# Free of charge (FOC) medicines schemes

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**Approvals**

This document must be approved by the following before distribution:

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| MO CRG | 21/11/17 | 0.3 |
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## 1. Executive summary

1.1 A free of charge medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients.

1.2 Commissioners and providers must only undertake a free of charge scheme if the principles outlined in this policy are followed.

1.3 Trusts or commissioners should not sign up to a free of charge (FOC) scheme which is solely offering a licensed medicine free of charge in advance of NICE approval.

## 2. Introduction

2.1 There are established frameworks in place in England to enable access to medicines without charge. These are the MHRA Early Access to Medicines Scheme (EAMS) and, for compassionate use in certain scenarios, as defined by the European Medicines Agency.

2.2 Independent of this, there are an increasing number of schemes being made available by pharmaceutical companies that offer medicines 'free-of-charge', to an identified cohort of patients, in advance of NICE approval.

2.3 These pre-NICE FOC schemes could potentially override existing local pathways that have been agreed that prioritise existing NICE approved treatments.

2.4 Some FOC schemes presented by pharmaceutical companies aim to provide the treatment for a licensed indication that falls outside of NICE recommendations e.g. as a 1$^{st}$ line treatment when NICE only recommends after other treatment options have been tried.

2.5 Unlike medicines that are part of the EAMS scheme, medicines made available via pharmaceutical FOC schemes have not yet been identified by the MHRA as providing significant advantage over existing treatments of life threatening conditions.

2.6 The aim of this policy is to address this issue and ensure there is a consistent and equitable approach through providing guidance when considering the use of FOC medicines schemes.

## 3. Background

3.1 There are an increasing number of FOC schemes being launched by pharmaceutical companies, which are designed to supply medicines FOC to an identified cohort of patients, in advance of a positive NICE technology appraisal or a local commissioning decision. These schemes have the potential to undermine the evidence based recommendations made by NICE or local commissioning organisations.

3.2 These schemes generally propose that for patients started on the FOC medicine prior to a national or local decision, when the treatment is outside of NICE recommendations, the pharmaceutical company will continue to supply it FOC until the clinician and the patient decide that the treatment should be stopped. In situations where NICE approves the treatment the proposal is that the free supply stops and the commissioner is expected to fund ongoing treatment thereafter.

3.3 Currently, there is no standardisation in the types of FOC schemes being offered. The terms can vary as can the complexity and workload involved in assessing, managing and administering schemes.

3.4 For most FOC pre-NICE schemes offered, there is already an established therapeutic treatment available.

3.5 Generally, medicines that are made available via FOC schemes are high cost, tariff excluded drugs. These drugs are ordinarily commissioned by NHS CCGs and NHSE, provided that they have a positive NICE TA. Alternatively, the medicine cost could be included in a block contract arrangement. The presence of FOC

schemes can unbalance the commissioning processes.

3.6 The motivation of pharmaceutical companies offering FOC schemes would appear to be an attempt to '*seed the market'*. Such a marketing approach can be used to build early clinician experience of a medicine, in effect creating advocates for the product that can support increasing sales over the long term. This is not an evidence based approach.

3.7 FOC schemes can also circumnavigate head to head trial processes in an attempt to gather 'real life data'. These schemes can require submission of data back to the pharmaceutical company.

## 4. Scope

4.1 This policy is intended to be used by anyone considering the implementation or approval of a FOC scheme.

4.2 This policy does not preclude access to treatments which are approved by the commissioner's individual funding request process.

4.3 This policy excludes schemes that allow access to treatments for rare conditions which would ordinarily be covered by a compassionate use scheme or clinical trial.

4.3 There are other mechanisms of free of charge medicines supply, which are outlined below, where there is a more defined framework. For the purpose of this work this policy will only provide signposting to these schemes.

- Compassionate use schemes as defined by the European Medicines Agency: www.ema.compassionate use schemes
- NICE approved Patient Access Schemes: www.nice.org.uk/atient-access-schemes-liaison-unit
- MHRA Early Access to Medicines Schemes: www.gov.uk/guidance/Early Access to Medicines Scheme

## 5. Key considerations

The principles outlined in section 6 should be adhered to in order to minimise governance and resource risks.

