Date7th November 2001VenueCommittee Room 3, The National Assembly for WalesTitleImplementing the recommendations made by the Task and Finish Group Report on
Prescribing

Purpose

- 1. To present a plan for the implementation of the recommendations made by the Task and Finish Group Report on Prescribing
- 2. The Health and Social Services Committee is responsible, under Standing Order 9.7, for contributing to the development of Assembly policies relating to the prescribing of drugs, the provision of pharmaceutical services and the supply of pharmaceuticals in Wales.
- 3. The Committee is asked to:

(i) agree to the establishment of the All Wales Medicines Strategy Group (AWMSG) as a statutory advisory ASPB to the Assembly and agree its constitution and terms of reference (Annex 1); in particular

a) note the need for secondary legislation for the establishment of the committee;b) that the AWMSG will advise on the implementation of the strategic recommendations made by the Task and Finish Group;c) comment on the inclusion of representation from the Pharmaceutical Industry (please refer to point 12 in this document).

(ii) agree to draft the working arrangements, Terms of Reference, and funding for the Welsh Medicines PartnershipNational Prescribing Support Service to support the work of the AWMSG (Annex 3);

(iii) note the implementation plan to introduce the Task and Finish Report's non-strategic recommendations, the progress already made towards meeting this and the work undertaken to support the function of the AWMSG, once established (Annex 4);

(iv) note the financial implications of implementing the recommendations of the report.

(v) note the response to the queries raised at the Health and Social Services Committee meeting on 14th March regarding the PPRS and generic and therapeutic substitution (Annex 6).

Summary / Recommendations

1. One of the key recommendations of the Prescribing Task and Finish Group is that an All Wales Medicines Strategy Group be established on a formal basis, accountable to the National Assembly.

2. The aim of the Strategy group is to provide advice in an effective, efficient and transparent manner to the Assembly on strategic medicines management and prescribing. This will enable the Assembly to provide guidance on a standard pattern of approach to prescribing issues across Wales whilst permitting local application but reducing duplication of effort. Establishment of the group, with support from the Welsh Medicines Partnership and subject to the Committee's advice , could realise early benefits to patient care by minimising the incidence of 'postcode prescribing' across Wales.

3. The Group's main functions would be to:

- advise Assembly of future developments in healthcare that involve the use of medicines and that will assist the Assembly in its strategic planning for their potential impact on the NHS. in Wales.
- develop timely, independent and authoritative advice on new drugs and on the cost implications of making these drugs routinely available on the NHS. (This would include making interim recommendations on the place in treatment of drugs awaiting appraisal by the National Institute for Clinical Excellence (NICE)).
- advise the Assembly on the development of a consistent cost-effective prescribing strategy for Wales ([with consideration to pharmaceutical developments, NICE guidance, National Service Frameworks, Welsh epidemiology)
- advise the Assembly on the implementation and cost-benefits of a range of other strategic Prescribing Task and Finish Group recommendations at local level within the NHS
- advise the Assembly on how consumer groups might be engaged to discuss consumer expectations and their impact on prescribing behaviour

4. The Task and Finish report's non-strategic recommendations will be taken forward by Officials, in consultation with the AWMSG.

Timing

5. In order to quickly realise the anticipated benefits of the AWMSG, we would wish to see it established and operational before 1 April 2002, and [without prejudice to the final configuration of the service] we would be seeking continuity of membership as far as is possible over the NHS restructuring period.

Background

6. The Minister for Health and Social Services set up a Task and Finish Group for Prescribing in late

1999. The Group was required to advise on the improvement of all aspects of the prescribing and provision of pharmaceuticals, quantifying the benefits and resources, identifying the barriers to implementing the improvements and on the gathering of data and its use as information.

7. The Group's report, containing some 96 recommendations, was submitted to the Health and Social Services Committee (HSSC) in March 2001. The HSSC welcomed the report and asked that Assembly officials draw up a costed implementation plan for consideration and prioritisation by the committee in Autumn 2001

8. One of the key recommendations of the Prescribing Task and Finish Group is that an All Wales Medicines Strategy Group be established on a formal basis, accountable to the National Assembly. Details of the proposed AWMSG, developed following a full written consultation with the NHS, professional groups, the Pharmaceutical Industry and public representative groups, are given in Annex 1.

9. The consultation revealed Industry representation on the AWMSG to be a contentious issue. Those keen to include the Industry felt that their presence would aid the strategic planning process and would enable engagement of the Industry in initiatives that improve communications with patients. Others felt that their inclusion would create a conflict of interest with the work of the group and could confer a competitive advantage to some Pharmaceutical companies with close links to the Group. . Current Government thinking in respect of the Pharmaceutical Industry is reflected by the United Kingdom report of the "Pharmaceutical Industry Competitiveness Task Force." A copy of the report can be obtained from the Internet at http://www.doh.gov.uk/pictf/pictf.pdf The preface is given in Annex 7.

10. Consideration should be given to establishment of a NHS-Industry Forum, as recommended by the Task and Finish Report, to discuss common issues between health professionals and the Pharmaceutical Industry. Areas for discussion would include the issue of Industry sponsorship, patient information and risk management. The Forum would report to the AWMSG. (Please note that this is a separate forum to the Assembly / Welsh Industry Group that discusses broader issues such as potential economic development of the Pharmaceutical Industry in Wales)

11. Similarly, consideration should be given to establishing a Patients' Forum to discuss consumer expectations and their impact on prescribing behaviour, and also an Information Technology (IT) Forum to discuss IT issues relating to prescribing, such as the electronic transfer of prescriptions.

Consideration

12. Details of the proposed working arrangements and terms of reference for the AWMSG are given in Annex 1.

13. A summary of the responses to the consultation exercise with the NHS on the working arrangements for the AWMSG is given in Annex 2

14. Details of the proposed working arrangements and terms of reference for the Welsh Medicines Partnership to support the work of the AWMSG are given in Annex 3; (Please note that the Welsh Medicines Partnership was referred to in the Task and Finish Report as the Welsh National Prescribing Support Service).

15. The implementation plan to introduce the Task and Finish Report's non-strategic recommendations, the progress already made towards meeting this and the work undertaken to support the function of the AWMSG, once established are given in Annex 4.

16. Details of the costs of implementing the initial recommendations of the report are given in Annex 5

17. The response to the queries raised at the Health and Social Services Committee meeting on 14th March regarding the PPRS and generic and therapeutic substitution is given in Annex 6.

The preface of the, "Pharmaceutical Industry Competitiveness Task Force" report is given in Annex
 A full copy of the report can be obtained from the Internet at <u>http://www.doh.gov.uk/pictf/pictf.pdf</u>

19. A copy of the Report of the Task and Finish Group, providing a full exploration of the issues supporting the recommendations, was presented to the Committee on 14 March 2001 (<u>HSS-05-01(p.1)</u>).

Compliance

20. The recommendations of the Task and Finish Group were wide ranging. A description of the delegated powers underpinning the group's recommendations is set out in Appendix 2 of the Task and Finish Report.

21. Subject to the HSSC agreement, the AWMSG would be formed under devolved powers of Section 6 of (and Schedule 4 to) the National Health Service Act 1977. This has been delegated to the Minister for Health and Social Services. The AWMSG would need to be established by order under the usual secondary legislation procedures.

