

A Strategy for the Assessment, Uptake and Implementation of Primary Care Pharmaceutical and Medical Device Financial Rebate Schemes Across Wales.

October 2015 (Revised September 2018)

Introduction

Primary care Rebate schemes are contractual arrangements offered by pharmaceutical companies or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s). Many CCGs in England have formed partnerships to consider these schemes and, after legal confirmation that they are allowed within current UK regulations, they have concluded that they offer genuine benefits to the NHS and to patients.

In recent years there has been an increase in the number of these schemes being offered to Welsh Health Boards by Pharmaceutical and Medical Device suppliers.

NHS Wales is facing challenging financial targets and every avenue for cost efficiency needs to be explored and in line with the principles of prudent healthcare, consideration must be given to equity of access, evidence based care and the impact on patient outcomes.

The All Wales Chief Pharmacist Group (AWCPG) has agreed that appropriately managed primary care rebate schemes can provide good value to NHS Wales and should therefore be considered by Health Boards. However there is a need to ensure that such schemes are considered in a transparent and appropriate manner and within an agreed and consistent framework across Wales.

This paper aims to define and articulate a set of common principles and a framework for good practice for Health Boards wishing to consider a rebate offer and which should be followed to ensure robust scrutiny, identification, adoption and implementation.

It is proposed that Health Boards (HB) collaborate and support an All Wales approach by providing guidance on the suitability of any individual scheme. The final decision will be made by the All Wales Drug Contracting Committee to:

- a) Provide consistency across Wales.
- b) Reduce duplication of work across Wales.
- c) Make best use of available resources and provide best value to NHS Wales

Strategy

There is a need to ensure that all primary care rebate schemes meet ethical, financial and governance requirements and that they can be administered to the requirements of the supplier to which it relates. As the number of individual rebate schemes being taken up increases, the burden of administering them will also increase. It is likely that individual schemes will be being implemented by multiple Health Boards and so there are considerable

opportunities to benefit from economies of scale by adopting an All Wales approach, with a single point of access and administration.

Following discussion and agreement by the All Wales Chief Pharmacist Group and the Welsh Medicines Procurement and Logistics Advisory Group (WMPLAG), all schemes should in future be scrutinised and evaluated by the All Wales Drug Contracting Committee, (AWDCC) on behalf of all Health Boards and Trusts. AWDCC will advise the health boards and Trusts on whether or not an individual proposal is suitable for adoption on a One Wales basis.

The development of a consistent and standardised process and strategy for assessing and implementing schemes will:

1. Reduce the administrative burden of managing rebates by individual Health Boards
2. Ensure parity and equity of access to medicines for the patients of Wales and across Health Board boundaries
3. Maximise potential cost savings by expanding rebate benefits across the whole of Wales rather than just individual Health Board areas.
4. Improve and standardise governance of rebate schemes and reduce potential variability on the way they are managed across Health Boards.
5. Enable utilisation of the One Wales Medicine Management platform to automate the calculation of rebate values based on publically available prescribing data and thus reduce the requirement for individual Health Boards to monitor and calculate usage and rebates due.

Principles underpinning the Strategy

The overarching principles of the proposed approach are based on the London NHS Procurement Partnership's document (February 2013), which has also been used by some Health Boards in Wales (e.g. ABMUHB) and the DH document '*Strategies to Achieve Cost-Effective Prescribing*' (October 2010).

These state that:

1. It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS.
2. Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development
3. The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, e.g. AWMSG, NICE or other authoritative sources;

4. Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, e.g. patients whose clinical history suggests they need a particular treatment should continue to receive it;
5. The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;
6. Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;
7. Schemes should be reviewed whenever relevant AWMSG, NICE or alternative authoritative guidance are updated.

Assessment

The detail of each rebate scheme will be considered on an individual basis to ensure that it fulfils agreed criteria to provide assurances of suitability for implementation within Wales. An All Wales approach will allow the review of the content of the scheme and determination of suitability to be completed with the minimum of duplication and administrative burden. The All Wales Drug Contracting Committee will assess whether an offered rebate meets the agreed criteria and recommend that the Health Boards reject, ask for clarification or accept the scheme, enabling economies of scale to be realised in review and administration, whilst improving the review process as a whole. This review should provide the HB with the assurance that the scheme considered is appropriate, providing that the medicine(s) within the scheme is approved for prescribing within NHS Wales. This will reduce duplication of work and provide the HB with assurances on the appropriateness and legality of the proposed scheme.

It is proposed that in future, Health Boards being offered schemes by individual pharmaceutical suppliers refer the scheme to NHS Wales Shared Services Partnership, Procurement Services – Acute Medicines (NWSSP) who will conduct an assessment on behalf of all Health Boards to gauge eligibility and suitability for administration across the whole of Wales and then present it at the next AWDCC meeting for adjudication. Alternatively companies or third party providers can approach NWSSP directly with a proposal.

