Free of charge (FOC) medicines schemes

Advice ratified by the
Regional Medicines Optimisation Committee
for adoption as local policy
(Principles drafted by the Medicines Optimisation Clinical Reference Group)

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This advice has been developed in collaboration with the NHS England Medicines Optimisation Clinical Reference Group.

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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Contents

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 company to an individual patient* or an identified cohort of patients.

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

1.3 Any uptake of free of charge medicines must be for direct patient benefit in order to address an unmet clinical need. The key considerations, principles, application process and roles/responsibilities outlined in this advice are to be applied.

1.4 It is recognized that there are various types of free of charge (FOC) schemes:

i) Access to medicines in advance of a commissioning agreement, for example prior to publication of a NICE Technology Appraisal Guidance. Within this document this definition will also include very deeply discounted products that are offered at a price so low that they are almost free of charge.

ii) Access to an individual medicine for an individual patient in circumstances where no other suitable commissioned alternative medicines are available for the specific indication. This context is not the prime focus of the advice, but safeguards documented will be relevant to assurance of patient safety. This includes compassionate use of medicines in accordance with the European Medicines Agency (EMA) definition in section 9.1.

1.5 Trusts or commissioners should assess unmet need and not sign up to a FOC scheme which is solely offering a licensed medicine free of charge for the purpose of market access in advance of a commissioning agreement.

*Any reference to patient/s are relevant to carer/s as appropriate

2. Introduction

2.1 There are established frameworks in place in England to enable access to medicines without charge. These are the Medicines and Healthcare products Regulatory Agency (MHRA) Early Access to Medicines Scheme (EAMS) and, for compassionate use in certain scenarios, access as defined by the European Medicines Agency (EMA). The advice in this document does not address either of these contexts; further information is available in section 4.5 below and on the MHRA and EMA websites.

2.2 Independent of this, schemes are made available by companies that offer medicines free-of-charge, to an identified cohort of patients, often in advance of potential commissioning approval.

2.3 Pre-NICE FOC schemes have the potential to override existing local pathways and existing NICE recommended treatment pathways. Early discussion of potential FOC charge schemes with the relevant commissioner should be undertaken to allow robust assessment of potential impact on currently commissioned pathways (locally or nationally commissioned through NICE or NHS England).

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

2.5 Unlike medicines that have been licensed, the safety and efficacy of unlicensed medicines made available via FOC schemes may not yet have been fully considered by the regulators.

2.6 The administrative burden of FOC schemes is also noted, so the impact on the pharmacy service is to be considered.

2.7 The aim of this advice is to highlight considerations that locally systems should take into account to address potential financial, administrative and clinical risks, to ensure there is a consistent and equitable approach through providing guidance for Trusts and commissioners when considering the use of FOC medicines schemes.

3. Background

3.1 There is concern that an increasing number of FOC schemes being launched by companies are designed to supply medicines FOC to an identified cohort of patients in advance of a decision from NICE or a local commissioner. FOC schemes have the potential to undermine the evidence based recommendations made by NICE or local commissioning organisations because they may alter existing local pathways.

3.2 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.

3.3 Trust experience is that for many FOC pre-NICE schemes offered, there is already an established therapeutic treatment available.

3.4 Generally, medicines that are made available via FOC schemes are high cost, tariff excluded medicines. These medicines are ordinarily commissioned by NHS CCGs or NHS England if they have a recommendation from NICE. Alternatively, the medicine cost could be included in a block contract arrangement. The presence of FOC schemes can unbalance the commissioning processes.

3.5 The motivation of companies offering FOC schemes could be perceived as a marketing approach to build

early clinician experience of a medicine, in effect to increase product sales over the longer term. This is not an evidence-based approach, although it is often argued that it provides earlier patient access and improves outcomes. To avoid FOC schemes being perceived as marketing tactic companies should clearly specify the unmet health needs addressed through introducing a FOC scheme, together with its duration and details of the relevant patient cohort.

3.6 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 company and can therefore be an administrative burden.

3.7 FOC medicines may be offered in circumstances where the company has chosen not to make a submission on a topic that NICE has identified as requiring guidance. In such circumstances, commissioners will not support funding, so any future financial risk remains with the Trust.

4. Scope

4.1 This advice is intended to support providers considering the implementation or approval of FOC schemes, or are developing local policies to ensure this is appropriately managed.

4.2 This advice does not preclude access to treatments which are considered exceptional and suitable for consideration through the commissioners IFR process.