22. The Assembly Compliance Officer and Office of the Counsel General have seen this paper and are content.

Finance

23. Since many of the recommendations made in the Task and Finish report are subject to negotiation with the contractor professions, it is not possible to quantify the financial implications of implementing the whole report at this time.

24. The funding of the initial recommendations and preliminary work to support the operation of the AWMSG has amounted to some £731,000, including £200,000 required to support the Welsh Medicines Partnership. These costs are to be met from programme budgets (Health Authorities and NHS Trusts, Revenue Budget Expenditure Line 1a, within the Health and Social Services Main Expenditure Group). Further details of the costs of implementing the report's recommendations are given in Annex 5.

25. Implementation of the recommendations made in the report should contribute to a better service for patients and a more efficient use of resources.

26. NHS Finance Division (JU/JG606) has been consulted about this submission and notes that there are no additional financial implications for the Assembly arising from these proposals.

Contact Point

27. Mrs Carolyn Poulter (Ext. 3014), Pharmaceutical Services Branch, Primary and Community Health Division is able to provide further information on details contained in this paper if required.

Annex 1

Draft Constitution of the all Wales Medicines Strategy Group

1. TITLE

1.1 The Committee shall be known as the All Wales Medicines Strategy Group (AWMSG)

2. DEFINITIONS

2.1 In this document, unless the context otherwise requires:

the 'Committee' refers to the All Wales Medicines Strategy Group (AWMSG), which is recognised in pursuance of Section 6 of (and Schedule 4 to) the National Health Service Act 1977.

3. MEMBERSHIP

3.1 The Minister for Health and Social Services will appoint the Committee following nominations from appropriate representative committees, and from responses to open advertisement, as appropriate. The Minister will also appoint deputies to attend in the absence of the principal members.

The Committee will consist of the following voting members:-

- one Director of Public Health Medicine*
- one Director of Pharmaceutical Public Health representative*
- representation from Local Health Groups* comprising:
 - one General Practitioner, with a prescribing lead role
 - one Nurse prescriber or nurse practitioner
 - one pharmacist,
 - Members will be appointed from different Health Economy areas;
- representation from NHS Trusts comprising:
 - one Medical Director
 - one Consultant
 - one Nurse Director
 - one Chief Pharmacist
 - Members will be appointed from different Health Economy areas;
- one representative from other healthcare professions eligible to prescribe
- one Health Authority Director of Finance*
- one Health Economist
- one representative from the Association of British Pharmaceutical Industry for Wales

* membership will need to be reviewed following the re-organisation of the NHS in Wales

and the following non-voting members:

- the Directors representing the partner organisations of the Welsh Medicines Partnership (WMP)
- one Lay person
- The committee will hold a list of specialists, nominated from existing statutory bodies, clinical or professional organisations, to be co-opted for advice on specialist subjects.

4. NATIONAL ASSEMBLY FOR WALES

4.1 The Chief Medical Officer (or representative) and the Chief Pharmaceutical Adviser (or representative) will be invited to attend all meetings of the Committee and will receive the agenda, minutes and other papers issued on behalf of the Committee. Other National Assembly Officials may also attend the meetings as appropriate.

5. DEPUTIES

5.1 In the event of any voting member being unable to attend a meeting of the Committee, a named deputy elected from the same representative committee, and from the same field of practice, may attend

in their place.

6. TERM OF OFFICE

6.1 A voting member's term of office shall be 3 years subject to paragraph 11.

7. OFFICERS

7.1 The Chairman will be appointed through open advertisement / Ministerial appointment, will serve for a period of 3 years, and will be eligible for re-appointment for an additional term of office. A Vice-Chairman will be elected from the voting membership, will serve for a period of 3 years.

7.2 The Vice-Chairman, or, in the absence of the Vice-Chairman, such other voting member as the other voting members may decide upon, shall preside over meetings in the absence of the Chairman.

7.3 Resignation of Officers of the Committee will be by written notice to the Chief Pharmaceutical Adviser.

7.4 Secretariat services will be provided by the Welsh Medicines Partnership

8. MEETINGS

8.1 The Committee will normally meet quarterly.

8.2 All discussions taking place in meetings should be confidential, unless stated otherwise, and not disclosed to any unauthorised person; in particular no view or opinion expressed should be attributed to any member by name.

8.3 The minutes of all meetings shall be made public.

8.4 The Constitution and roles and responsibilities of the Committee should be readily available to any relevant party on request.

9. FINANCIAL OR PERSONAL INTERESTS

9.1 Members should declare, in advance, financial or personal interests, whether pecuniary or otherwise, in any related matter that is the subject of consideration. All declarations of interest made as a result of this provision, and any action taken, should be noted in the minutes of the meeting.

10. VOTING

10.1 Questions at any meeting should be resolved, if possible, by consensus. Only the voting members will have voting rights. In case of an equality of votes, the person presiding at the meeting will have a second casting vote.

11. QUORUM

11.1 The quorum for meetings of the Committee will be 7 voting members, with at least one WMP representative and one National Assembly representative present.

11.2 A mechanism for minority reporting should be established

12. VACANCIES IN MEMBERSHIP

12.1 Membership of the Committee shall end if:

- a member resigns by giving notice in writing to the Chairman. In the case of the Chairman, resignation will be by written notice to the Chief Pharmaceutical Adviser
- a member has been absent from three consecutive ordinary meetings, unless the Committee is satisfied that the absence is due to a reasonable cause
- a member ceases to belong to the body which they represent
- a member's term of office expires
- a member dies.

13. CASUAL VACANCIES

13.1 Any casual vacancy will be filled by the elected deputy or otherwise by a representative elected from the appropriate district pharmaceutical committee.

13.2 The proceedings of the Committee will not be invalidated by reason of a casual vacancy.

13.3 The term of office of a member filling a casual vacancy shall be for the remainder of their predecessor's term of office.

14. POWERS OF THE COMMITTEE

14.1 The Committee may set up sub-committees or working groups, not all members of which need be members of the Committee. The Committee may seek independent advice as to particular aspects of the health service. Such sub-committees or working groups should incur the minimum necessary expenditure to enable their work to be carried out. These expenses will be the responsibility of the National Assembly for Wales. The Chairmen of the sub-committees may attend meetings of the full Committee by invitation.