You can contact NHS Shared Services Partnership, Procurement Services – Acute Medicines (NWSSP) with these proposals on the following contact details: Keeley Davies keeley.davies@wales.nhs.uk

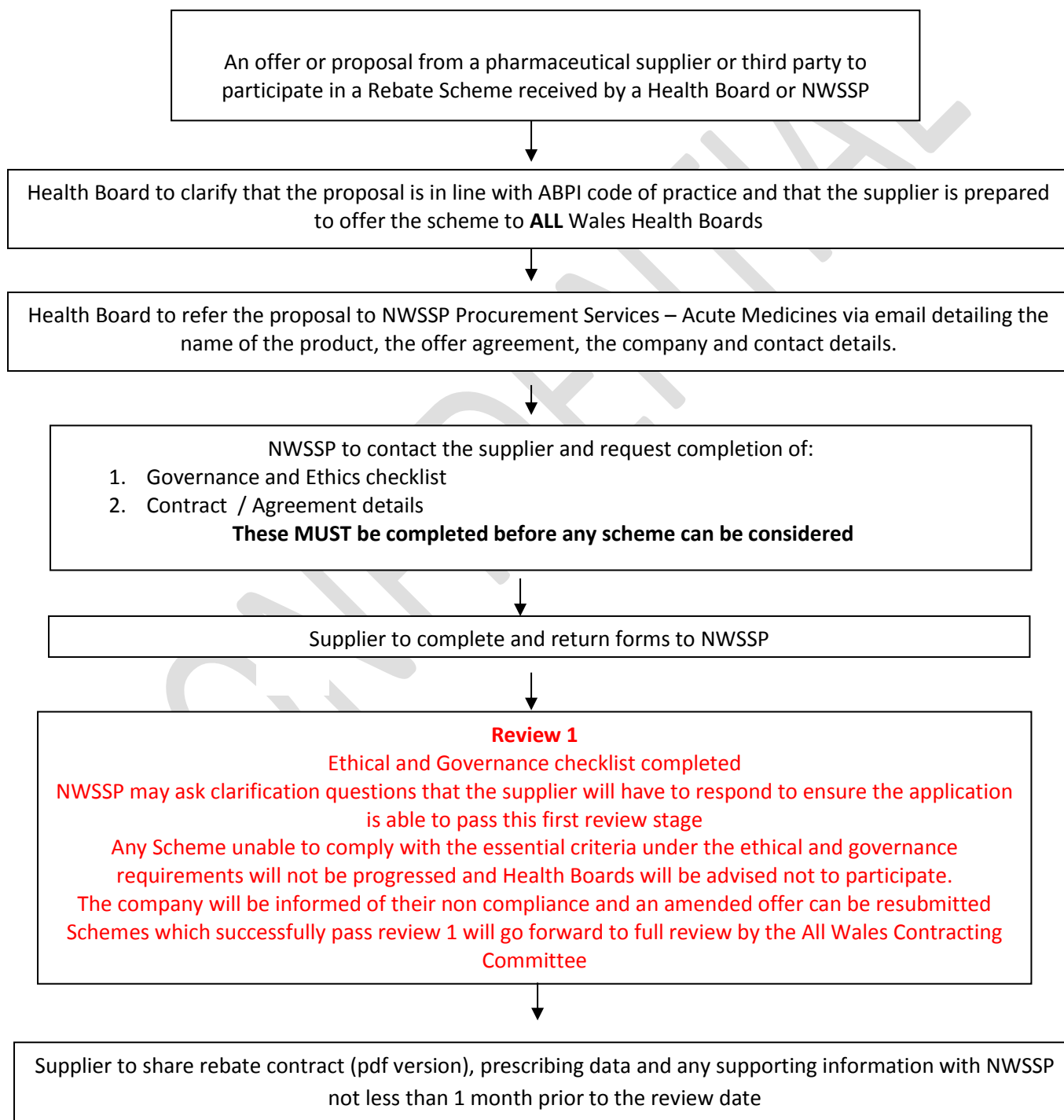
To ensure a consistency of approach, this assessment will be undertaken utilising principles developed by the NHS London Procurement Partnership (LPP) along with a series of screening questions. (**Appendix 1**)

These Good Practice Principles will assist in the assessment of these schemes, and provide assurances that there is no breach of any other UK legislation; in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing made under the 2006 Act; the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness.

In addition, if the answer to one or more of the screening questions is affirmative, the rebate scheme will not be approved by the group. If the answers are all negative, the proposed scheme will be considered in more detail and will be progressed as appropriate.

The process being proposed for the All Wales Drug Contracting Committee is described in the diagram below:

Process for the Agreement and Administration of All Wales Pharmaceutical Primary Care Rebate Scheme October 2015 (revision September 2018)



Review 2

All Wales Drug Contracting Committee considers the individual scheme based on agreed criteria to include; Ethics, Financial Impact, Clinical appropriateness, Burden of administration, Complexity, and Contract terms.

