APPENDIX Q - Procedure for the Managed Entry of New Medicinal Products to the Hywel Dda University Health Board Formulary.

The Medicines Management Group (MMG) will make final recommendations on the formulary status of all formulary requests for medicinal products. Final decisions can only be made by the HDUHB Corporate Directors Group

Process

1. 'Medicinal Products' are defined as all substances defined under the Medicines Act as being medicinal products. For the purpose of this Policy this definition may be extended to cover some products licensed as medical devices (e.g. bladder installations) which are used to treat patients and are supplied on prescription. Discussion with the Medical Devices Committee may be required to determine which committee is more appropriate to consider the application.

2. Requests for the inclusion of medicinal products onto the HDUHB Formulary will be accepted from an appropriate Consultant or General Practitioner. In addition the Tissue Viability Nurses may apply for the addition of a wound care product and Dieticians for a nutritional feed or product.

3. New Treatment Fund (introduced January 2017)
On the 10th January 2017, WG announced the establishment of the New Treatment Fund. This makes money available to all HBs to facilitate the prompt availability of NICE & AWMSG recommended medicines.

The key changes are:
i. Medicines recommended by AWMSG are to be made available within 2 months of Ministerial Ratification (this will happen sooner after the AWMSG meeting).
ii. Medicines recommended by NICE will be made available within 2 months of the first publication of the Final Appraisal Determination (FAD). Currently it is within 3 months after the TA is issued.
iii. New cancer medicines recommended for an interim period by NICE will also be made available within 2 months as long as manufacturers offer a same or similar package to NHS Wales as to NHS England.
iv. One Wales Interim Commissioning recommended medicines will not be funded under the New Treatment Fund (because of licence status).
v. A 3 month timescale is being retained for exceptional circumstances where service planning will take longer than 2 months and must be agreed in advance with the WG.
vi. Infrastructure and capacity issues can also be addressed using the New Treatment Fund to enable medicines to be made available within the 2 month target.

The process for the introduction of medicines approved by NICE or AWMSG is as follows:

1. The Lead Clinical Development Pharmacist will assess the impact of a new AWMSG Ministerial Ratification or a NICE Final Appraisal Determination and propose a preliminary Formulary Status within 3 working days of the issue of the guidance. This will be in conjunction with the relevant Consultant, Clinical Pharmacist or service. Service issues preventing prompt implementation will

be identified and a preliminary budget impact will be forwarded to the Head of Financial Planning.

2. The Lead Clinical Development Pharmacist will draft the NICE TA /AWMSG Initiation audit where medicines are not supplied via homecare or Chemocare and arrange for it to be uploaded onto the webpage and linked to the Formulary.

3. This preliminary recommendation will be added to the Formulary with a note that it will be ratified with its place in the local treatment pathway at the next MMG. The suggested wording is: 'This medicine is available for prescribing to patients within HDUHB who meet the criteria set out by AWMSG/NICE FAD on the (date). The PAS/WPAS required as part of the recommendation is in place (date)/under discussion. The final place in the patient pathway is under consideration by the clinical service. This entry will be updated once MMG have ratified the pathway place'.

4. The relevant clinicians and services/IPFR will be informed that the recommended medicine has been added to the formulary, the preliminary status and the advice that it will be available to prescribe.

5. The Lead Clinical Development Pharmacist will liaise with the Lead Pharmacist for Procurement and Lead Pharmacist for Homecare (where appropriate) to ensure that any PAS/WPAS/rebates are in place prior to dispensing.

6. The preliminary formulary status/pathway will be ratified at the next MMG.

7. A quarterly report of the timeline for making AWMSG/NICE recommended medicines available and expenditure since will be submitted to the Head of Medicines Management and Head of Financial Planning.

8. Horizon scanning will be carried out at 3 monthly intervals to identify forthcoming NICE FADs & AWMSG Ministerial Ratifications and prepare for their implementation.

