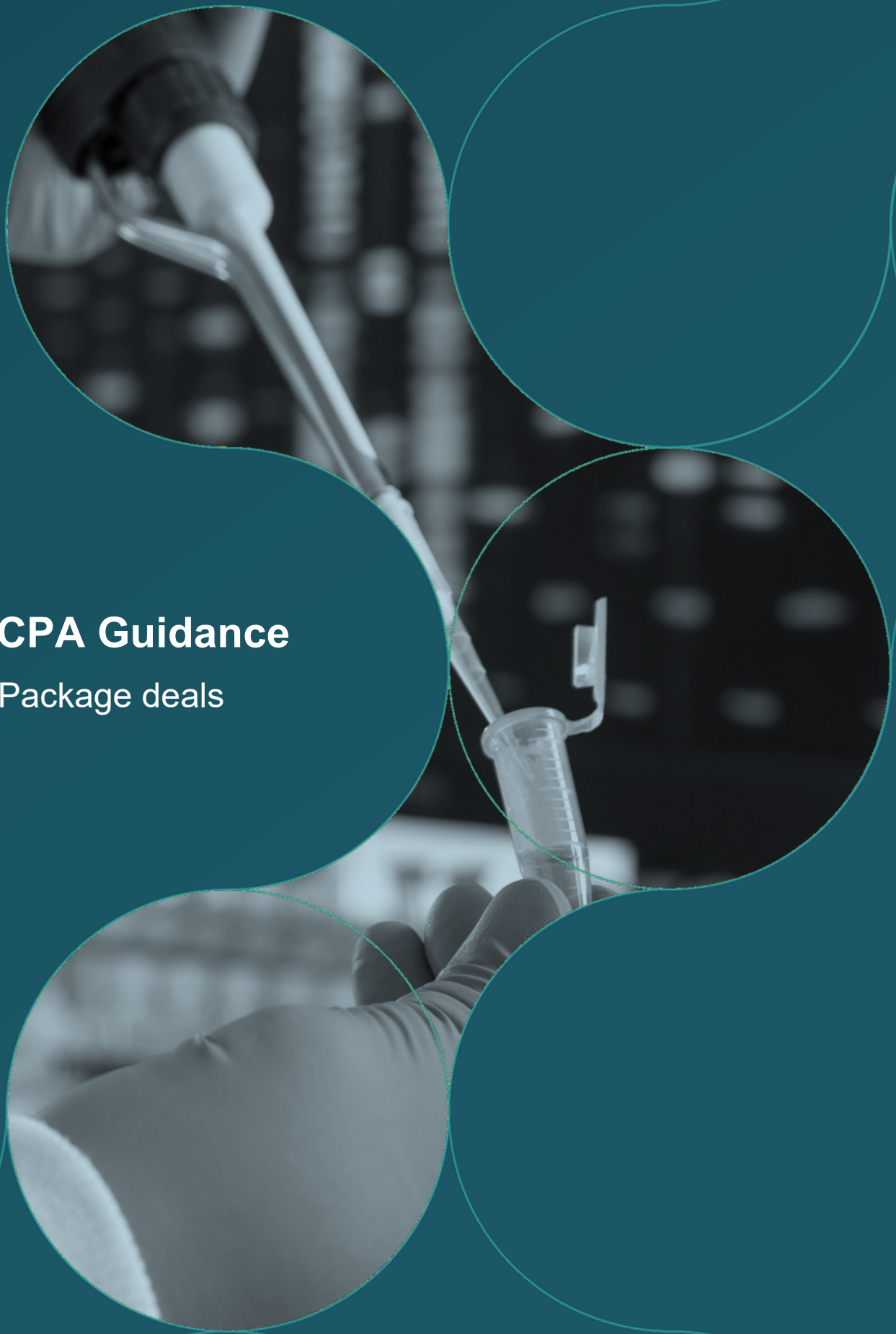
PMCPA



PMCPA Guidance

Package deals

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19 January 2026

Package deals

The PMCPA cannot approve any materials or activities: it can only give informal advice based on its interpretation of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice ("the Code"). In the event of a complaint being received about any matter referred to in this document, it would be considered in the usual way; the Code of Practice Appeal Board would make the final decision if a case went to appeal. Each complaint is considered upon its own merits and based upon the allegations raised by the complainant.

