Briefing: Reviewing Proposed Free of Charge (FOC) Medicine Schemes Offered when SMC/Formulary Guidance is Pending

1. Introduction

There are established frameworks in place to provide access to medicines, without charge, as part of the MHRA Early Access to Medicines Scheme (EAMS) and for compassionate use in certain scenarios defined by the European Medicines Agency. Separate from this, there are an increasing number of pricing schemes being offered by manufacturers that offer medicines free-of-charge, up to the point of SMC assessment and in some cases, until the point of formulary decision-making. This is the scheme type covered by this briefing.

There are currently no national arrangements in place for the assessment or monitoring of FOC schemes; it is for Health Boards to individually weigh the benefits and risks and to determine whether to enter into an agreement. This briefing provides background information on the trend and highlights areas for consideration in the assessment of schemes.

2. Background to Free-of-Charge Medicine Schemes

There is no standardisation in the scheme types being offered; the terms can vary as can the complexity and workload involved in assessing and administering schemes. Schemes are being offered in a range of therapy areas; examples in the past year include the PCSK9 Inhibitors (cholesterol lowering treatments) as well as treatments for plaque psoriasis, rheumatoid arthritis, MS and cancer.

Unlike medicines that are part of the EAMS scheme, these medicines have not been identified by the MHRA as providing significant advantage over existing treatments for serious or life threatening conditions. For most schemes offered, there is established therapeutic competition – or a direct competitor in the late stages of development. For example, Pfizer are offering a FOC scheme for Xeljanz® (Tofacitinib), their new JAK Inhibitor which has not yet been considered by SMC; a competitor JAK Inhibitor, baricitinib (Olumiant®; Eli Lilly) will be reviewed by SMC in August.

The motivation of manufacturers offering these schemes is often unclear. It is possible that some manufacturers are using this approach as an attempt to '*seed the market*'; a marketing approach that be used to build early clinician experience of a medicine, creating advocates for the product that can support increasing sales over the long term.

3. Key Considerations

3.1 Standard Medicines Governance Processes

The provision of free stock does not remove the need to go through due process within Boards for patient access to non SMC/Formulary approved medicines. If standard governance processes are not followed, there is a risk that these schemes could introduce inequity with patients with equal clinical need being treated differently. There is also a risk of undermining the SMC process and local formulary processes. If a medicine has not yet received its Marketing Authorisation, unlicensed medicine governance processes should also be followed.

3.2 Process for Entering into Schemes

Free of charge schemes can introduce financial, operational and information governance risks. There have been examples in the past year of staff at clinic level registering patients on to schemes without clarity on the terms of the scheme or formal authorisation from their board.

As part of the assessment of schemes, relevant stakeholders within the board should be consulted to understand the operational implications of the scheme (e.g. purchasing lead if there are additional purchasing requirements) with legal advice sought on the scheme terms where necessary. Approval to enter into the scheme should be sought from an appropriate level of seniority within the Health Board (e.g. Acute Lead Pharmacist or Director of Pharmacy).

3.3 Clarity on Scheme Terms

To enable the Board to properly consider benefits and risks, it is essential that the terms of the scheme are clear and set out by the company in writing. This is not always the case. Key questions to answer include:

- Which indications are covered by the agreement? For example, all usage, only an indication that is currently being assessed by SMC or a sub-set of patients within the indication(s) being considered by SMC.
- How long will the agreement last? To the point of an SMC decision (when guidance is communicated to Boards or put in the public domain?), a defined number of days following an SMC decision, to the point of an individual Health Board making a formulary decision or to patient discontinuation?
- Are there restrictions on the number of free-packs that will be provided to an individual patient or Health Board? For example, is all usage up to a set deadline free or only a defined number of packs per patient or per Health Board?
- For patients initiated on the medicine under the scheme, what are the long-term arrangements for medicine pricing in the event of a negative SMC decision or a restriction on SMC advice? Is there sufficient detail available to understand the long-term costs of maintaining patient treatment on the medicine?
- How will the free-stock be administered? For example is it free at the point of purchase or is there a need for reconciliation via a retrospective rebate? What information needs to be provided to the company to access the free stock and how is this provided? Are there any restrictions on supply route to access the stock, for example do patients need to be registered on a homecare service first?
- Is there provision in the agreement for the manufacturer to unilaterally change the terms of the agreement, for example to stop the enrolment of new patients or terminate the scheme?

3.4 Financial Impact Assessment

FOC Schemes offer the potential for a short-term saving in the cost of the medicine but there will be a staff time cost associated with assessment of the scheme, for example discussing with the company, reviewing the written agreement and obtaining legal advice where required. There will also be a cost involved in administering the scheme, for example if there is a need to put in place bespoke purchasing and financial reconciliation processes. There is potential for the cost of the administrative burden in assessing and managing schemes to outweigh the benefits.

The long-term financial implications of entering into the scheme should also be assessed, for example if SMC issue restricted advice which doesn't encompass the specific indication in use, the Board could be faced with continuing to fund a medicine that is not cost-effective.

3.5 Operational Impact Assessment

Areas to consider in assessing the detailed operational impact of the scheme include:

- Is the manufacturer proposing free stock at the point of invoice? This would need to be managed through manual purchasing processes, can mean creating multiple drug files on the pharmacy system and is prone to error. If rebates are being proposed, how will this be managed, for example does the Board need to provide an invoice to the company?
- Is the manufacturer asking for information to be provided to access the free stock? Is this feasible and what administrative burden would this create? Ensure that the Board has reviewed any claim forms that need to be completed before entering into the agreement.
- Supply Route: Is the manufacturer limiting the scheme to patients receiving the medicine via homecare? If so, is homecare an appropriate route for the long-term supply of the medicine to the patient? There are new national governance arrangements for manufacturer-commissioned homecare; due process checks on the homecare arrangements need to be completed before patients can be initiated on to the service.

Given the volume of schemes, a concern is the cumulative burden of managing multiple schemes, each with bespoke arrangements and the associated risk of errors from the level of complexity in managing this.

3.6 Information Governance Assessment

There have been examples of manufacturers asking for patient-identifiable information as part of free-of-charge schemes, for example the patient's CHI number; this is not acceptable. Expert advice should be sought where necessary to ensure compliance with NHS information governance guidance.