### 5.1 Governance risks and arrangements

5.1.1 Standard medicines governance processes must be followed in order to prevent the introduction of inequity with patients of equal clinical need being treated differently. There is also the risk of undermining the NICE process and local commissioning decision making processes including pathways and guideline development.

5.1.2 A memorandum of understanding (MOU) between the pharmaceutical company supplying the FOC medicine and the trust must be signed.

### 5.2 Resource risks

5.2.1 Resource risk includes financial, workforce and operational risks. FOC schemes may appear to offer the potential for a short-term saving in the cost of the medicine, however, the need for supporting infrastructure and ongoing monitoring of the medicine could outweigh the resource benefits.

5.2.2 **Financial risks**

- Provider tariff activity costs that have not been commissioned, e.g. admissions, outpatient appointments, follow up ratios, monitoring, treating adverse effects.
- Staff costs, equipment costs, concomitant medicines provision.

- Ongoing drug costs following the end of the FOC scheme.

5.2.3 **Workforce risks**

- Staff time needed for assessment of the scheme, e.g. discussions with the pharmaceutical company, reviewing the written agreement, producing the MOU, following governance processes, obtaining legal advice where required.
- Ongoing management of the scheme.
- Procurement – FOC schemes require individual patient ordering, anonymised stock etc.

5.2.4 **Operational risks**

- Cumulative burden of managing multiple schemes.
- Failure of supply route.
- Waste management.

### 5.3 Inequity

5.3.1 It cannot be presumed that NICE will make a positive recommendation. Patients started on a medicine via a FOC scheme prior to NICE approval are likely to continue to receive this drug. However, patients for whom the FOC scheme was not available at the same time will not have the same opportunity. As such these schemes have the potential to introduce inequity and, moreover, to undermine the evidence based recommendations made by NICE or local commissioning organisations.

5.3.2 FOC schemes that allow patients to access medicines that contradict NICE or locally agreed pathways should not be endorsed.

5.3.3 The FOC scheme may reduce the impact of local commissioning arrangements including approved pathways and guidelines.

### 5.4 Clinical governance

5.4.1 Details of transparent arrangements for criteria for use and monitoring of the medicine should be included in the MOU.

5.4.2 The FOC medicine should not replace an existing therapeutic option in an established pathway simply to reduce cost.

5.4.3 The appropriate route for the long-term supply of the medicine to the patient should be considered. When the pharmaceutical company chooses to provide the medicine via homecare as one of the delivery routes, the national governance arrangements for pharmaceutical company commissioned homecare must be followed and standards adhered to.

### 5.5 Patient consent

5.5.1 Discussions with the patient (or their parent/carer) must take place prior to commencing the treatment. The patient must be made aware and understand that, where there is already a NICE approved treatment available, treatment with the FOC medicine will be stopped if the medicine is no longer provided free of charge by the pharmaceutical company, even if they perceive they have had benefit from treatment.

5.5.2 The patient must be provided with the following information as a minimum:

- How to take or use the medicine.
- What to do if they develop any side effects to the medicine.
- A written record of details of their treatment (including start date, dose, frequency and monitoring requirements), so it can be shared with other healthcare staff, particularly when not clearly within patients health records.
- How to obtain supplies of the medicine.
- Details of what will happen if the treatment is stopped due to end of FOC scheme.

5.5.3 Each patient receiving a medicine via the FOC scheme must sign a consent form which states that they have received the above information and that they understand that treatment might be stopped.

## 6. Principles

6.1 The Royal Pharmaceutical Society (RPS) has published guidance and a framework for medicines optimisation[1]. In this guidance there are 3 overarching global dimensions and 4 principles. The FOC scheme principles listed below have been mapped to the 4 RPS principles. However, when considering a FOC scheme the following two RPS global dimensions should be considered first:

- The scheme must have patient-centred approach.
- The scheme should have the aim of improving patient outcomes.