This guidance is not a substitute for a detailed study of the 2024 Code and does not replace the need for pharmaceutical companies, including their employees, third parties and the like to follow the ABPI Code and all other applicable codes, laws and regulations to which they are subject. It also does not identify all the requirements that must be followed for each activity, as they may vary significantly depending on the nature of the activity.

Contents

1. Definition of a package deal and the scope of this guidance

There are many different types of package deals and therefore it is difficult for the PMCPA to give universal guidance in this area. Companies must be confident that the arrangements they have in place meet the requirements of the ABPI Code and that, if a complaint were received, they would be able to explain the rationale for their actions and decisions.

Definition of a package deal

The supplementary information to Clause 19.1 defines package deals as commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration of the medicine, the provision of training on its use or the services of a health professional to administer it. Transfers of value made in the course of these package deals would need to be disclosed in accordance with Clause 28. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

Clause 1.25 exempts package deals solely relating to ordinary course purchases and sales of medicines from the requirement to disclose transfers of value.

Companies can provide genetic testing or other biomarkers/specific testing in relation to the rational use of its medicines.

Where the use of a medicine requires specific testing prior to prescription, companies can arrange to provide such testing as a package deal even when the outcome of the testing does not support the use of the medicine in some of those tested.

Package deals are arrangements with a healthcare organisation (HCO) where the company provides an associated benefit, such as a service or item, as part of the purchase price of its medicine. An 'associated benefit' in this context **does not** include:

- Financial discounts considered as terms of trade referred to in the supplementary information to Clause 19.1. These are ordinary course purchases and sales of medicines and exempt from disclosure of transfers of value.
- Free of charge company goods. A commercial arrangement including some free goods (such as '10 for the price of 9') might be considered a term of trade. These are exempt from disclosure of transfers of value. The provision of unlimited or excessive free goods would not be acceptable under the Code.
- Materials. While materials for health professionals and patients may be provided to an HCO in association with a package deal, they may also be provided directly to health professionals/patients outside of a package deal. There are no transfers of value to disclose in relation to materials.

By their very nature, package deals are inextricably linked with a specific medicine and cannot be considered a donation under Clause 23.

Examples of package deals **include** (non-exhaustive):

- Home delivery and/or administration services (including homecare). For example, where a pharmaceutical company provides the services of a health professional (e.g. a nurse), either directly employed by the company or via a third-party agency, to administer the company medicine to patients to whom it has been prescribed. Such health professionals do not have the authority to prescribe the medicine or amend the prescription. They will administer the medicine to the patient as prescribed.
- Medicine-related support service, e.g. specific testing prior to prescription (such as genetic testing or biomarkers). Where the use of a medicine requires specific testing prior to prescription, companies can arrange to provide such testing as a package deal even when the outcome of the testing does not support the use of the medicine in some of those tested.
- Patient education services, e.g. service of a health professional to educate patients on the medicine that has been prescribed to them.
- Patient support service, e.g. a telephone line.
- Digital tools, e.g. remote monitoring. Companies will need to consider all relevant regulations including medical devices regulations, data privacy and MHRA guidance on software and artificial intelligence as a medical device: www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device

Items for patient support referred to in Clauses 19.2 and 26.3 may be supplied to an HCO as part of a package deal, however, they may also be provided directly to health professionals/patients outside of a package deal. Either way, they are exempt from the requirement to disclose transfers of value. See the **Value** section, below.

2. Governance of package deals

a. Policies

It is important that companies have clear policies (or similar) which cover the approval and oversight of package deals, with clearly defined roles and responsibilities.

It would be advisable for a company to convene an appropriate cross-functional group (which would typically include medical, legal and representation from pharmacovigilance) to review package deals from initial concept to approval and ongoing oversight. Other personnel, including commercial, may also need to be involved.

b. Classification and certification

A package deal is a commercial arrangement and therefore in general terms considered promotional. It is acknowledged that some materials/activities/items associated with a package deal may be non-promotional. For example, when a service for patients is provided with a medicine, the patient interaction itself and any associated materials/items intended for patients must be non-promotional.

