Prograf
zotepine	Zoleptil

AMBER SUB GROUP

The Regional Group on Specialist Drugs recommends that the following drugs should appear as a subgroup of the Amber list. It is acknowledged that some of these drugs, while not falling within the definition of a "specialist drug", cause particular monitoring difficulties for general practitioners. Individual Boards should have local flexibility in deciding whether these require a shared care agreement (amber) or whether the Board recommends that they should be prescribed without protocol (green).

warfarin
amiodarone
lithium
azathioprine
sodium aurothiomalate/
auranofin (gold)
chloroquine/hydroxychloroquine
sulfasalazine
penicillamine
methotrexate(oral)
testosterone
monoamine-oxidase inhibitors