4.3 This advice does not primarily focus on FOC schemes that allow access to treatments for rare conditions which would ordinarily be covered by a compassionate use scheme or a clinical trial.

4.4 It is appreciated that some medicines are provided FOC following the completion of a clinical trial to specific patients who experienced benefit during the trial. In this context such arrangements should be clear at the commencement of the trial. The company should have an exit strategy which could include expanded access, so many of the key considerations and risks detailed in this advice are relevant.

4.5 This advice excludes those medicines approved by regulatory agencies as outlined below, where more defined frameworks are specified. This advice will only provide signposting to these schemes:

- Compassionate use schemes as defined by the EMA:
  www.ema.compassionate use schemes
  Compassionate use schemes are 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.
- NICE approved Patient Access Schemes:
  www.nice.org.uk/patient-access-schemes-liaison-unit
  Any free of charge supplies through a NICE Patient Access Scheme are supplied as an integral part of the NICE Technology Appraisal Guidance.
- MHRA Early Access to Medicines Schemes:
  www.gov.uk/guidance/Early Access to Medicines Scheme
  The 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 when there is a clear unmet medical need. Under the scheme, the MHRA will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available when the EAMS submission was made.

5. Key considerations

Adherence to the principles outlined in section 6 will minimise governance and resource risks detailed below.

5.1 Governance, risks and arrangements

5.1.1 FOC schemes should include provision for patients started on the FOC medicine where NICE do not recommend the treatment, or for situations where the NICE approved eligibility criteria are not met, such that the company will continue to supply it FOC until the clinician and the patient decide that the treatment should be stopped. In situations where NICE recommends the treatment and the patient meets the eligibility criteria, the FOC scheme should specify that the free supply stops at the implementation date and the commissioner is expected to fund ongoing treatment thereafter.

5.1.2 In principle, Trusts or commissioners should not sign up to a FOC scheme for a medicine indication that the company has chosen not to submit to NICE, which has meant that NICE are unable to issue guidance. Such arrangements are therefore not generally supported because the clinical and cost effectiveness of the treatment is unknown.

5.1.3 Standard medicines governance processes must be followed to prevent the introduction of inequity with patients of equal clinical need being treated differently. The introduction of FOC schemes also carries the risk of undermining the NICE process and local commissioning decision making processes including pathways and guideline development.

5.1.4 A written agreement between the company supplying the FOC medicine and the Trust must be signed (as specified in section 8.7.6 below).

5.1.5 The Government Master Indemnity Agreement (https://www.gov.uk/government/publications/master-indemnity-agreement-mia) states that the scope focuses on the free use of equipment; the NHS legal advice is that this definition does not relate to free of charge medicines.

The absence of such indemnity cover should be noted by Trusts, and this situation is unlikely to be resolved by introducing payment of a very low nominal fee for such medicines.

5.1.6 Trusts and commissioners are to decide the most appropriate medicines management committee locally for discussion and approval of any free of charge schemes.

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 if the administrative burden is high.

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. These can be quite significant and should be brought to the attention of the relevant commissioner before a decision to progress the scheme is made, particularly if new activity is involved.

- Staff costs, equipment costs, and concomitant medicines provision.
- Ongoing medicines costs following the end of the FOC scheme.
- Additional medicine costs if FOC medicine is used in combination with another (funded) treatment.
- If the commissioner has not agreed the FOC scheme (including additional spend on funded medicines) then **the entire** financial risk lies with the Trust.
- Potential for harm and medical negligence claim should an untoward event occur, plus the resulting reputational risk.

5.2.3 **Workforce risks**

- Staff time needed for assessment of the scheme, including discussions with the company, reviewing the written agreement, producing the written agreement, following governance processes, obtaining legal advice where required.
- Ongoing management of the FOC scheme.
- Procurement – FOC schemes often require individual patient ordering and more onerous stock management.

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 recommend a treatment. Patients started on a medicine via a FOC scheme prior to a decision from NICE are likely to continue to receive this medicine. However, new patients, for whom the FOC scheme may not be available, will not have the option. As such these FOC schemes have the potential to introduce inequity and postcode prescribing, 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 undermine NICE or locally agreed pathways should not be endorsed.

5.3.3 Trusts jointly with commissioners, should confirm that the FOC does not undermine the impact of local or national 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 written agreement.

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 company chooses to provide the medicine via homecare as one of the delivery routes, the national governance arrangements for 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 recommended treatment available, treatment with the FOC medicine will be stopped if the medicine is no longer provided free of charge by the company, even if the patient perceives they have had benefit from treatment.