Companies should bear in mind the requirements of Clauses 8 and 12 when creating package deal materials.

- Materials communicating the package deal to health professionals and other relevant decision makers will likely be considered promotional and thus must be certified under Clause 8.1, contain prescribing information, adverse event reporting statement and other obligatory information as required by Clause 12.
- Package deal materials/items intended for patients must be non-promotional and certified under Clause 8.3. Companies must bear in mind the requirements of Clause 26.

c. Training and supervision of service providers

Where a package deal involves the provision of services, the training and support materials provided to the health professionals *delivering* the service must be non-promotional. The company should ensure that those delivering the service (whether an employee or third-party) are adequately trained, including on the:

- company's pharmacovigilance procedures
- medicine's summary of product characteristics (SPC) and any risk minimisation material approved by the MHRA – with timely notification about updates to these regulatory documents
- company's withdrawal of materials procedure
- relevant requirements of the ABPI Code, including transparency.

Documentation of training is important.

Package deals which involve the provision of services should follow some of the same principles outlined in the supplementary information to Clause 23 of the Code in relation to services, specifically:

- The service provider should be a suitably qualified person.
- Health professionals involved in the delivery of services are required to adhere to all relevant professional standards of conduct.
- Service providers must operate to detailed written instructions provided by the company. The written instructions should include, among other things: setting out the role of the service provider, patient confidentiality issues, pharmacovigilance, and instructions regarding declaration of pharmaceutical funding.
- Internal company and service provider instructions should be certified under Clause 8.3.

The company must have ongoing oversight of the service provider in its conduct in relation to the package deal and this may be best performed by the cross-functional group referred to in the **Policies** section, above, which must include pharmacovigilance representation. If the health professionals involved in the service are directly employed by the pharmaceutical company, they should report into the medical/scientific side of the business.

d. Use in accordance with licence

Promotion must encourage the rational use of a medicine. Therefore, package deal arrangements must not encourage the use of a medicine in a manner inconsistent with its SPC. While the prescribing health professional will make the ultimate decision as to how the medicine should be used in each patient, pharmaceutical companies must not encourage off-label use in association with a package deal. Documentation, including written agreements and internal company and service provider briefings related to a package deal must not be inconsistent with the medicine's SPC.

e. Value

The transaction as a whole must be fair and reasonable, and the associated benefits must be relevant to the medicine involved.

Items for patient support referred to in Clauses 19.2 and 26.3 may be supplied to an HCO as part of a package deal, however, they may also be provided directly to health professionals/patients outside of a package deal. Either way, they are exempt from the requirement to disclose transfers of value. Such items must be inexpensive and directly benefit patient care. An 'inexpensive' item for patient support means one that has cost the

donor company no more than £15, excluding VAT. The perceived value to the health professional and the patient must be similar. See the requirements for patient support items in Clauses 19.2 and 26.3 of the Code.

As a general rule, companies cannot use a package deal as a way to circumvent the financial limit for patient support items referred to in Clauses 19.2 and 26.3.

However, if the company deems it unethical or unsafe to supply the medicine without the patient support item and it has no retail value (for example, a demo auto-injector for the patient/carer to practice technique at home) then the company may be able to justify going above the £15 excluding VAT limit in Clause 19.2 when providing the item as part of a package deal. Companies must always bear in mind the impression of their activities and that the transaction as a whole must be fair and reasonable. In the event of a complaint, each case would be determined on its individual merits.

f. Prohibition on inducements, anti-competitive behaviour and other laws

Package deals must not be inducements to prescribe, supply, administer, recommend, buy or sell any medicine. The transaction as a whole must be fair and reasonable.

When entering into commercial arrangements related to pricing such as package deals, companies must also consider relevant competition law requirements.

Clause 3.4 of the Code requires companies to comply with all applicable codes, laws and regulations to which they are subject. These include but are not limited to: medical device regulations, competition law, intellectual property, data privacy and data protection laws as well as anti-bribery, anti-corruption and environmental, corporate and sustainable reporting legislation.