| Free of charge scheme principle | Additional information |
|---|---|
| **6.1.1 Aim to understand the patient's experience** | |
| The FOC scheme must be for a medicine where there is an unmet clinical need. | The consideration should be for the benefit of a specified cohort of patients and not for the purpose of accessing the market prior the medicine being commissioned for use in the NHS. |
| There is equal access for all patients with the agreed indication in the trust or unit that has signed a contract for the scheme. | When a FOC scheme is implemented there should be consideration of equity across the local health economy. i.e. all providers of this therapeutic area of care. Commissioners should be involved in the approval of FOC schemes in order to plan for future developments. |
| When the FOC scheme involves some element of patient data collection, the scheme must have a non-disclosure agreement or the explicit consent from patients to share relevant, non-identifiable information. | This protects patient data that would not be available if the patient hadn't entered into a FOC scheme.<br>Sharing of patient identifiable information is not acceptable. |
| Any patients undergoing treatment with a medicine in a FOC scheme must be fully informed of the characteristics of the medicine and how the scheme will operate. | This will involve the patient in the process of informed consent and make an informed decision. |
| Full informed consent should be documented according to local procedures for each patient who opts to use a medicine supplied through a FOC scheme, including any restrictions on duration of treatment. | As part of the consent process, patients who opt to start treatment with a FOC medicine must be made aware of, and agree to, the scenario that the medicine may not be available after the FOC period. |
| **6.1.2 Evidence based choice of medicines** | |
| The submission to the trust's medicines management committee (MMC), or equivalent, should be supported by all the published evidence for the effectiveness of the medicine. | When the medicine is waiting a NICE decision, and existing treatments already have a positive NICE TA, evidence of effectiveness compared with established treatment options should be provided. |
| Where an established treatment pathway exists, the evidence for the proposed place in treatment should be submitted. | The FOC scheme must not support the introduction of a medicine that circumvents an existing treatment pathway or increases the number of treatment options currently commissioned. |
| There should be clear expected outcomes from the use of this treatment. | Commissioning for outcomes should be included in any agreement to ensure that the appropriate patient cohort is targeted. |
| **6.1.3 Ensure medicines use is as safe as possible** | |
| The submission to the trust's MMC should be supported by information that identifies any clinical risks with the product. | As with all medicines the identified risks need a strategy in place to minimise risks and to monitor them. |
| Patients who are entered into the scheme must be monitored appropriately so that any adverse events or treatment failures can be identified | As clinical experience with most of the medicines available via FOC will be limited, a monitoring plan must be in place, particularly for the medicines with a black triangle status. All |

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| and future incidents dealt with efficiently. | adverse events must be reported to the pharmaceutical company and the MHRA through the yellow card scheme. |
| **6.1.4 Make medicines optimisation part of routine practice** | |
| All proposals for a FOC medicine scheme must be reviewed and supported by the trust's MMC. The trust must approve the use of the medicine prior to agreeing the FOC. | The same medicines governance arrangements should be in place for FOC schemes as for other medicines introduced into an organisation. |
| Details of each FOC scheme must be shared with local commissioners and agreement reached when there are financial implications. | Commissioners must be aware of all FOC schemes approved in the local health economy in preparedness for future financial and resource implications and planning for future service development. Commissioning support organisations must be aware of all FOC schemes in order to monitor high cost data efficiently. Where applicable Blueteq forms can be made available to support monitoring. |
| Each organisation should have a transparent process for considering FOC schemes to ensure a planned and efficient response. | Consultants and specialist pharmacists will communicate potential FOC schemes to the trust chief pharmacist as early as possible and in line with this policy. |
| Consideration should be made to any potential burden for pharmacy departments that might be related to ordering and storage requirements. | All FOC schemes must be agreed with the directorate pharmacist and pharmacy procurement team. |
| Medicines in a FOC scheme may only be purchased or acquired by a pharmacist or member of pharmacy staff acting under delegated authority. | Under no circumstances should medicines be supplied directly to wards, clinics or medical staff. If a FOC medicine is available via homecare, the pharmacy must be involved in the process as per national homecare standards. |
| The FOC scheme must only be undertaken after a written contract has been signed with the pharmaceutical company. | This provides assurance that the pharmaceutical company is able to meet their contractual obligations as the medicine provider. |
| There should be consideration of the local health economy impact of adopting a FOC scheme. | FOC schemes offer the potential for a short-term saving in the cost of the medicine but there might be risks associated with the supporting infrastructure plus an ongoing use of the medicine after a NICE recommendation. These risks could outweigh the benefits. These include financial, resource and operational risks. See section 5 for further details. |
| The FOC scheme should be clear about funding responsibilities once the NICE TA or local commissioning agreement has been decided, depending on whether the outcome is positive or negative. | The MOU should express clearly where financial responsibility lies following the end of the FOC scheme. This could be a mutual responsibility. This should include drug costs and associated on-going care of the patient. |
| There should be mechanisms put in place to monitor the FOC schemes and to ensure that MOUs are adhered to. | There is a risk to an organisation if schemes are not administered according to the agreements with the pharmaceutical company. |

## 7. Application process

7.1 When approached by a pharmaceutical company with a proposal of FOC scheme, the clinical teams must liaise with their lead or specialist pharmacist as soon as possible, in order that the trust's chief pharmacist (or pharmacist with delegated authority) is informed of a proposed FOC scheme.

