

Package deals

Q&A slides from webinar on PMCPA
learning portal



Questions and answers

The PMCPA cannot approve any materials or activities; it can only give informal advice based on its interpretation of the ABPI Code. In the event of a complaint received about any matter referred to in the package deals guidance document or on this webinar, it would be considered in the usual way

Is it just ongoing package deals that need to comply with this guidance?

No.

Information that is publicly available on Disclosure UK from 1 July 2027 must be correct regardless of where the package deal was in its lifecycle at the time this guidance was published.

- Information that is publicly available on Disclosure UK from 1 July 2027 will include transfers of value made in 2026, 2025 and 2024.

In relation to the governance and communication sections of the guidance document, these will be most relevant to ongoing package deals. However, there may be some aspects that are relevant to package deals that have already ended, depending on the particular arrangements, and that is for companies to assess.

The guidance states there is no ToV to disclose in relation to materials. Does this apply generally to all materials whether independently or in association with a package deal?

The guidance has been written in relation to package deals and therefore it should not be extrapolated to other activities. For example, if a company were to sponsor an HCO to produce materials, the funding would be disclosed as a sponsorship ToV against the HCO.

The statement in the package deals guidance (bottom of page 3) is referring to **company produced materials** (e.g. company websites, leaflets etc.), which are not assigned a value for disclosure under the Code. However, Clause 5.5 states *“extremes of format, size or cost of material must be avoided. Informational or educational materials must be inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.”*

Are there any scenarios in which materials in a package deal might create a reportable ToV?

Materials that are available for **retail purchase** (e.g. an app produced by an independent organisation that can be purchased by the public) will have a value.

Some apps may offer a **personalised service to the user**, which may also have a value under the Code. However, some apps are just like a website containing information that is free to access.

Each case needs to be looked at individually.

If an app met the requirements of Clause 19.2, its provision by the company would not require disclosure of ToV.

Do all package deals need a written agreement?

The guidance states companies *should* have written agreements in place governing package deals.

The Code is silent on package deal written agreements in relation to the purchasing HCO, however, the PMCPA would always recommend having a written agreement in place.

If there is a service provider, the Code mandates a written agreement (see Clause 24).

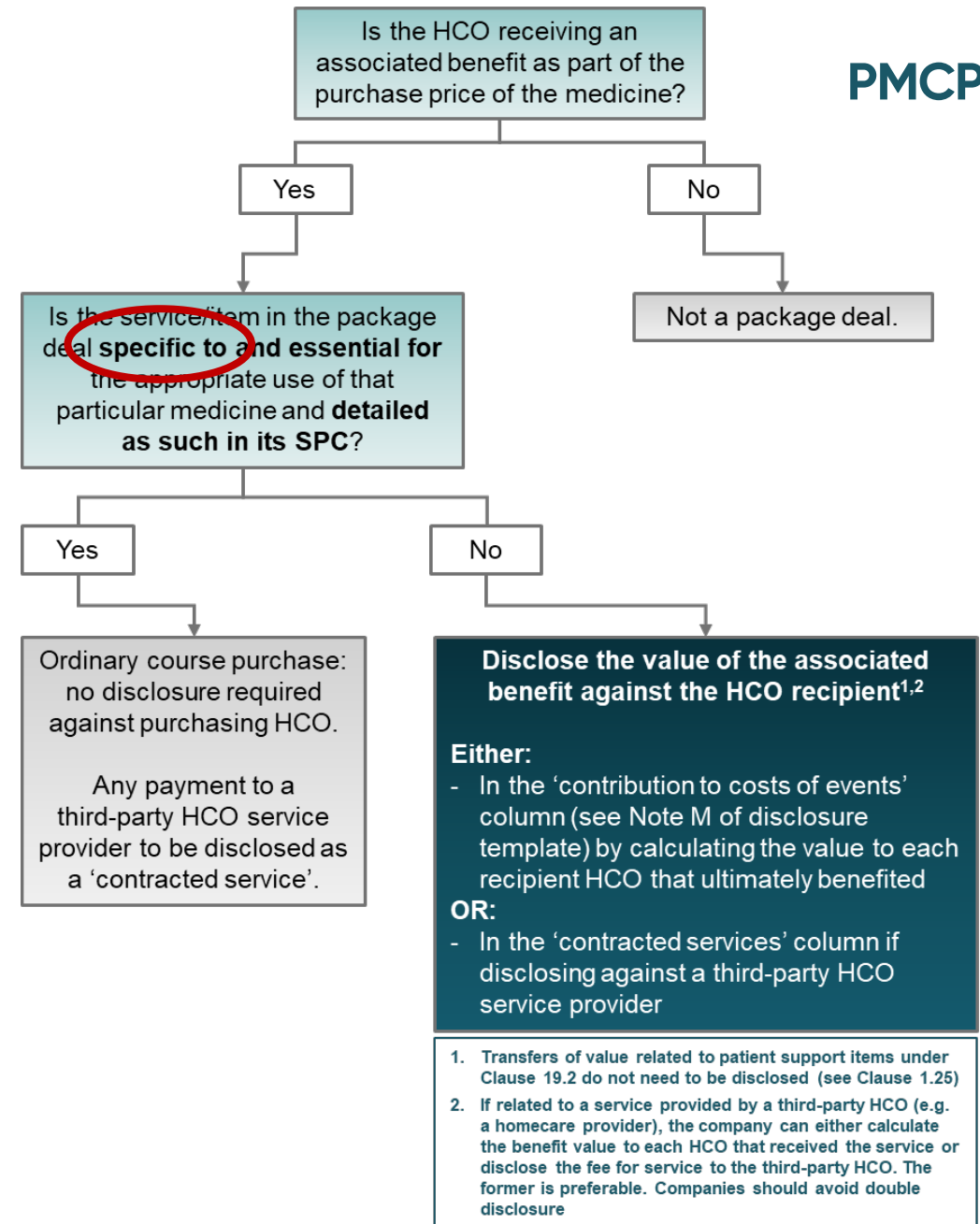
Depending on the type of package deal, there may be multiple contractual relationships.