Companies should review package deal arrangements against the UK Bribery Act. The UK Bribery Act covers public and private sector bribery. Companies will likely need to do separate risk assessments for NHS and private HCOs. Package deals must not result in individual health professionals or other relevant decision makers being the ultimate beneficiary.

g. Transparency/declaration of funding

Materials and communications related to a package deal (including for patients) must make it clear, at the outset, that the associated benefit is being funded by the pharmaceutical company. The patient reserves the right to decline the associated benefit funded by the company and such a decision must be respected. Depending on what the benefit is, the refusal may need to be communicated back to the patient's prescriber promptly so that alternative arrangements for the patient's care can be made. It is thus important that transparency to the patient is communicated at the outset of care and appropriate written materials related to the package deal should emphasise this requirement.

h. Termination considerations

Companies should consider documenting and communicating an exit plan for each package deal. The termination of a package deal must take into account any impact that this might have on patient care.

i. Written agreements

Companies should have written agreements in place governing package deals. Agreements should make clear the roles and responsibilities of all parties involved (including any third-party service providers).

It may be appropriate (depending on the type of package deal) for written agreements to include the following, in addition to other legal considerations:

- the parties to the agreement, and the date and term of the agreement
- a description of the package deal, including naming the particular medicine
- patient data and confidentiality
- patient safety (including pharmacovigilance requirements)
- a reminder that the medicine should be used in accordance with its SPC
- contingency arrangements to cover possible unforeseen circumstances, such as changes to SPCs and updated clinical guidance; agreements should include a dispute resolution clause
- notice periods for withdrawal of the package deal and exit criteria
- transparency at the outset to all stakeholders (including patients) that the associated benefit is funded by the pharmaceutical company
- an explanation of whether there are any transfers of value to be disclosed.

Depending on the type of package deal, there may be multiple contractual relationships.

Written agreements for package deals do not require certification under the Code. However, it would be advisable for the cross-functional group, referred to in the **Policies** section above, to review the written agreement.

3. Communication to health professionals and other relevant decision makers

A package deal is a commercial arrangement. Bearing in mind the broad definition of promotion, discussions with health professionals and other relevant decision makers about package deals would likely be considered promotional and thus would need to comply with all the relevant requirements of the Code, including Clauses 8 and 12.

Companies should also consider the requirements of Clause 5.7 when communicating package deals to health professionals or other relevant decision makers. Clause 5.7 states that material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed. Material should be tailored to the audience to whom it is directed.

Detailed discussions about the potential for a package deal should be with those responsible for budget and formulary decisions in an HCO rather than individual prescribers.

Communications with individual prescribers must never misleadingly imply that their HCO has agreed to a package deal. Communication of package deals must not be misleading regarding the availability of the associated benefit.

Company personnel promoting package deals to health professionals and other relevant decision makers should be appropriately briefed. Companies should consider the requirements of Clause 17.

4. Disclosure of transfers of value related to a package deal

There are many different types of package deals. The supplementary information to Clause 19.1 includes that transfers of value made in the course of certain package deals would need to be disclosed (via Disclosure UK) in accordance with Clause 28.

Clause 1.25 exempts items for patient support covered by Clause 19.2 from the requirement to disclose transfers of value.

Clause 1.25 also exempts package deals **solely relating to ordinary course purchases** and sales of medicines from the requirement to disclose transfers of value.

a. Determining whether a package deal is an ordinary course purchase

Services and/or items provided by the company as part of a package deal that are **specific to and essential for** the appropriate use of **that particular medicine, and detailed as such in its SPC**, may be considered an ordinary course purchase. In these cases, the value of the service/item to the purchasing HCO is therefore exempt from the requirement to disclose transfers of value. Companies are reminded that the transaction as a whole must still be fair and reasonable. Any payment to a third-party HCO to provide a service will still need to be disclosed in accordance with Clause 28.

Example of a package deal that could be considered an ordinary course purchase
The use of a medicine requires a specific genetic test prior to prescription. The company offers to provide the genetic testing as part of the purchase price of the medicine. The company pays a third-party HCO to conduct the genetic tests. The genetic test required is specific to and essential for the appropriate use of that particular medicine, and detailed as such in its SPC, and thus the package deal may be considered an ordinary course purchase. Therefore, the value of the genetic testing provided by the company does not need to be disclosed against the HCOs taking up the package deal. **However, the fee paid to the third-party HCO providing the genetic testing service should be disclosed as fee for service.**

For the avoidance of doubt, it would not be a breach of the Code if the company chose to disclose against the purchasing HCO the value of a service/item in such a package deal that might be considered an ordinary course purchase. Companies should describe the approach taken in their methodological note.