7.2 The principles of the FOC policy should be applied to the application process.

7.3 The responsible consultant should liaise directly with the lead pharmacist for the specialist area who must review the medicine as clinically appropriate. Using a multi-disciplinary approach the team should ensure all existing formulary options have been optimised.

7.4 If the medicine is for a cohort of patients, and is not already used for the proposed indication, the responsible consultant should first submit a new drug request form to the trust's medicines management committee (MMC) (or equivalent as agreed by trusts and commissioners).

7.5 The medicine, for the specified indication, must be approved by the trust's MMC before (or at the same time as) the FOC application is made.

7.6 An agreement (also described as a Memorandum of Understanding, MOU) between the pharmaceutical company supplying the medicine free of charge and the trust must be obtained.

7.7 The application must include confirmation by the directorate manager that funding is available for any additional drug and non-drug costs incurred by the scheme. Where there is a potential financial risk to the trust this should be approved by the divisional director of finance.

7.8 Any potential financial risk to the commissioner must be agreed with the commissioner prior to the FOC scheme being started.

7.9 The MOU should be approved by:

- Lead clinician
- Trust chief pharmacist (or person with delegated authority)
- Homecare manager (where applicable)
- Lead commissioner when financial risk to commissioner
- Trust legal team (where applicable)
- Caldicott Guardian (when data sharing considered)

7.10 The MOU must be signed by:

- A representative of the pharmaceutical company
- The trust MMC chair
- The trust lead clinician
- The trust chief pharmacist
- Lead commissioner representative

7.11 Under no circumstances should FOC medicines be supplied directly to wards, clinics or medical staff.

## 8. Roles and responsibilities

### 8.1.1 Trust chief medical officer

8.1.1 The CMO is the lead director responsible for the free of charge medicines policy and ensures organisational adherence on behalf of the trust board. This can be delegated to the chief pharmacist.

8.1.2 The CMO is responsible for approving FOC schemes when a significant financial or clinical risk has been identified.

8.1.3 The CMO will delegate authority for assuring monitoring of adherence to this procedure to the clinical directors.

### 8.2 Chair of the trust medicines management committee (MMC) or equivalent

8.2.1 The Chair of the MMC is responsible for ensuring its decisions are clear as to whether a FOC medicine scheme is considered to have potential benefits that outweigh any harm and therefore is suitable to be offered and administered to a patient within the NHS trust.

8.2.2 The MMC is responsible for ensuring that the FOC medicine offers the patient additional benefit over and above existing treatment options.

### 8.3 Clinical directors

8.3.1 The clinical director (CD) is responsible for having an overview of FOC medicines schemes and ensuring the affected specialties comply with this policy.

8.3.2 The CD or delegated manager is responsible for planning any expenditure and resource issues that may be necessary if entering a FOC scheme. Particularly planning for if the scheme is ceased by the company, if the medicine becomes commissioned by the NHS and for the non-drug costs that may be incurred.

### 8.4 Consultant / directorate manager

8.4.1 The consultant is responsible for ensuring that the MMC has considered and supported a medicine available through a FOC scheme prior to offering it as option to patients.

8.4.2 The consultant must liaise with the lead / specialist pharmacist as soon as possible and the trust's chief pharmacist should be informed of any proposed FOC scheme.

8.4.3 Consultants are responsible for providing information to the directorate manager to allow them to plan for the on-going management of patients on a scheme and identify the potential financial risk the division may be exposed to.

8.4.4 The directorate manager must confirm that funding is available for any additional drug and non-drug costs incurred by the scheme. Where there is a potential financial risk to the trust this should be approved by the divisional director of finance.