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

- Uncertainties in the efficacy/safety data (if drug is still in development/unlicensed/off-label).
- 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 patient's health records.
- How to obtain supplies of the medicine.
- Details of what will happen if the treatment is stopped due to the end of FOC scheme.

5.5.3 Each patient receiving a medicine via the FOC scheme should 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 three overarching global dimensions and four principles. The FOC scheme principles listed below have been mapped to the four RPS principles. However, when considering a FOC scheme the following two RPS global dimensions should be considered first:

- The scheme must have patient-centered 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 to 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 written agreement 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 consulted as part of an impact assessment 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 had not entered a FOC scheme. 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

and future incidents dealt with efficiently.	adverse events must be reported to the company and the MHRA through the yellow card scheme.
Labelling of products must meet regulatory and quality standards.	Pharmacy Quality Assurance processes must ensure that product labelling is appropriate and does not introduce risk.
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 to assure 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 advice.
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 agreement has been signed with the company.	This provides assurance that the company can 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 decision. These risks may 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 written agreement should express clearly where financial responsibility lies following the end of the FOC scheme. This could be a mutual responsibility. This should include medicine 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 written agreements are adhered to.	There is a risk to an organisation if FOC schemes are not administered according to the agreements with the company.

7. Application process

Note: This process should be adapted to local organisational structures.

7.1 When approached by a 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 before offering to patients.

7.2 The principles of this FOC scheme advice 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 submit a written application to the Trust's medicines management committee (MMC or equivalent as agreed by Trust and commissioners). In the case of a cancer medicine or medicine impacting on a regional specialist service agreement, advice from a local expert chemotherapy group or equivalent should be sought.

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 A written agreement between the company supplying the medicine free of charge and the Trust must be obtained, approved and signed as detailed in section 7.12 and 7.13 below.

7.7 The application must include confirmation by the appropriate service manager that funding is available for any additional drug and non-drug costs incurred by the FOC scheme. Where there is a potential financial risk to the Trust this should be approved by the appropriate level officer as defined in that Trust's Standing Financial Instructions or equivalent policy.

7.8 In principle the agreement is to be in place until the point at which commissioning of the medicine for the identified patient or patient groups is funded. If patients do not meet the treatment criteria set by NICE, NHS England or the relevant commissioner, the position regarding continuation on the FOC medicine and the management of the financial risk is to be specified in the agreement.

7.9 The application must meet the commissioners' prior notification requirements, and any potential financial risk to the commissioner is to be identified and agreed prior to the FOC scheme being started.

7.10 In the context of section 7.9 above, some FOC schemes require the FOC medicine to be used in combination with an existing commissioned medicine. This can change how the existing commissioned medicine is used, particularly in cancer where the addition of a FOC medicine can extend usage of the existing medicine where the combination is considered to be more effective than the existing medicine alone, thus increasing the budget impact. It is important that this has been discussed with commissioners in advance.

7.11 A template for submission to the commissioner has been appended (see appendix 1).

7.12 The written agreement (see section 8.7.6 below) should be approved by:

- Lead clinician
- Trust Chief Pharmacist (or person with delegated authority)
- Trust Chief Medical Officer (or person with delegated authority) where potential financial or clinical risk
- Homecare manager (where applicable)
- Trust legal team (where applicable)
- Caldicott Guardian (when data sharing considered)

Note – The lead commissioner is to be informed as in section 7.9 above.

7.13 The written agreement (see section 8.7.6 below) should be signed by:

- A representative of the pharmaceutical company.
- The Trust MMC chair
- The Trust lead clinician
- The Trust Chief Pharmacist

(or persons with delegated authority if necessary)

7.14 The signed written agreement must be copied to:

- Lead commissioner representative

7.15 FOC medicines are to be supplied through Pharmacy. Under no circumstances should FOC medicines be supplied directly to wards, clinics or medical staff.

8. Roles and responsibilities

Note: These roles and responsibilities should be adapted to local organisational structures.

8.1 **Trust Chief Medical Officer (CMO)**

8.1.1 The CMO is the lead director responsible for the FOC 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 relevant service medical / clinical leads / 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 **Service Medical / Clinical Lead / Director**

8.3.1 The relevant service medical / clinical lead / director (CD) is responsible for having an overview of FOC medicines schemes operational in the service and ensuring the affected specialties comply with this advice.

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 FOC scheme is ended by the company, if the medicine becomes commissioned by the NHS and for the non-drug costs that may be incurred.