15. ROLES AND RESPONSIBILITIES

15.1 The Committee shall advise the Assembly Minister for Health and Social Services on strategic developments in prescribing, including:

- i. forecasting developments in healthcare which involve the use of medicines, to advise on the potential impact for the NHS of such developments and strategically plan for their impact within the available resources. The WMP will work in conjunction with the National Horizon Scanning Centre, the Pharmaceutical Industry, Research and Ethics Committees and the National Prescribing Centre to inform the AWMSG of such developments.
- ii. reaching a consensus, based on the available evidence, regarding the place in treatment locally of relevant new drugs/formulations, or of existing drugs with new indications, and on the cost implications of making these drugs routinely available on the NHS. (This will include making interim recommendations on the place in therapy of drugs awaiting appraisal by NICE. The group should compliment and support the work of NICE and <u>not in any way duplicate or conflict with its work)</u>
- iii. advising the Assembly on the development of a consistent cost-effective prescribing strategy for Wales, (with consideration to matters such as pharmaceutical developments, NICE guidance, National Service Frameworks, Welsh demography and epidemiology).
- iv. advising the Assembly on how the HA, LHGs, NHS Trusts and other relevant organisations might implement the strategy within the financial constraints placed upon them. Monitor and review the approved strategy, responding promptly to national changes in NHS policy that will affect prescribing and medicines management locally, including NICE guidance and National Service Frameworks, and advise the Assembly accordingly.
- v. advising the Assembly on the implementation and cost-benefit of a range of strategic recommendations made by the Task and Finish Group on Prescribing as appropriate.
- vi. reviewing the roles of Trust Drug and Therapeutic Committees and LHG Prescribing committees in the light of their own role and the impact of the creation of Health Economies
- vii. where appropriate, advise the Assembly on areas where legislative changes would support the development of prescribing and medicines management initiatives.
- viii. advising the Assembly on when medicines management policies / formularies and guidelines can be best co-ordinated across primary and secondary care.
- ix. make recommendations to the Assembly to assist in the resolution of problems relating to prescribing at the interface between primary, secondary, tertiary and social care.
- x. receiving for consideration , documents or issues referred to it by the National Assembly for Wales and other stakeholders, and advise the Assembly accordingly.
- xi. acting as a focus for developing and refining local professional opinion on drugs, therapeutics and associated prescribing issues, including risk management, and to convey such opinions through appropriate mechanisms.
- xii. advising the Assembly on how consumer groups might be engaged to discuss consumer expectations and their impact on prescribing and medicines management.
- xiii. the production of an annual report for review by the National Assembly for Wales
- xiv. bring to the attention of the First Minister and the Assembly Minister for Health and Social

Services, through the Chief Pharmaceutical Adviser, issues concerning the maintenance and development of health services and health issues in Wales generally

16. CONSTITUTION

16.1 This constitution will be reviewed at regular intervals and amended as necessary to reflect policy and structural changes within the NHS in Wales.

16.2 Changing the constitution must be conducted with the approval of the Minister for Health and Social Services

Annex 2

Summary of Responses to the Consultation paper on the Formation of the All Wales Medicines Group

1. Introduction

The creation of an All Wales Medicine Strategy Group was a key recommendation of the Prescribing Task and Finish group that reported in March 2001. This new body was envisioned as the conduit through which consensus could be reached on medicines management issues, and was to be accountable to the National Assembly. In order to get the opinions of people working in healthcare and related professions across Wales and beyond on the form this group should take, the Assembly conducted a consultation exercise, contacting many of these professionals and receiving almost 50 responses. A summary of these responses is provided below.

2. Structure and Role

The formation of an All Wales Medicine Strategy Group was welcomed by the large majority of the respondents. Most also agreed broadly on the form the group should take. However, some differing views on the composition of the group did emerge.

Respondents expressed differing views on the method that should be used to pick the Chair of the AWMSG. Most of those who expressed a preference took one of two equally well supported options; that the chair be appointed by the Assembly, or elected by the group itself. A smaller number felt that the position should be open to public advertisement and competition. A number of respondents expressed the belief that the group's head should be someone of considerable stature.

Most of those who expressed their views on the issue felt that the rest of the group's members should be

nominated by relevant groups. The exception to this was the role of patient's representative. Most respondents who expressed their views on the matter felt that the patient representative role should be open to advertisement and public competition. A small minority felt that this member should be appointed; a similar number felt that there should be no patient representative on the group.

Many respondents identified professions that they felt could make a significant contribution through having a representative on the group. These included nursing, finance, education, the allied health professions, paramedics, dentistry, clinical governance and community pharmacy. More specific suggested inclusions were the Welsh Ambulance Services Trust Medical Director, a member of the Independent Medical & Pharmaceutical Advisers Forum, a representative of Community Health Councils, a health economy director of finance and a Trust Medical Director.

The idea of having a pharmaceutical industry representative on the group was opposed by a significant minority of the overall respondents. Several respondents felt that there should not be a consultant microbiologist on the group itself; instead, one should be co-opted as and when necessary.

The concept of the group having the capability to co-opt specialists when needed was widely supported, and it was suggested that there be a formal panel list of regular contacts. It was also suggested that the group may contain a smaller executive group that could take quick decisions. Another idea was that the group should have an IT and information subgroup.

Several respondents pointed out that membership of the group should be representative of all of Wales. Many also pointed out that it would be better, where possible, to appoint professionals who deal regularly with patients.

The All Wales Medicines Strategy Group, most respondents agreed, should have a strategic and advisory role. Some looked for it to lead and set standards as well as advise. Its potential to eliminate the problem of 'postcode prescribing' was appreciated.

It was seen as important that the AWMSG's deliberations be transparent and their advice clear and promptly delivered. Also, it was felt that there should be set channels through which health professionals could suggest ideas for or request action by the group. The AWMSG must, in general, have a strong mechanism for communicating with interested parties. Many respondents stressed the role of Information Technology in dispensing information from the group.

The respondents were divided over whether to allow minority reporting from within the group, with roughly equal numbers supporting and opposing the idea.

Many of the respondents stressed the need for the group to have adequate funding to back up its decisions.

3. Relations with other groups

The place of the AWMSG within the wider network of health care organisations was carefully considered in the responses. The respondents felt that the group should have a good and open relationship with organisations at all levels.

The most important set of relationships, most respondents felt, were those between the AWMSG and existing NHS professionals and groups. It was seen as vital that NHS professionals across Wales were involved and had influence in the group. The relationship between the group and the Assembly was seen as important, with the view that the Assembly should observe, but not participate in, the group being expressed.

The link between the AWMSG and the proposed Welsh National Prescribing Support Service was another matter for consideration. Many proposed the concept of the AWMSG operating largely as the WNPSS management board, and most saw the support of the WNPSS as crucial.

Many stressed that the group should avoid duplicating the work of existing bodies. Several felt that there must therefore be clear divisions, especially with the National Institute for Clinical Excellence.

Other groups that various respondents saw as important contacts included the Welsh Office of Research and Development (WORD), the Welsh Medicines Resource Centre (WeMeRec), (WMIC), the Clinical Governance Support Group, the University of Wales College of Medicine, Research Ethics Committees, the Information Technology Forum, the Communicable Disease Control Committee for Wales, the Medicines Control Agency, the European Medicines Evaluation Agency (EMEA), the PRODIGY (Prescribing Rationally with Decision Support in General Practise Study) team and the National Prescribing Centre (NPC).

4. Conclusion

Overall, the response to the proposal to create the All Wales Medicine Strategy Group was very positive. It was generally believed that the AWMSG could prove very useful in improving health care in Wales.

The Assembly would like to thank all those who responded to this consultation paper.

To see the actual responses to the consultation paper, contact Steve King at the Primary and Community Health Division of the National Assembly for Wales, Cathays Park, Cardiff CF10 3NQ, telephone 02920 823979 or email at stephen.king2@wales.gsi.gov.uk.