All Wales Drug Contracting Committee agree recommendation as follows:

1. Agreed
2. Agreed with minor amendments or clarifications
3. Rejected

AWDCC decision will be internally recorded and decision letter sent by email to the supplier

Contract signed by NWSSP on behalf of the Health Boards/Trusts and the supplier.
Copy filed in document management section of the One Wales MM Platform

See Appendix 2 for details outlining the approx. dates for data, invoice issue and payment of invoices

Recommendation to Health Boards

- All approaches made by the pharmaceutical industry with proposals for reimbursement or rebate schemes should be referred to NWSSP Procurement Services – Acute Medicine team for review stage 1 and clarity of offer as outlined in the flowchart above at Health Board level.
- NWSSP will screen and review any submitted scheme based on the proposed screening questions and good principle guidance using the checklist. This checklist and screening questions will be reviewed by the All Wales Drug Contracting Committee, in consultation with Health Board leads as part of this proposed collaborative work.
- If a scheme is deemed suitable for implementation, this will be ratified by Velindre NHS Trust for the All Wales Drug Contracting Committee and will provide Health Boards with assurances that it is an appropriate scheme for consideration.
- Health Boards are asked to review these recommendations and decide if any local implementation plans are required.

Appendix 1:

Good Practice Principles for Health Board Rebate Schemes for Medicines and Medical Devices

NHS London Procurement Partnership

The detailed content of rebate schemes offered will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. These principles aim to facilitate robust scrutiny and identification, adoption and implementation of NHS Wales rebate schemes (NWRS) that are judged to offer genuine benefits to the NHS and to patients. They are not in order of priority but all should be considered when making the local decision to support a NWRS.

1. *Before any consideration of price*, the clinical need for the medicine and its place in care pathways should have been agreed by the health board. The clinical decision should inform the financial / procurement decision and not vice versa.
2. Benefits should be clearly identified including improved productivity benefits without compromising patient care.
3. Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate.
4. The rebate scheme should not be directly linked to requirements to increase market share or volume of prescribing.
5. Health professionals should always base their prescribing decisions on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.
6. The administrative burden to NHS Wales of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.
7. There should be no requirement to collect or submit to the manufacturer any data other than volume of use (quantity and NIC) as derived from NHS Wales Primary Care Prescribing Services. The requirements of the Data Protection Act must be met and patient confidentiality must never be compromised.
8. All drugs to be considered under rebate schemes should be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be linked to a particular indication for use. Rebate schemes promoting unlicensed or off label uses must not be entered into. Medicines not recommended by NICE might still be the subject of a rebate scheme, but must be subject to AWMSG approval for use in Wales.
9. Rebate schemes should be agreed at a NHS Wales level, they should not be agreed at GP practice level.
10. Schemes encouraging exclusive use of a particular drug should be avoided.
11. Rebate schemes are not appropriate for medicines in Category M and some medicines in Category C of the Drug Tariff, because of the potential wider impact on community pharmacy reimbursement.

12. NWSSP Procurement Services on behalf of the Health Boards should ensure that a formal written contract is in place, signed by both parties to ensure (i) that the terms of the scheme are clear and (ii) to maximise the legal protection. All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties.
13. Exit criteria and an exit strategy should be defined before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. Rebate scheme agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a sensible notice period, e.g. three or six months. Similarly, it should be clear under what circumstances the manufacturer can exit/terminate a scheme that has been signed up to.
14. NWSSP Procurement Services on behalf of the Health Boards should not enter into any rebate schemes which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These rebate schemes should all be considered using the same criteria.
15. Freedom of Information requests– As a general principle information relating to rebate schemes is likely to be releasable, these issues should be discussed with the manufacturer before a Health Board enters into any agreement with them. Ideally, provisions about FOIA requests and commercially sensitive information should be contained in the contract.
16. The financial details of the rebate scheme should be kept confidential to ensure that the decision to prescribe or add to formulary is not influenced by the value of the rebate. Discounts and details of any rebate scheme offered should be allowed to be shared within NHS Wales. This should be agreed as part of the rebate scheme contract.

Screening questions

In entering into such schemes with a pharmaceutical industry partner there are a number of questions which must be asked to ensure that the proposal is in the best interests of both patients and the organisation. All proposals must be treated equally and decisions made will need to stand up to scrutiny if questioned.

- Is there a possibility that engaging with the proposed rebate scheme could encourage prescribing contrary to national or Health Board prescribing policy?
- Does the proposed rebate scheme require a change in current practice outside of national or HB guidelines / agreed pathways?
- Does the proposed rebate scheme disadvantage individual areas of the local health community?
- Will the integrity of the organisation be compromised in any way by engaging in the proposed rebate scheme?
- Are the anticipated net (financial or improvement in quality/ safety) rewards through the proposed rebate scheme not of sufficient value to warrant engagement?

Appendix 2:

Table outlining the approx. dates for prescribing data, invoice and payment

NHS Wales Rebate Scheme - Data, Invoice and Payment Schedule												
Month	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
Quarter	Q4			Q1			Q2			Q3		
Invoice	June			Sept			December			March		
Payment	July			October			January			April		