

Methodological Note for Reporting Period 2019

In collecting and preparing the information to be used in the submission of transfers of value to Health Care Professionals (HCP's) and Health Care Organisations (HCO's), Blue Earth Diagnostics Ltd set up the following processes in order to ensure a robust and accurate system was used.

Consent:

- For each activity, consent is requested at the inception of a HCP agreeing to provide services for the organisation or accepting sponsorship. This consent form is stored electronically on a password protected network to ensure data protection is maintained whilst allowing review of records if required in future.
- Should a HCP provide consent for one activity but decline consent for another, all interactions will be included in the aggregate value. No partial disclosures will be made.
- All transfers of value with no consent to disclose are included in the aggregate value for the organisation.
- Consent is not required from HCOs and all Transfers of Value (ToVs) to HCOs will be disclosed.

Collation of data:

- Through the process of recording and authorising the relevant activities with HCP's or HCO's, consent is or is not obtained as above. Once all relevant activities have taken place, expense claims are processed onto the in-house accounting system.
- A specialised internal coding and allocation process is used to ensure that all data are collated for reporting purposes in an appropriate manner and to aid the visibility of all records for audit purposes.
- Should third party membership associations have utilised the service of HCP's, a disclosure has been made based on the appropriate allocated proportion of total costs incurred split by total number of members in association.
- Where a third party arranged for HCP's to travel to educational events and a separate breakdown is unavailable for each individual, a proportion of the total expenditure has been allocated to the HCP this has been disclosed or not depending on the HCP's request for disclosure response.
- ToVs related to the planning or conduct of non-clinical studies, clinical trials and non-interventional studies that are prospective in nature are considered Research & Development ToVs and are reported on an aggregate basis. Retrospective non-interventional studies or other studies that are not submitted to authorities as per local drug law do not fall under the category of R&D activities.

Reporting Disclosure:

- Through a process of reviewing all internal code allocations, and specific in house financial codes, a detailed data download is performed for all payments made to HCP's and HCO's during the calendar year.
- This data set is then analysed and reviewed for accuracy and completeness and amalgamated into the relevant sections for disclosure on the ABPI portal.
- The individual HCP data set is reviewed and agreed by the relevant HCP prior to submission.

Points to note in relation to the values declared:

- All payments to HCOs and HCPs are made in full to the recipients. It is the responsibility of the recipients to declare payments to HMRC for tax purposes. All payments are made inclusive of VAT (where relevant).
- Any expenses received in a foreign currency have been converted at the rate of exchange ruling on the date shown on the expense claim.
- Blue Earth Diagnostics Ltd does not work jointly with other pharmaceutical companies and therefore all declarations made for transfer of value are solely for Blue Earth Diagnostics Ltd.