List of Respondents

Dr Terry Davies, RCGP Wales

Dr Mark Turtle, Carmarthenshire NHS Trust Drugs & Therapeutic Committee Mike A Pollard, Chief Pharmacists Committee, Wrexham Maelor Hospital **Advisers Forum** Pembrokeshire Local Health Group Cheryl Davies, Chief Pharmacist, Singleton Hospital, Swansea Colin Ranshaw, St Mary's Hospital, Penarth Tony Hurrell, Carmarthenshire LHG Dr A J Howard, Public Health Laboratory Service Keith Thomson, Chief Executive, North West Wales NHS Trust Jane Perrin, Iechyd Morgannwg Health Authority Professor David Cohen, Welsh Health Economists Group Georgina Burns, Velindre NHS Trust David Ashcroft, The Society of Chiropodists and Podiatrists Catherine O'Sullivan, Gwent Community Health Council Gareth Williams, Wales Industry Group Rhian Thomas, Vale Local Health Group Susan Lewis, North Glamorgan NHS Trust Professor PA Routledge, University Hospital of Wales Karen Fitzgerald, Bro Taf Health Authority Dr D Nicholas Looker, Welsh Microbiological Association

Susan Perrin, Caerphilly Local Health Group Alison Gittins, Dyfed Powys Health Authority Gwynedd Local Health Group Mark Lord, Ceredigion Local Health Group P Buss, Gwent NHS Trust Carol Kirkham, University of Wales, Bangor Helen Stanforth, College of Optometrists Philippa Ford, Chartered Society of Physiotherapy Welsh Ambulance Services NHS Trust Peter Jackson, Pembrokeshire & Derwen NHS Trust David AB St George, Celtic Dimensions Carl Phillips, Bro Taf Local Research Ethics Committee Health Solutions Wales PSU Team Professor Roger Walker, All Wales Medicines Forum Richard Wynne, North Wales District Pharmaceutical Committee Welsh Central Pharmaceutical Committee Doug Russell, Dyfed Powys Health Authority June Clark, Swansea University Heather Giles, WORD Liz James, North Wales Health Authority Research Ethics Committee (West)

Dr Brynley Williams, Bro Taf Health Authority

Annex 3

Welsh Medicines Partnership

Draft Constitution

1. Title

1.1 The Welsh Medicines Partnership (WMP) is to be formed from a partnership between the following existing organisations:

- The University Wales College of Medicine Therapeutics and Toxicology Centre
- The Welsh Medicines Information Centre
- The Welsh Medicines Resources Centre and
- The Committee on Safety of Medicines (CSM Wales)

2. Definition

2.1 In this document, unless the context otherwise requires:

the "WMP" refers to the Welsh Medicines Partnership, which is established under Section 2 of the National Health Service Act 1977;

the "Committee" or "AWMSG" refers to the All Wales Medicines Strategy Group, which is recognised in pursuance of Section 6 of (and Schedule 4 to) the National Health Service Act 1977.

3. Structure

3.1 The WMP Secretariat will consist of the Directors from each of the partnership organisations with appropriate administrative support

3.2 The WMP will have a non-hierarchical structure and will be responsible to an Executive Group

3.3 The Executive Group will oversee the running and performance of the WMP

3.4 The Executive Group will consist of

(i) the Chair of the AWMSG

(ii) the Chief Pharmaceutical Advisor (or representative)

(iii) the Directors of the WMP

3.5 The Executive Group will normally meet in advance of the AWMSG

4. Role and Responsibilities

4.1 At least one Director from the WMP will attend each meeting of the All Wales Medicines Strategy Group

4.2 The WMP will provide the following functions in support of the AWMSG and the National Assembly for Wales:

- i. to provide a secretariat role to the AWMSG, ensuring effective and timely communication between the AWMSG and its major stakeholders.
- ii. to work in conjunction with the National Horizon Scanning Centre, the pharmaceutical industry, research and ethics committees, the National Prescribing Centre, and others to forecast developments in healthcare which involve the use of medicines. To provide regular reports to the AWMSG on such matters for strategic planning purposes.
- iii. to collate and evaluate available evidence on new drugs / formulations or existing drugs with new indications, to enable the AWMSG to provide advice to the Assembly on their place in therapy. (This will include for making interim decisions on the place in therapy of drugs awaiting appraisal by NICE).
- iv. to disseminate guidance from the Assembly on the place in treatment of new drugs/formulations, or of existing drugs with new indications.
- v. to disseminate advice from the Assembly to health authorities, Local Health Groups, NHS Trusts and other organisations on the implementation of plans for the introduction of new treatments, local policies and national guidance involving medicines (including the Welsh prescribing strategy)
- vi. to maintain a dedicated Internet and Intranet Web site relating to the work of the AWMSG, the WMP and its constituent and related organisations.
- vii. to facilitate the dissemination and implementation of therapeutic guidance from bodies such as the National Institute for Clinical Excellence.
- viii. to contribute to, and encourage the development of educational programmes related to quality prescribing for health professionals through the WMP partner organisations.
 - ix. to provide regular communications with the "prescribing community" through newsletter, contributions to relevant publications and a dedicated Internet and Intranet Web site.
 - x. to advise on research that may be required to examine and support the development of initiatives as appropriate
 - xi. to establish close working arrangements with the major stakeholders.

5. Constitution

5.1 The constitution and functions of the WMP will be reviewed at regular intervals and amended as necessary to reflect the requirements and functions of the AWMSG, and any policy and structural changes within the NHS in Wales.

5.2 Changes to the constitution must be conducted with the approval of the Minister for Health and Social Services.

Annex 4a

Summary of the Implementation Plan for the Recommendations of the Task and Finish Group Report on Prescribing

The table below summarises the action to be taken on each of the recommendations made by the Task and Finish Group Report on prescribing. This table has been compiled following a written consultation with the NHS, professional groups, Pharmaceutical Industry and patient representative groups on the roles and remit of the All Wales Medicines Group (AWMSG)

Please refer to the summary of the recommendations given in the Task and Finish Group Report (Pages 10 to 22) (Annex 8) when reading this table

Key

AWMSG = All Wales Medicines Strategy Group WMP = Welsh Medicines Partnership DSRU = Drug Surveillance Research Unit ADR = Adverse Drug Reaction

Recommendations in bold = Work in progress. Details given in Annex 4b (or main HSSC document)

RECOMMENDATION	ACTION	START DATE	EXPECTED COMPLETION
A1 Joint professional working	To be considered by the AWMSG		
A2 Patient information	To be considered by the AWMSG		
A3 Professional standards	To be considered by the AWMSG		
A4 Pharmacist as part of primary	To be considered by the AWMSG		
care team			
A5 Repeat dispensing	North Wales pilot to examine cost benefit of system	- January 2002	December 2002
A6 Funding FP(10)HP	To be considered by the AWMSG		