Why does the guidance state that service provider instructions should be certified under Clause 8.3 when these are non-promotional materials for HCPs?

- The guidance states that package deals which involve the provision of services *should* follow some of the *same principles* outlined in the supplementary information to Clause 23 (donations and grants) in relation to services.
 - Internal company and service provider instructions for donations and grants **must** be certified under Clause 8.3 – it is a Code requirement.
- Internal company and service provider instructions for package deals which involve the provision of services (e.g. instructions for homecare staff) **should** be certified under Clause 8.3 – it is not a Code requirement. It was included in the package deals guidance due to the similarity in risk to donation services.
 - Certification will help ensure that important information in relation to patient confidentiality, pharmacovigilance and declaration of pharmaceutical funding is within the instructions given to service providers.
- Depending on the nature of the service being provided, there may be other certification requirements under the Code. Each activity should be assessed individually.

What is meant by ‘specific to’ for a package deal to be considered 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.
- ‘Specific to’ essentially means that the service/item being provided is *only* required for that particular medicine
- See the examples in the guidance.
- If a company is unsure, they should follow the right-hand side of the flow diagram and not treat the package deal like an ordinary course purchase. The right-hand side of the flow diagram still allows for disclosure against a third-party HCO service provider.



If an item is essential for the use of the medicine and mandated in the SPC, but the item can also be used with other medicines, should this be treated as an ordinary course purchase or a disclosable package deal?

If an item can be used with multiple different medicines, then it is **not specific** to the use of the particular medicine that the HCO is purchasing. Therefore, the provision of the item by the company as part of the purchase price of its medicine is **not an ordinary course purchase** and the value of the item should therefore be disclosed against the HCO recipient.

However, if the item is manufactured and sold by the same company as the medicine being purchased (i.e. it is the company's own proprietary item) then its provision with the medicine at no extra cost may be considered free of charge company goods – these are exempt from disclosure of ToV. However, companies cannot provide unlimited or excessive free company goods.

If an item (e.g. a piece of equipment) is essential for the use of the company's medicine, detailed in the SPC, but an HCO is only provided with one for use with multiple patients, can this be categorised as a donation?

If the company provides the item **as part of the purchase price of its medicine**, then it will be linked to the use of its medicine and **therefore cannot be considered a donation** under Clause 23. This is because donations cannot be linked to the use of a specific medicine.

Does the full value of homecare need to be disclosed as a ToV? What about delivery only services?

- Homecare is not considered an ordinary course purchase and therefore the ToV must be disclosed
- Homecare that is delivery only must still be disclosed.

Where a homecare company provides a delivery only service (no clinical services, no administration, no monitoring), would that homecare provider be considered an HCO for the purposes of transparency obligations under Clause 28?

It is for the company to assess whether the service provider meets the definition of an HCO in **Clause 1.8**.

If the pharmaceutical company does not consider that the service provider meets the definition of an HCO, then they should disclose the value of the service against the recipient HCO that benefits from the service.

- Disclosure against the recipient HCO that benefits from the service is always preferable.
- The relationship between the pharmaceutical company and the HCO benefiting from the service is likely to be of greater public interest than the relationship between the pharmaceutical company and its service provider.

For services delivered across multiple NHS Trusts, how should companies retrospectively determine which HCOs ultimately benefited? Where granular allocation is not feasible based on historical data, is it acceptable to disclose the full fee-for-service value to the third-party provider rather than allocate across individual Trusts?

If the package deal relates to a service provided to multiple HCOs, the company can disclose the total fee-for-service against the third-party HCO service provider.

- Important to remember that Clause 28.3 states that payments to HCOs are required to be disclosed on a per activity basis.

The PMCPA's preference is that companies calculate the value to each recipient HCO that ultimately benefited from the service 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.

- However, the PMCPA acknowledges that this may be difficult for historical data if the contractual relationship was not arranged to capture this detail.

Moving forwards, companies should have a contract with the HCO that purchases the package deal. Therefore, companies should be able to disclose the value of the associated benefit against the purchasing HCO rather than the third-party service provider.

Companies should use their methodological note to describe the approach taken.

What should companies do? How will the PMCPA enforce this?

- Review your package deals arrangements against the guidance as soon as possible and conduct a gap analysis and a plan of action.
- Ensure that all package deal ToV is correct on Disclosure UK by the **end of June 2027**.
- **If in doubt, disclose. Always err on the side of transparency. Describe the approach taken in the methodological note.**



Thank you

Prescription Medicines Code of Practice Authority

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