

## Methodological note for Teva UK Limited

### Update (January 2018):

When first published in June 2017, Teva UK Limited disclosed details of 2016 transfers of value – in the form of attendance at scientific meetings, consultancy fees, or related travel and accommodation – made to 650 individual healthcare professionals and other relevant decision makers who had consented to having these transactions disclosed on a named basis.

These consents were embedded into our contracts and fully complied with both the Data Protection Act 1998 and the ABPI Code. We were proud that over 96% of the individuals we worked with in this way had agreed to support the pharmaceutical industry's important new initiative on transparency.

However, in view of the forthcoming General Data Protection Regulation (GDPR), which comes into effect on 25<sup>th</sup> May 2018 and sets a new standard for the nature and form of consent, the ABPI has prompted companies to consider how they should manage risks related to historic disclosures of individual transfers of value. The options discussed included re-consenting to GDPR standards, or putting HCP details into aggregate (anonymous) reporting.

As it is not practical to obtain new consents from healthcare professionals and others that we dealt with two years ago, Teva UK Limited has now made the decision to aggregate the 2016 individual data and republish it without naming any of the healthcare professionals and decision makers.

The notes that follow are unchanged and reflect the methodology used in our original data gathering. They are still relevant to the extent applicable to aggregate reporting and to the disclosure of 2016 transfers of value to healthcare organisations (entries which are not impacted by new rules on the handling of personal data).

### **1. A general summary of the methodologies used in preparing the disclosures and identifying each category of transfer of value (TOV)**

- a) Consent to named disclosure per event or transaction has been obtained in advance of the TOV by way of contractual clauses in Teva's template agreements. Teva UK has not proactively offered any opt-out to recipients, but has managed and documented any refusal or opt-out on an *ad hoc* basis.
- b) It is noted that disclosure of subsistence is not required, however some meal provision may be included in the data (particularly where TOVs have been provided by other affiliates) in preference to understating the relevant amounts. Many accommodation-related TOVs are inclusive of breakfasts and no attempt has been made to deduct the value of breakfast provision from the sums disclosed.

- c) Over-the-counter and medical device TOVs to recipients outside the scope of the ABPI Code are not included. Any such TOVs to recipients otherwise in scope of the Code would be included in disclosure without distinguishing them from other TOVs.
- d) The terminology for various types of TOV is consistent with the meaning of those transactions as defined in the ABPI Code.
- e) Any non-monetary TOVs, and any arrangements under which a TOV has been divided between parties, have been quantified on the basis of the actual monetary cost to Teva.
- f) The aggregated figure for R&D relates to TOVs made by Teva's non-UK affiliates and entities. The figure for R&D conducted by Teva's UK entities is zero. Studies conducted by Teva's UK entities do not fall within the R&D exemption defined by the Code and therefore any such TOVs are disclosed on a named basis against the individual HCOs/HCPs.

## **2. Treatment of multi-year contracts**

- a) Where a TOV relates to activities or expenses wholly or partly occurring in a different reporting year from the deemed date of the TOV as defined in clause 5 below, no accruals will be made for disclosure purposes.
- b) Where a Joint Working initiative, MEGS project or fee for service arrangement involves staged payments or other multiple TOVs, all transfers occurring in the same reporting period will be disclosed as a single total. Separate TOVs of value for the same activity that are deemed to occur in different reporting periods will be disclosed in respect of the applicable years. No accruals will be made for disclosure purposes.

## **3. Treatment of VAT and other tax aspects**

- a) Individual and corporate recipients are liable for declaring the revenue and benefits provided to them directly or indirectly, including any payments made to employers on behalf of individuals, and for paying any income tax, corporation tax and the like arising in respect of TOVs.
- b) TOVs relating to Joint Working initiatives are where applicable disclosed exclusive of any VAT.
- c) TOVs relating to MEGS fees are where applicable disclosed exclusive of any VAT. Expenses associated with MEGS are disclosed as set out in (e) below.
- d) TOVs relating to service-related honoraria (whether for individual consultancy or corporate service providers) are where applicable disclosed exclusive of any VAT. Expenses associated with fee for service activities are disclosed as set out in (e) below.
- e) TOVs relating to hospitality and expenses (including meeting registration fees, accommodation and travel) are declared gross (e.g. ticket face value) and therefore include VAT where applicable.

## **4. Currency aspects**

- a) All disclosed TOVs are expressed in GBP.
- b) Any payments remitted or costs incurred in another currency have been converted into GBP by applying the exchange rate for the month that is deemed to be the date of the TOV (see below), in accordance with the rate tables published online by HMRC at <https://www.gov.uk/government/collections/exchange-rates-for-customs-and-vat#monthly-rates>

## 5. Other issues relating to the timing and amount of transfers of value

When determining whether a TOV falls into the 2016 reporting year, the deemed date of transfer of value to the recipient for each category of TOV has as far as possible been defined by Teva UK as follows, irrespective of the actual date of remittance:

<b>The date on which funds were due under the contract</b>
<ul style="list-style-type: none"><li>• Joint working initiatives</li><li>• MEGS fees</li></ul>
<b>The date on which services were provided to Teva*</b>
<ul style="list-style-type: none"><li>• Fee for service honoraria/fees (individuals or organisations)</li></ul> <p>*Where billable preparation time is incurred and/or a follow up report or meeting is part of the service, the service date for the purposes of TOV is defined as the start date of the principal meeting.</p>
<b>The start date of the relevant trip/event</b>
<ul style="list-style-type: none"><li>• MEGS expenses</li><li>• Sponsorship of individuals' registration fees, accommodation and travel</li><li>• Accommodation and travel related to service provision</li></ul>