A7 Drug supply from outpatients	WHC Direction to be issued from NAW	January 2002	
A8 – A10 patient pack dispensing and automation of dispensing	WHC Direction to be issued from NAW	January 2002	
A11 Electronic transfer of prescribing information THE PATIENT IN HOSPITAL	Project underway to examine the most effective way forward Wales	August 2001	December 2002
B1 Patients' understanding B2 – B5 Use of patients' own drugs	To be considered by the AWMSG Already in place in a number of Welsh Trusts. Virement of funding required from HA to Trusts to pump-prime the system. Staffing problems in Trusts are restricting the implementation and expansion of such projects. WHC Direction to be issued from NAW	January 2001	
B6 Drug administration training B7 All Wales prescription chart THE PRESCRIBING OF MEDICINES	To be considered by the AWMSG To be considered by the AWMSG		
C1 Expenditure increase	Noted		
C2 – C3 Staff training	To be considered by the AWMSG		
C4 Extended prescribing roles	Project underway to develop the role of pharmacists and nurses as supplementary prescribers	October 2001	December 2002 (legislation); April 2004 (training programme)
C5 Effective prescribing C6 WNPSS (now WMP)	Key role for the AWMSG *Subject to HSSC agreement. Membership, role, remit and relationship with proposed AWMSG consulted upon.	*November 2001	ongoing
C7 Medication review	To be considered by the AWMSG		
C8 Decision opportunities	To be considered by the AWMSG		
C9 Ring fenced funding	To be considered by the AWMSG.		
	Not favoured by some consultees.		
CI0 Benzodiazepine	To be considered by the AWMSG	September 2001	January 2002
	Expert panel established by NAW		
	to review instalment prescribing.		
INFLUENCES OF			

PRESCRIBING

D1 CPD D2 Training programmes D3 Practice based CPD D4 WeMeReC development	To be considered by the AWMSG in conjunction with the professional bodies To be considered by the AWMSG To be considered by the AWMSG Successful bid made to the NAW's Web Development Group to develop an interactive web site for WeMeReC. This will increase the circulation of educational material and distance learning programmes to a variety of prescribers in	s July 2001	January 2002
D5 Prescribing strategy D6 Establish the AWMSG	primary and secondary care Key role for the AWMSG Subject to HSSC agreement. Consultation undertaken with the service, professionals, Pharmaceutical Industry and public.	1 August 2001	1 April 2002
D7 HA responsibility D8 LHG prescribing committees	Noted Noted. Revised role in relation to the AWMSG to be considered by the AWMSG		
D9 Local priorities	Noted. To be noted by the AWMSG		
D10 Prescribing data	To be considered by the AWMSG and the NAW		
	Improvements to data accessibility underway. Data to be available on the Internet soon as workload pressures at Prescribing Services Unit permit		
D11 Trust D&T committees	Noted. Role in relation to the AWMSG to be considered by the AWMSG		
D12 Prescribing support	Subject to HSSC agreement. To be facilitated by the AWMSG and WMP	April 2002	Ongoing
D13 - 16 Formularies D17 PRODIGY	To be considered by the AWMSG Funding made available by NAW for PRODIGY awareness training	April 2002 April 2001	April 2002

D18 – 20 Prescribing Incentive schemes	Local schemes at LHG / HA are being developed and linked to quality indicators.	March 2003	
	Arrangements will be revised following the implementation of 'Improving Health in Wales'		
DISPENSING IN THE COMMUNITY			
E1 Patient Information Leaflets	To be considered by the proposed NHS-Industry forum and the AWMSG		
E2, E4-5 Pharmacist remuneration	LPS pilots to be used to examine alternative methods of remuneration. NAW to consult and negotiate with the professional organisations	Proposal to introduce legislation from April 2002. Pilots invited following this	
E3 Repeat medication	North Wales pilot to examine implications (As A5 above)	January 2002	December 2002
E6 Co-location of GPs and Pharmacists	Subject to maintaining public access to pharmacies and subject to the conditions provided for under the NHS Pharmaceutical Service Regulations 1992		
E7 e-pharmacy	Provided for under the Health and Social Care Act 2001	April 2002 (implementation of the Act in Wales)	ongoing
E8 -E10 generic and therapeutic substitution	To be considered by the AWMSG		
E11 GP access to medication E12 'Specials' DISPENSING IN	To be considered by the AWMSG To be considered by the AWMSG		
THE HOSPITAL F1 Out of Hours access to pharmaceutical services F2 - F4 Use of patients' own drugs INFORMATION AND FINANCIAL SYSTEMS	To be considered by individual Trusts and their Chief Pharmacists As B2 to B5 above (WHC Direction to be issued from NAW)	January 2002	
G1 Coding of Welsh drugs	Underway under the Medusa Project.	October 2001	March 2002
G2 Electronic connection of Welsh Pharmacies	Feasibility of this to be examined as part of the e-prescribing project	-	December 2002

G3 Prescription pricing problems	Close monitoring of Recovery Programme ongoing. Examination of future funding arrangements underway		Ongoing
G4 Electronic pricing of	Feasibility of this to be examined	August 2001	December 2002
prescriptions G5- G6 Comparison of hospital	as part of the e-prescribing project To be made possible under the	October 2001	March 2002
prescribing data G7 Allocation formula	Medusa project above (G1) Considered under the Resource		March 2003
G8 Eunding drug expenditure	Allocation Review (Townsend)		
G8 Funding drug expenditure G9 Use of NSF data	For consideration by the AWMSG For consideration by the AWMSG		
G10 Budget setting	To be considered by the AWMSG		
PURCHASE OF	To be considered by the TTW MbG		
MEDICINES			
H1 Drug purchase contracts	Consultation on generics	August 2001	November 2001
	purchasing in progress		
H2 LHG purchasing	For consideration by the AWMSG		
PARTNERSHIP AND			
GOVERNANCE	Galia et ta UCCC a manual ta ha	A	
I1 – I4 NHS-Pharmaceutical	Subject to HSSC agreement, to be established as a sub-committee	April 2002	
	reporting to the AWMSG		
Industry Forum I5 – I6 Sponsorship of staff	Survey undertaken to establish the	July 2001	February 2002
15 – to sponsorsnip of stan	level of Industry sponsorship	July 2001	Teordary 2002
	within the NHS in Wales. The		
	results of which will be used to		
	inform the debate held by the NHS	-	
	Pharmaceutical Industry Forum		
I7 – I10 Codes of conduct	For consideration by the NHS-	April 2002	
	Pharmaceutical Industry Forum		
I11 Watchdog arrangement for			
coloc promotion	For consideration by the NHS-	April 2002	
sales promotion	Pharmaceutical Industry Forum	April 2002	
I12 Managed introduction of new	•	April 2002	
I12 Managed introduction of new drugs	Pharmaceutical Industry Forum	April 2002	
I12 Managed introduction of new	Pharmaceutical Industry Forum A key function of the AWMSG	April 2002	
I12 Managed introduction of new drugs	Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the 	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card 	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card reporting to all prescribers. 	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card reporting to all prescribers. Increased awareness of Adverse 	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card reporting to all prescribers. Increased awareness of Adverse Drug Reaction Reporting to be 	April 2002	
I12 Managed introduction of new drugsI13 ADR reporting	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card reporting to all prescribers. Increased awareness of Adverse Drug Reaction Reporting to be continued via the proposed WMP 	April 2002	
I12 Managed introduction of new drugs	 Pharmaceutical Industry Forum A key function of the AWMSG Extension of the Yellow Card scheme is not a devolved function. CSM(Wales) and NAW Officials to make representation to the MCA to extend Yellow Card reporting to all prescribers. Increased awareness of Adverse Drug Reaction Reporting to be 	April 2002	

I15 Green Card Scheme	Discussions underway with the ongoing Drug Surveillance Research Unit in Southampton and Prescribing Support Unit, Health Solutions Wales. To be managed by the WMP.
I16 Monitoring of 'black triangle' drugs	Prescribing information reports to ongoing denote those drugs under intensive surveillance. Enabled under the Medusa project (above). Negotiations underway
I17 Error reporting	To be considered by the AWMSG, ongoing building on an existing hospital dispensing error reporting scheme and the electronic prescribing project
I18 Link with the DSRU	As I15 (above)
I19 Electronic prescribing safeguards PREVIOUSLY PUBLISHED	Subject to HSSC agreement, to be considered by the IT Forum, sub- group to the AWMSG
REPORTS	
J1 Further consideration	To be considered by the AWMSG

Annex 4b

Overview of the Implementation of the Non-Strategic Recommendations made in the Task and Finish Group Report on Prescribing

Electronic transmission of prescriptions – scoping study

Recommendation	A11, E7, G2, G4
Contact/ Lead	Andy Blewitt, HIMT Division, National Assembly

The Electronic transmission of prescriptions (ETP) is a complex area of redevelopment and development of systems and infrastructure. On investigation it becomes quickly apparent that there are many possible solutions with varying benefits and risks, many of which are difficult to quantify.