Examples of package deals that would NOT be considered ordinary course purchases
Example 1 The use of a medicine requires monthly liver function tests (LFTs). The company offers to provide the monthly blood testing service as part of the purchase price of its medicine. The company pays a third-party HCO to conduct the service. While the requirement for LFTs may be detailed in the medicine's SPC and essential for the appropriate use of that medicine, such clinical monitoring is not specific to the use of that particular medicine. Therefore, this package deal would not be considered an ordinary course purchase. The value of the service provided should thus be disclosed against those HCOs taking up the package deal **(see below)**.
Example 2 The company offers to provide a homecare service as part of the purchase price of its medicine. The company pays a third-party HCO to provide the homecare. As homecare is not detailed in the medicine's SPC and not essential for the appropriate use of the medicine, this package deal would not be considered an ordinary course purchase. The value of the homecare service should thus be disclosed against those HCOs taking up the package deal **(see below)**.

b. Disclosing package deals that are not ordinary course purchases

Package deals are arrangements made with an HCO, and therefore any disclosure will likely be against an HCO.

Clause 1.25 includes that an indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.

Companies should disclose against the recipient HCO (e.g. an NHS Trust) that will ultimately benefit from the transfer of value. The company should calculate the transfer of value to each HCO that ultimately benefits.

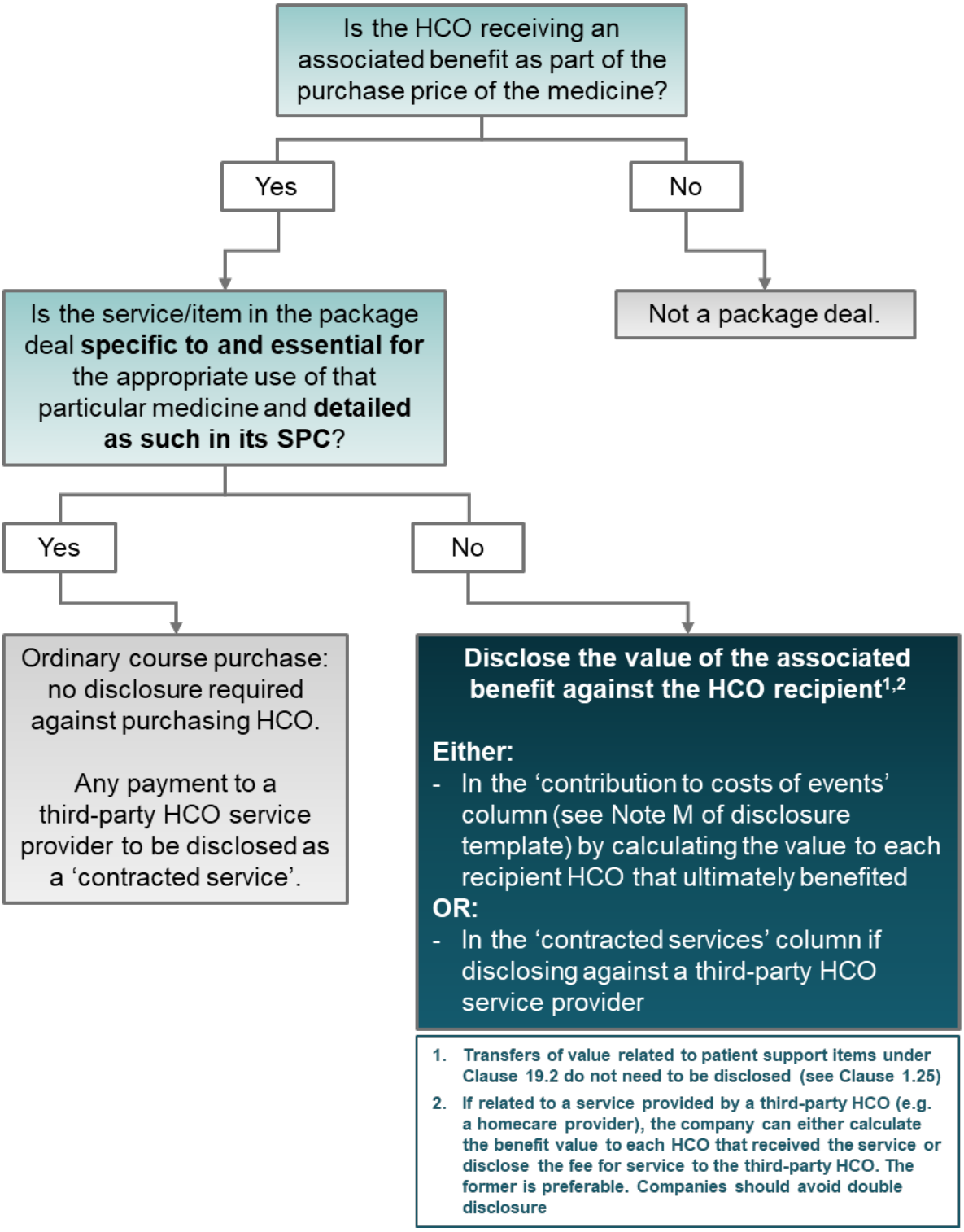
However, if the package deal relates to a service provided by a third-party HCO (e.g. a homecare provider) the company can **either** calculate the value to each recipient HCO that ultimately benefited from the service **or** disclose the fee-for-service to the third-party HCO. The former is preferable as the relationship between the pharmaceutical company and the HCO recipient benefiting from the service is likely to be of greater public interest than the relationship between the pharmaceutical company and its service provider. Companies should avoid double disclosure wherever possible. It is important that the company describes the approach it has taken for disclosing package deals in its methodological note.