8.4 **Consultant and relevant service 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 FOC scheme and identify the potential financial risk the division may be exposed to.

8.4.4 The relevant service manager must confirm that funding is available for any additional drug and non-drug costs incurred by the FOC scheme. Where there is a potential financial risk to the Trust this should be approved by the by the appropriate level officer as defined in that Trust's Standing Financial Instructions or equivalent policy.

8.4.5 Consultants are responsible for taking patients and/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 FOC scheme end without on-going NHS funding being 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 FOC medicines prescribed.

8.4.7 Consultants must not agree supply of medicines and associated contracts with a company directly. All FOC schemes must 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 NICE recommendations, guidance or local commissioning arrangements.

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

8.5.3 All written agreements for FOC schemes should be scrutinized 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 or prior notification requirements.

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

8.7 **Pharmaceutical Industry**

8.7.1 Early engagement is required with the Chief Pharmacist who must approve the operation of the FOC scheme in collaboration with the MMC.

8.7.2 Companies offering Free of Charge schemes to the NHS should ensure that they are aware of the principles and processes set out in this guidance and the information required for patients outlined in section 5.5.

8.7.3 Companies offering FOC schemes under schemes such as Clinical Trials, EAMS or Compassionate Use Schemes should ensure they follow appropriate national guidance.

8.7.4 Similarly companies offering FOC schemes outside the national schemes should ensure they appropriately support the NHS to both agree and subsequently operationalize any agreed scheme.

8.7.5 In particular companies should prepare a draft written agreement which sets out an overview and specific operational details of the proposed scheme for initial discussions with the Trust clinical staff, Chief Pharmacist and other relevant NHS colleagues.

8.7.6 A formal written agreement must be in place between the Company and Trust before commencement of any scheme. This must clearly set out:

- Clinical criteria/cohort and unmet clinical need.
- Patient information.
- Any data collection requirements.
- Labelling, packaging, storage requirements and pack inserts of the necessary clarity and legibility to enable to the product to be safely administered in the NHS.

- The length and scope of the agreement, particularly in regard to continuity of supply until NICE or commissioning approval. Similarly, there should be clear agreement as to the consequences of any anticipated NICE approval/commissioning decisions not being approved.

8.7.7 In principle, all FOC supplies must continue until the medicine is commissioned and funding is in place. Any exceptions to this principle must be detailed in the formal written agreement outlined above.

8.7.8 Companies should not introduce FOC schemes that cap the number of patient numbers who are eligible for access.

8.7.9 Any data collection requirements must be formally agreed by the Trust prior to commencement.

8.7.10 All supplies must be processed through the Pharmacy department.

8.7.11 Labelling, packaging, storage requirements and package inserts are of the necessary clarity and legibility to enable the product to be safely administered in the NHS.

8.7.12 Companies must provide clinical evidence for use of the medication in the patient cohort upon request.

8.7.13 Companies must operate under the ABPI Code of Conduct and Prescription Medicines Code of Practice. The pharmaceutical industry is committed to benefitting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and support the provision of high-quality healthcare.

9. Definitions

9.1 **EMA Compassionate use schemes** refer to schemes involving unlicensed medicines assessed by the EMA. 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.

9.3 **Patient Access Schemes (PAS).** The Patient Access Scheme Liaison Unit (PASLU) has been set up by NICE to work with companies who are considering a patient access scheme for their treatment. The Patient Access Scheme Liaison Unit (PASLU) looks at the proposal made by the company 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 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 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. Separate arrangements for funding are in place for cancer drugs, via the cancer drugs fund (CDF).

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; this may include use for a different indication.

10. References & acknowledgements

1. RPS Medicines Optimisation Principles (2013)

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Pan Mersey: Manufacturer's free of charge medicines schemes where NICE guidance is pending

11. Appendix 1: Free of Charge (FOC) Supply – Request for approval template

Standard template for commissioner approval of free of charge medicines schemes

Completion of this form **does not** ensure future commissioning arrangements.

Trust name	
Drug name – Approved (and generic / biosimilar – if known)	
Preparation (strength and formulation)	
Drug company	
UK license status	
Clinical indication	
Line in therapy and what this replaces (if any)	
Regimen (i.e. dose, route, duration and frequency, number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug)	
Estimated number of anticipated patients per financial year	
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval	
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval but the patient does not fit the funding criteria	
Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval	

Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug			
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)			
Requesting clinician			
Completed by:			