There are various models to support ETP (Data Push, Data Pull, Mixed) and strategic decisions will have to be considered regarding privacy and ownership of data utilised in an ETP environment. Issues such as digital signatures, data encryption, security, accessibility will need to be analysed before final selection of an ETP infrastructure can be decided.

Aim: A scoping study is to be procured to examine all of the issues surrounding ETP. This exercise will

need to be defined extremely carefully and will need to involve varied areas of expertise and all stakeholder groups. It is estimated that this scoping study will take between 6 and 9 month of work to produce a robust requirements system specification. It will need to take on board the issues of change and how to manage the expectations of the stakeholders in such a large development project.

If the documentation to support the scoping study can be progressed we would aim to tender through OJEC for the study in November 2001. The study will produce a detailed specification and change plan and lead to an OJEC Procurement December 2002.

At this stage and in the absence of a robust option appraisal it is not possible to commit to a comprehensive investment plan and therefore budget figures are necessarily indicative.

Start date	August 2002
Completion date	December 2002 (for OJEC procurement)
Cost of study	some £400,000 (to be funded from the Invest to Save initiative)

Common Drug Codes for Wales (The Medusa project)

Recommendation	D10, G1, G5, G6, H1, H2, I17
Contact / Lead	Robin Burfield, Health Solutions Wales (HSW)

Aim

- To enable a common IT database to be built, containing the drug purchasing and issue data from the Hospital Pharmacy systems in Wales and to link this to the Prescribing Services Unit's database of drug prescribing by GPs and drug dispensing by Community Pharmacists in Wales. This will **provide comparative information of medicines usage between Trusts and between the primary and secondary care sectors**.
- To support the All-Wales Drug Contracting process
- To underpin the implementation of a **unified health record (EPR)** and **electronic transmission of prescriptions (ETP)** (without prejudice to the outcome of the option appraisal and selection of preferred solution).
- The Medusa project enables the recording and analysis of **dispensing errors** so that lessons may be learnt and information shared to minimise further incidents. This has built on the work on dispensing errors undertaken by the University Hospital of Wales, who now hold records of dispensing errors from some 60 Trusts across the UK over a period of 6 years. This data has been entered onto a database that can be accessed via the Medusa website.
- It is proposed that this database will be expanded to form a confidential **Medication Error and Incident Reporting system** initially in hospitals but eventually rolled out to primary care to encompass all errors associated with prescribing, administration and supply of medicines.

HSW will issue a tender for the common drug code scheme. The coding scheme that is eventually

adopted will cross-refer to other drug coding schemes, e.g. EAN, PIP and the proposed UKCPRS, and therefore has the potential to rollout to other drug databases in use within Wales.

Start date	October 2001
Completion date	March 2002 (phase 1)
Cost	some £60,000 (phase 1) (funded from "Delivering Care, Meeting
	needs" money)

Repeat dispensing pilot

Recommendation Lead / Contact Aim	 A5, E3 Robert Gartside, Secretary, North Wales Local Pharmaceutical Committee To investigate the feasibility of implementing a repeat dispensing system across Wales To investigate the costs and benefits to stakeholders, including patients, General Practitioners, Pharmacists, the prescription pricing service and the National Assembly 	
Proposed	January 2002	
start date Proposed completion date Cost	n December 2002 £25,000	
(to Assembly)		
Supplementary prescribing role for pharmacists and nurses		
Recommendation	C4	
Lead / Contact	Carwen Wynne-Howells (CPhA), June Smail (Nursing Division), National Assembly	
Aim	 To introduce supplementary prescribing by pharmacists and nurses in parallel with the extension of prescribing by independent nurse prescribers. Work has commenced on scoping the requirements to develop an 	

• work has commenced on scoping the requirements to develop an interactive, internet based training programme to support this initiative

Provision for the introduction of supplementary prescribing was made in the Health and Social Care Act

2001 for a range of healthcare professions. It is anticipated that the necessary legislative changes to facilitate this will be in place by the end of 2002. Any proposals to introduce supplementary prescribing will be subject to consultation.

Start Date	October 2001
Completion date	December 2002 (legislation); training programme April 2004
Cost	Cost neutral (excluding training costs, which are to be advised)

Development of an interactive web site for the Welsh Medicines Resource Centre (WeMeReC)

Recommendation Lead / Contact Aim	 D4 Felicity Newton-Savage, WeMeReC Creation of an Internet site to improve general practitioner, community pharmacist, prescribing advisors and practice nurse access to the prescribing advice issued by WeMeReC Further development of the existing CymruWeb pages to similarly improve access to hospital doctors and pharmacists. Distribution of information bulletins via the web sites and use of an interactive web site for practitioner self-assessment to reduce printing, materials and distribution costs and reduce the associated administrative burden More effective use of resources would enable the benefits provided by the distance learning modules to be extended to include other healthcare providers such as pharmacists and nurse prescribers
	providers such as pharmacists and nurse prescribers

A successful bid has been made to the Assembly's Web Development Group to create the interactive websites.

Start date	August 2001
Completion date	January 2002
Cost	None (service provided under an existing service level agreement Health Solutions Wales)

Survey to investigate the extent of Industry sponsorship within the NHS

Recommendation	14, 15, 16
Lead / Contact	Gemma Nye, PCH2, National Assembly

Aim	To clarify the nature and extent of current Industry sponsorship by gaining the co-operation of GPs and Trust managers to complete postal questionnaires. The study will contribute to an understanding of the forms of sponsorship current in GP practices and NHS Trusts. It is important that the project outcomes are informative, reliable and relevant to NHS corporate thinking.
	The project might also invite the co-operation of other health professionals to comment on their perceptions of forms of sponsorship in both primary and secondary care.
	The study is being procured from Opinion Research Services Ltd, University of Wales, Swansea.
Start Date	The results of the study will inform the debate on sponsorship to be led by the proposed All Wales Medicines Strategy Group and the NHS-Industry Forum. The study was commissioned in July 2001. The questionnaire is
Completion Date Cost	expected to be circulated from November 2001 February 2002 awaiting final cost. Estimated at some £15,000

Review of prescribing for addicts

Recommendation	C10 (partial)
Lead / Contact Aim	Karen Morgan, PCH2, National Assembly To review the present arrangements for prescribing and dispensing under the Misuse of Drugs Regulations 1985 and the NHS (General
	Medical Services) Regulations 1992. An expert group has been established to consider and advise on these matters.
Completion date	January 2001
Cost	total cost to be advised