8.4.5 Consultants are responsible for taking patients or their representatives through treatment options available to them and for providing high quality written information on treatment and ensuring they have enough information to consent to entering a FOC scheme. This should include explicitly explaining that should a scheme cease and no on-going NHS funding is identified the treatment will cease, even if it is being effective.

8.4.6 Consultants must ensure that the patient's General Practitioner is made aware of any 'free of charge' medicines prescribed.

8.4.7 Consultants must not agree supply of medicines and associated contracts with a company directly. All schemes should be referred to pharmacy for processing.

8.4.8 Consultants are responsible for monitoring outcomes of treatment.

### 8.5 Chief pharmacist (or delegated authority) and pharmacy team

8.5.1 The chief pharmacist is responsible for ensuring that the FOC scheme does not contradict current NICE guidance or local commissioning arrangements.

8.5.2 Appropriate specialist pharmacists are responsible for supporting consultants providing information to MMC to help make a decision whether to support a FOC scheme.

8.5.3 All contracts for FOC schemes should be scrutinised by the lead procurement pharmacist and the agreement signed by them or their appointed deputy if supported by them and MMC.

8.5.4 The pharmacy team is responsible for the ordering of all FOC medicines.

### 8.6 Commissioning organisation

8.6.1 Commissioning organisations should ensure that all parties are aware of any relevant local commissioning arrangements.

8.6.2 Commissioners should be in a position to advise on the impact of potential FOC schemes in preparedness for future financial and resource implications and planning for future service development.

## 9. Definitions

**9.1** **Compassionate use schemes** refer to schemes involving unlicensed medicines.
The EMA defines compassionate use as "a treatment option that allows the use of an unauthorised medicine. Under strict conditions, products in development can be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials."

**9.2** **Early Access to Medicines Scheme (EAMS**) aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation where there is a clear unmet medical need. It offers a way by which unlicensed medicines can be made available to patients. EAMS enable companies to gain additional knowledge and the NHS to gain experience of these medicines in clinical use. As part of the process the MHRA will give a scientific opinion on benefit / risk balance of the medicine, based on the available data when the EAMS submission was made. For an EAMS to be granted the medicinal product must offer promise i.e. benefit or significant advantage over and above existing treatment options. The medicine is provided free by the company during the scheme.
The MHRA EAMS is an example of a compassionate access to medicines programme.

**9.3** **Patient Access Schemes (PAS).** The Patient Access Scheme Liaison Unit (PASLU) has been set up by NICE to work with manufacturers who are considering a patient access scheme for their drug or treatment. The Patient Access Scheme Liaison Unit (PASLU) looks at the proposal made by the manufacturer to see if it is a scheme that would work in the NHS
PAS proposals are made in the context of a NICE technology appraisal with the aim of enabling a positive NICE recommendation.
The term 'patient access scheme' should only be used to refer to pricing agreements within the context of a NICE TA.

**9.4** A **clinical trial** is a study performed to investigate the safety or efficacy of a medicine. The regulation of clinical trials aims to ensure that the rights, safety and well-being of trial subjects are protected and the results of clinical trials are credible. The European Medicines Agency relies on the results of clinical trials carried out by pharmaceutical companies to reach its opinions on the authorisation of medicines.

**9.5** **The NICE Technology Appraisal (TA)** process is designed to appraise medicines based on the clinical and economic evidence for the medicine. The TA considers clinical and economic evidence principally provided by the manufacturer or pharmaceutical company.
The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE technology appraisals. When NICE recommends a treatment 'as an option', the NHS must make sure it is available within 3 months (unless otherwise specified) of the date of publication of the TA.

**9.6** **A licensed medicine** is one that has been granted a UK marketing authorisation for one or more indications.

**9.7** **An unlicensed medicine** is a medicine that currently does not have a UK marketing authorisation.

**9.8** **An off-label medicine** is one that is being used in a way that is different to that described in the UK licence.

## 10. References & acknowledgements

1. RPS Medicines Optimisation Principles (2013)

Acknowledgements to the authors of the following:
NHSE MO CRG: Draft free of charge medicines principles
CMFT: Draft industry sponsored use of medicines policy
SRFT: Free of charge medicines scheme policy
NHS Scotland: Reviewing proposed free of charge medicine schemes offered when SMC guidance is pending.
Pan Mersey: Manufacturer's free of charge medicines schemes where NICE guidance is pending