c. Disclosure UK – transfers of value category

The mandatory disclosure template does not include a specific column for package deals. However, companies can use the column in the disclosure template that corresponds with NOTE M which includes that transfers of value to an HCO which cannot be disclosed elsewhere on the template (i.e. is not considered to be a donation or grant or contracted service or related to collaborative working) should be included in this column and an explanation given in the methodological note.

If the company discloses against an HCO service provider, this should be within the contracted services column of the disclosure template.

d. Flow diagram



5. Q&As

My company has historically not been following some of the recommendations in this guidance. What should we do?

This guidance document is based on the PMCPA's current interpretation of the Code and the ABPI principles of patients, integrity, transparency and respect. The PMCPA is aware from its current state analysis conducted in 2025 that there are varying longstanding practices in relation to package deals among companies, particularly in relation to disclosure of transfers of value.

The PMCPA understands that existing practices may not comply with all the requirements in this guidance document and that contracts and policies/procedures may take some time to be updated. The PMCPA does not want to prevent companies from conducting legitimate activities.

Therefore, we suggest that companies review all their ongoing package deals against this guidance as soon as possible and conduct a gap analysis and a plan of action.

If companies have not been disclosing transfers of value for package deals in line with this guidance document, they should ensure that data that is publicly available on Disclosure UK is correct by the **end of June 2027**.

How will the PMCPA enforce this guidance?

The PMCPA will not take up complaints solely because the activity is not in line with anything in this guidance that goes beyond the requirements of the 2024 Code.

However, some of this guidance may be incorporated into the next Code update and therefore companies should make best efforts to start operating in line with this guidance as soon as possible.

Given the PMCPA is already aware of the varying practices related to disclosure of transfers of value for package deals, and given disclosure of transfers of value is a Code and not a legal requirement in the UK, the PMCPA has decided not to adjudicate on complaints related to disclosure of package deals transfers of value made between now and the **end of June 2027**. We hope that companies will make full use of this amnesty period to review their disclosure of transfers of value practices against this guidance and take appropriate action to update the information on Disclosure UK that is still in the public domain.

PMCPA Guidance

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The Prescription Medicines Code of Practice Authority (PMCPA)

The Prescription Medicines Code of Practice Authority (PMCPA) was established by the Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI.

Complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports are published on the PMCPA's website: www.pmcpa.org.uk