Review of Pharmacists' roles and remuneration

Recommendation	E2, E4, E5
Contact / Lead	Gavin Parry, PCH2, National Assembly

Aim	to allow Health Authorities to negotiate different local arrangements for the provision of community pharmacy services, outside the restrictions of the existing legal framework in Part II of the NHS Act. Provision for the introdu- of Local Pharmaceutical Services Pilots was made in the Health and Social C Act 2001 and the necessary legislative changes to facilitate this will be in pla	
Start date	Wales from April. from April 2002	
Completion date	Ongoing	
Cost	total cost to be advised	

A7, A8 – 11, B2 – 4, F2 – 4

Carolyn Poulter, PCH2, National Assembly

Dispensing in the Hospital

Recommendation

Contact / Lead

Aim	 The Assembly will issue guidance on the use and supply of inpatients' medication in hospital. Current guidance on discharge from hospital and shared care arrangements, given in WHC(91)94, will be revised 	
Date	January 2002 following publication of the Audit Commission's report, "A spoonful of sugar" on medicines management in hospitals	
Cost	cost neutral	
Extension of the Green Card Scheme		
Recommendation	I15, I18 Draf D. Dratta da a. CSM (Walas)	
Lead / Contact	Prof P Routledge, CSM (Wales)	
	Agreement to link the Wales to the Drug Surveillance Research Unit and to extend the Green Card Scheme has been established.	
	Negotiations are ongoing	
Prodigy for prescribing decision support		
Recommendation	D17	
Lead / Contact	Dr D Russell, Dyfed Powys Health Authority	
Cost	The Assembly has made funding available to Local Health Groups for awareness training on PRODIGY. £10,000	

Financial Implications of Implementing the recommendations of the Task and Finish Report, to date

Action	Source of funding	Cost (£'000)	
AWMSG, NHS-Industry Forum, IT Forum	Programme budgets		20
Welsh Medicines Partnership	Programme budgets		200
Electronic transmission of prescriptions (scoping study)	Invest to Save		400
Common Drug codes	"Delivering Care, Meeting needs"		60
Repeat dispensing pilot Supplementary prescribing role	Programme budget		25
Web site for WeMeReC	Existing SLA		None
Industry sponsorship survey	Programme budgets		15
Instalment prescribing			1
 expert group total cost	Programme budgets		to be advised
Local Pharmaceutical Pilots - legislation change			
	Developed "in-house"		to be advised
- running costs Dispensing in the hospital			Cost neutral
PRODIGY awareness training			10
TOTAL			731

Annex 6

Task and Finish Group for Prescribing: note on

(ii) effect of local purchasing arrangements on the Pharmaceutical Price Regulation Scheme (PPRS).

(ii) generic and therapeutic substitution

Summary

1. The first part of this annex describes:

- The purpose, nature and scope of the PPRS.
- Present arrangements for drug purchasing by the National Health Service purchasing consortia the Drug Tariff.
- Proposals by the Task and Finish group possible models.
- Benefits and risks.
- Concerns expressed by the Association of the British Pharmaceutical Industry (ABPI).

The second part gives a very brief description of the state of play over generic and therapeutic substitution.

PPRS - Background

2. The paper HSS-05-01 that Dr Norman Mills presented to the Committee in March 2001 included among its recommendations a proposal to test the hypothesis that Local Health Groups (LHGs) and consortia of LHGs should be the purchasing bodies for specific items which are already being purchased within GP practices. They could, therefore, negotiate better terms with respect to the cost of medicines supplied to LHG populations. The Committee agreed that officials would provide further information on the effect of local purchasing arrangements on the PPRS.

<u>3. The PPRS</u> is an agreement between the Department of Health (DH), on behalf of the UK Health Departments, and the ABPI, which is the trade association for about a hundred companies in the UK producing prescription medicines. (It is open to companies that are not members of the ABPI to be scheme members too). The objectives of the scheme are

- to secure the provision of safe and effective medicines for the NHS at reasonable prices,
- to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines, and
- to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The scheme is essentially a voluntary agreement, but it has a statutory basis under section 33 of the Health Act 1999. This is not a provision which is devolved to the National Assembly for Wales.

4. The scheme itself is published at <u>www.doh.gov.uk/pprs.htm</u>. (Further details can be found in the Fourth Report to Parliament, available on the same site.) It applies to all branded, licensed NHS medicines, including branded generics and branded products supplied through tendering processes and on central or local contracts. It does not apply to unbranded generics, which are covered by a separate

maximum price scheme.

5. The scheme works, simply, by putting a ceiling on individual companies' return on capital employed (as shown in their UK audited accounts) from home sales of NHS medicines. The scheme does not, by and large, control prices directly. Companies bringing new active substances to market can set what prices they choose, within the constraint of their overall profit target. Subsequent price increases have to be approved by the DH. The 1999 PPRS agreement also included provision for an overall price reduction of $4\frac{1}{2}\%$ from 1 October 1999.

6. The scheme refers to central or local supply contracts. Contracts of this kind are the norm in the secondary sector (NHS hospitals). However, at the time of writing local contracting arrangements are unusual in the primary sector, where nearly all prescribed drugs are supplied through independent contractors under arrangements set out in the Drug Tariff. (Exceptions are discussed below.) Apart from this, the PPRS does not specify any particular mechanism under which the NHS purchases its drugs.

7. The list price referred to in the PPRS, equivalent to the basic price used in the Drug Tariff for the calculation of payments to NHS dispensing contractors, does not represent the actual sale price of the drug to NHS contractors. The Deduction Scale in Part V of the Drug Tariff is intended to take account of the difference between list and sale price.

8. Present arrangements for drug purchasing by the National Health Service in the secondary sector are outlined in HSS-05-01. Items whose value exceeds £3,000 a year for the whole of Wales are contracted for centrally through the All-Wales Drugs Contracting Committee. Purchasing of other items is the responsibility of pharmacists in individual hospitals. These arrangements, which cover some 15% of prescribing in Wales, have been endorsed by the Prescribing Task and Finish Group. The remaining 85%, representing prescribing by GPs, community dentists, community nurses and others, is supplied mainly through NHS dispensing contractors (community pharmacists, dispensing doctors and appliance contractors). Contractors are reimbursed the price of the drugs and appliances they dispense under the NHS, under arrangements set out in the Drug Tariff. For generic drugs the rates are calculated from the "basic price" set out in Part VIII of the Drug Tariff, which itself is based on regular surveys of suppliers' prices. For listed appliances the basic price is the price quoted in Parts XIA-C. For other products, including most products covered by the PPRS, the "basic price" is the list price of the manufacturer, wholesaler or supplier. The basic price is abated by the appropriate amount calculated from the Deduction Scale in Part V of the Drug Tariff, according to the total price of items dispensed by the contractor for the month in question. This Deduction Scale is based on periodic surveys of the discounts contractors receive from their suppliers.

9. In some areas of Wales GP prescriptions are dispensed in the community by NHS Trusts. The Trusts purchase materials in the usual way and the necessary accounting

adjustments are made by the Health Authority "reimbursing" the Trust at Drug Tariff rates.