4. The applicant will discuss a specific formulary application with the Lead Clinical Development Pharmacist. If the requested medicinal product is:

- approved by NICE or AWMSG for the indication requested see above (3).
- due to be considered by NICE/AWMSG for the indication requested within the next 12 months it will not be considered. A non-formulary request remains available to the applicant for individual patients in the meantime
- a new preparation/strength/indication of an existing Formulary medicine. An abbreviated application may be appropriate .This will decided on an individual basis
- for the use of a medicine within a procedure not currently carried out in HDUHB a CEAC application is required before Formulary approval can be given. Processes can run concurrently

- for an unlicensed medicine or 'off-label' indication or dose. A group unlicensed form or full Formulary application may be required. This will be decided on an individual basis
- The applicant will be asked to complete an 'Addition to HDUHB Formulary Request Form', which is available on the HDUHB website (link). Forms must be completed fully and correctly to ensure that the application is considered promptly. The Lead Clinical Development Pharmacist can provide advice and will contact the applicant where additional information is required.

4. A 'New Product Evaluation' will be completed by the Lead Clinical Development Pharmacist or Lead Medicines Information Pharmacist. This evaluation will be based on the 'STEPS' methodology (Safety, Tolerability, Effectiveness, Price and Simplicity). In addition, a summary page will be included, where necessary with a background section, to assist non-clinicians in reaching a formulary decision.

5. A recommendation will be made to the Medicines Management Group (MMG) from the Clinical Formulary subgroup (CFsg)as to whether the medicinal product should be approved for addition to the Formulary, any restrictions on use (primary Care, Secondary Care, Specialist Use only or Shared Care) or rejected. The rationale for the decision will also be given. The Clinical formulary subgroup minutes will be presented to the MMG meeting, which includes a summary of the discussions held in the CFsg (including the points for and against approval based on the evidence presented and whether the decision reached was unanimous or split.

Financial Considerations

1. Formulary requests for medicinal products which will only be prescribed in the Acute Sector and with a net cost impact of more than £10,000 per year, will require a business case form to be completed and submitted to the Director of Finance through MMG.
2. Formulary Requests for medicinal products which be used in both Primary and Acute Care and with a net cost of more than £80, 000 per year, will require a business case form to be completed and submitted to the Director of Finance through MMG.
3. Wherever possible, the potential cost impacts of new medicines under development will be identified through an annual 'Horizon Scanning' report prepared by the Lead Clinical Development Pharmacist.

Note: The Director of Finance will receive a completed business case for medicines that meet the criteria defined above within 48 hours of a positive decision being made by the Clinical Formulary Subgroup. This will allow the Director of Finance 3 weeks before the MMG meeting to consider the business case submitted and make recommendations to MMG.

Safety Considerations

Risk Assessments for new medicines will be required as part of the formulary application process. This will partly fulfil the 'Purchasing for Safety' recommendation from the NPSA and allow risk reduction measures to be put in place (where appropriate) before the new medicine is in use. The MEPA (Medication Error Potential Analysis) (http://www.qcnw.nhs.uk/docs/QA%20&%20Risk%20Assessment%20of%20licensed%20Medicines%20for%20the%20NHS.pdf)and NPSA 'Risk Assessment for

Injectables' (http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812)are recognised tools for this process. The MEPA score requires a sample of the product/packaging (or electronic proofs of the packaging) to assess fully. The assessment with be carried out by the Lead Clinical Development Pharmacist with advice from the Lead Quality Assurance Pharmacist and Lead Clinical Pharmacists or Dispensary Managers.

Dissemination/Communication

Following each MMG meeting:

1. Recommendations will be added to the:
    a. HBUHB electronic Formulary (http://hywelddahb.inform.wales.nhs.uk/)
    b. Scriptswitch® (active on GP prescribing systems across the HB)
    c. Hospital Pharmacy Computer system
2. Prescribing Outlook Newsletter (for Primary and Secondary Care Staff) (within 2 weeks of the meeting)

3. Applicants will be informed of the recommendations made by MMG by e-mail/letter promptly. Pharmaceutical representatives will not be informed of the outcome before the applicant.

4. The draft minutes of the MMG meeting will circulate to members within 2 weeks of the meeting

5. The outcomes of MMG will be summarised and circulated to members, County Lead Pharmacists and Prescribing Advisors within 2 days of the meeting.

6. A cumulative list of approvals/rejections will be hosted on the Pharmacy & Medicines Management website.

7. Recommendations will be presented at the GP Prescribing Leads meetings.

8. Recommendations will be discussed by hospital pharmacists with the relevant healthcare staff.

9. A summary of recommendations will be sent to Community Pharmacies in HDUHB.

10. A copy of the minutes will be sent to ABMU and Powys UHB for information.

11. A list of pending formulary applications will be posted on the Pharmacy & Medicines Management website until a final formulary decision is reached.