10. In some areas of England Primary Care Trusts have been trialling local tendering arrangements for certain drugs and appliances, particularly the latter. We understand that they can deliver service improvements, but financial savings can be hard to realise in practice because the NHS pays VAT on Trust purchasing but not on reimbursement of contractors for dispensing in the community.

11. Proposals by the Task and Finish group – possible models. The report gives two specific examples (pages 100-101):_

- If an LHG were to agree to the use of one PPI, for example, then that body would be in a position to negotiate cost with the competing industries. In order not to upset the market forces on the supplier side of the market the LHG could negotiate a "cash back" to the "coffers" of the LHG if agreed targets were achieved.
- Some medicines, e.g. influenza vaccine, are bought directly by the surgeries. If the purchasing power of the whole LHG were to be used then it is probable that better prices could be obtained.

Other possibilities include consideration of whether the FP10 route (dispensing through community pharmacy) is appropriate for personally administered items such as wound management products.

12. Benefits and risks would need to be identified and quantified by way of pilots. One immediate effect of local tendering could be to remove business from dispensing contractors in the area. The need to maintain the adequate provision of pharmaceutical services could well be a limiting factor for the expansion of such schemes. This could be mitigated by moving in parallel on changes recommended elsewhere in the report for alternative payment mechanisms based on medicines management rather than items dispensed, or by continuing to dispense through local contractors but changing terms of service to link supply of specified products to national or regional supply contracts. These will need further discussion with the contracting professions and other stakeholders. We think the effect on the PPRS itself is likely to be hard to detect.

13. Concerns expressed by the Association of the British Pharmaceutical Industry. The ABPI has commented that the proposal that Local Health Groups should be given a specific responsibility for negotiating the price of medicines is incompatible with the PPRS. They have referred in discussion to additional administrative costs, and to the risks of destroying the stability of drugs prices within the NHS throughout the UK, saying that in the long term this could do considerable damage to the health service.

14. Our view is that as the PPRS would continue to set the maximum price allowable under the NHS and allow for discounts through tendering processes and hospital contracts, the effect on the PPRS of an extension of such arrangements to the community sector should be minimal. Sales revenue for some companies might fall but this seems unlikely to affect profitability to the extent of generating price increases.

15. The ABPI have prepared a detailed commentary on the Task and Finish Group's recommendations, which we understand they are making available to the Committee. We have assured the ABPI that there will be full consultation with stakeholders before implementing the recommendations.

Generic and therapeutic substitution

16. Drugs are frequently marketed under brand names rather than the Recommended International Nonproprietary Name (rINN). So for example cimetidine, an ulcer-healing drug, is also sold as the branded product Tagamet, and amoxycillin, an antibacterial, is also sold as Amoxil. The generic product is usually, but not always, cheaper than the branded version.

17. Community pharmacists are contractually obliged to dispense what the GP has written on the prescription. Where a GP specifies a brand name then that is what they dispense. Where a GP writes down the rINN the pharmacist can dispense a branded or a generic version and be reimbursed accordingly, except that where the drug is listed in Part VIII of the Drug Tariff this reimbursement would be based on prevailing generic prices.

18. For drugs that are in patent and available only as a proprietary brand, the pharmacist is reimbursed the brand price irrespective of whether the prescription specifies the rINN or the brand name. This applies to all the newer kinds of drug and explains why generic dispensing is usually materially lower than generic prescribing.

19. GPs are encouraged, as a matter of good professional practice, to use rINN on prescriptions except where bioavailability problems are so important that the patient should always receive the same brand, in which case the brand name or the manufacturer should be stated. Many local prescribing incentive schemes have "quality targets" for generic prescribing which give GP practices a financial incentive to prescribe generically.

20. As a result of these and other measures, generic prescribing in Wales has risen from about 40% in the early 1990s to around 70% now (generic dispensing is thought to be around 50%, for the reasons already given). Because of concerns expressed by NHS prescribing advisers, the NHS Wales performance management framework includes indicators for inappropriate generic prescribing on a range of drugs (indicator 28), and these indicators are now being included in local incentive schemes.

21. There are still potential cost savings to be made through increasing generic prescribing. Although material, these are relatively low – probably of the order of a few per cent of the total drugs bill. It appears to be within the Assembly's powers to change pharmacists' contract to allow them to substitute generic for branded versions of the same drug, but steps taken to increase generic prescribing over present levels need to be managed carefully to ensure that it is always appropriate.

22. The Task and Finish Group recommended that a small group representing all relevant parties should

produce an action plan and run a pilot to test the model. The action plan would be an appropriate task for the proposed AWMSG.

23. Therapeutic substitution – substituting a different kind of drug from that prescribed, raises much wider issues of clinical governance, audit and the needs of patients. The Group's recommendation for a research site is probably best taken forward within the general framework of extending prescribing rights and responsibilities to pharmacists and other professionals. Again, we envisage that the AWMSG will be charged with producing an appropriate model.

Annex 7

Preface to the final report of the Pharmaceutical Industry Competitiveness Task Force (March 2001)

The Pharmaceutical Industry Competitiveness Task Force (PICTF) has provided a structured, actionoriented platform for effective dialogue between Government and the pharmaceutical industry. The involvement of Ministers from a number of Government Departments and senior industry executives, who are able to reflect both UK and global perspectives, has been of great benefit. PICTF has strengthened industry-Government relationships, significantly increased mutual understanding and delivered some valuable outputs. The commitment and hard work of all those involved in PICTF should be acknowledged and applauded.

PICTF is an important and timely initiative. The pharmaceutical industry is one of the UK's most successful industrial sectors, but the global business environment is changing. The traditional factors that underpinned the UK's past success in pharmaceuticals are no longer on their own sufficient to guarantee good performance, and we need to work together to ensure that the UK retains its competitive edge. Decisions and actions taken by Government will have a major influence on future investment decisions made by the industry and thereby on the contribution it makes to the UK economy.

This report from PICTF reflects many positive outputs. PICTF has addressed a number of important areas, including protection for intellectual property, tensions in the EU Single Market for Pharmaceuticals, overcoming impediments to competitive clinical research, and improving the competitiveness of the pharmaceutical and biopharmaceutical research sector. It has also engaged in a much more strategic debate about future developments in the UK pharmaceuticals market.

PICTF has demonstrated the importance of ensuring that proposed changes to the pharmaceutical regulatory environment are considered very carefully in terms of their potential to impact on the UK based industry. New policy measures should not be viewed in isolation, but as part of the overall environment. We have agreed competitiveness and performance indicators for the pharmaceutical sector that should allow us to test future major changes to the pharmaceutical regulatory environment for their

likely impact on industry competitiveness.

PICTF has allowed us to take important steps towards ensuring that the UK remains a competitive location for the continued development of a vibrant pharmaceuticals sector. There are issues – such as market access for new products, and the environment for animal research – where further dialogue is required and where industry and Government continue to work together to identify effective ways forward. We are delighted that a high level successor mechanism to PICTF has been identified and that a plan of future action has been drawn up. We are confident that the key strengths of PICTF will be inculcated into future dialogue, and that the benefits of partnership for the UK and the industry will be delivered.

Annex 8

For a Copy of the Report of the Task and Finish Group, providing a full exploration of the issues supporting the recommendations, please click <u>here</u>.