12. Any amendments to policies, guidelines and prescribing information will be made, checked by the Lead Clinical development Pharmacist and approved by Chair's Action (unless MMG have directed otherwise).

NB: The HDUHB electronic Formulary is available on the Internet, so patients and other stakeholders will be able to access information about Formulary decisions.

Review

All requests for non-formulary medicines will be reviewed every 6 months to ensure that formulary applications are made for frequently requested items.
The expenditure on all new medicinal products added to the formulary will be monitored every 6 months for 2 years (primary & Secondary Care data) for 2 years and compared against cost predictions.

Exceptions and Non-formulary Requests

1. The HDUHB Formulary applies to both prescribing and recommendations to prescribe. Routine recommendations to prescribe non-formulary medicines should be discussed with the local Prescribing Advisor or the Lead Clinical Development Pharmacist. The Lead Clinical development Pharmacist will contact the relevant Consultant (or Independent non-medical prescriber) to discuss the reasons for the recommendation and determine whether a formulary application is appropriate.
2. Where a non-formulary medicine is the most appropriate choice for a patient the prescriber must complete a Non-Formulary Medicine Request form as well as a prescription and sent to the hospital Pharmacy department.

3. Approval mechanism:

Medicine cost per year		**Approval by**
less than £500		Site Lead Pharmacist (or deputy)
more than £500		Hospital Clinical Lead (or deputy) or Directorate Clinical Lead (Mental Health or Women & Child health Directorate)
More than £2000	Urgent	Acute Services Clinical Lead or Medical Director in discussion with Head of Pharmacy & Medicines Management or Site Lead Pharmacist
	Non-urgent	IPFR Application (http://www.wales.nhs.uk/sitesplus/862/page/70502) (N.B: the NHS list price of the medicine will be considered when calculating the cost. Discounts/ FOC or Patient Access schemes will not be taken into account.) MMG May 2015.

Drugs on the Formulary will be categorised as follows:

Category	Definition
H = Hospital only drugs	All prescriptions are issued from the hospital medical team or are restricted to use only within the hospital Primary care prescribers should not be asked to prescribe
S = Specialist initiated drugs	A specialist (Consult ant, GP with a special interest or specialist independent prescribers) should undertake the initiation and stabilisation of the medicine. Follow up prescriptions may be issued by GPs, if they agree to take on responsibility for future prescribing. Medicines for which a Shared Care protocol are included.

	Specialist Recommended. This will apply where the Specialist has reviewed the patient and it is appropriate for the GP (or another speciality prescriber) to initiate the medicine. The medicines involved will not usually require detailed monitoring or careful titration and stabilisation.[MMG Feb 2017]
1st = First Line drugs	Drugs recommended in both primary and secondary care
2nd = Second line drugs	Alternatives, often in specific conditions (eg allergy or ADR to first-line) in primary and secondary care)
Non-Formulary Medicines	Medicines that have been assessed by NICE/AWMSG or MMG and deemed to have either insufficient evidence or are not cost-effective.

Appeals Process

It is recognised there may be occasions where there is a difference of scientific opinion and/or interpretation of available data. There is also a responsibility to ensure that due process has been followed.

An appeal may be lodged in writing, by the original applicant, with the Lead Clinical Development Pharmacist within 30 working days of being informed of the non-approval decision of MMG.

An appeal will be considered where:

- There has been a failure to act fairly and in accordance with the HDUHB Procedure for the Managed Entry of New Medicinal Products to the Hywel Dda University Health Board Formulary.
- A decision is contrary to the evidence submitted
- Submission of new relevant supporting data or evidence.

The appeal request and grounds will be considered at the next meeting of the MMG. Where there is still a disputed decision, an Appeals Panel will be constituted. The applicant will be informed.

The Appeals Panel will consist of three members nominated by the HDUHB Medical Director, including a pharmacist, GP and hospital Consultant, none of whom have been involved in the original formulary application, discussion or decision.

The acceptance of the Appeals Panel's conclusions will be at the discretion of the HDUHB Corporate Directors Group.

Flowchart: Procedure for the Managed Entry of Medicinal Products to the HDUHB Formulary