

Bial Pharma UK Ltd

1) Introduction

BIAL Pharma UK Ltd was established in the UK in May 2016. The company is a wholly owned subsidiary of Bial Portela & C^a., S.A; a Portugal Headquartered Pharmaceutical company.

This disclosure submission relates solely to the UK operation of BIAL Pharma UK Ltd.

EFPIA states that the collaboration between the pharmaceutical industry and Healthcare Professionals / organisations benefits patients. Collaborative working has been a driver for advancements in patient care and helps the progression of innovative medicine.

HCP's and HCO's are fairly compensated for the legitimate expertise and services that they provide to the industry. We acknowledge that such transactions should be transparent.

This methodological note describes the methods used by BIAL to meet the obligations for disclosing the Transfers of Value (ToV) made to HCPs and HCOs under the EFPIA disclosure code.

2) Definitions

Transfer of Value

The definition of Transfer of Value means a direct or indirect payment made, whether for promotional purposes or otherwise, in connection with development of sale of medicines.

ToV can be made to an HCP directly, for e.g. honorarium for speaker activities at a Bial organised meeting. This ToV is disclosed within the HCP section of the submission.

ToV can also be considered indirectly i.e. any 3rd party working on behalf of Bial, in which case this would be disclosed within the HCO section of the submission.

Healthcare Professionals

Healthcare Professional (HCP) HCP's include members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their activities may administer, prescribe, purchase, recommend or supply a medicine.

Health care Organisations

HCO means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HCPs or other relevant decision makers provide services.

Other Relevant Decision Maker

(ORDM) ORDMs particularly include those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not HCPs.

3) ABPI code requirements

The ABPI has translated the requirements of the EFPIA disclosure code in the ABPI code of practice which states that the ToV which are declarable are:

- a) Joint working
- b) Donations, grants and benefits in kind provided to institutions, organisations and associations
- c) Contracts between companies and institutions, organisations, and associations
- d) Sponsorship of attendance by health professionals and other relevant decision makers at meetings
- e) Fees and expenses paid to health professionals and other relevant decision makers, or to their employers on their behalf
- f) Contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of health professionals by way of registration fees and accommodation and travel.

4) Scope

BIAL understands that certain ToV are not covered by the EFPIA and the ABPI code therefore BIAL does not disclose such ToV.

Food & Drink costs are excluded from ToV disclosure in respect of sponsored meetings unless BIAL have specifically contributed towards subsistence as part of sponsorship. This will then be disclosed in the ToV.

5) Consent

BIAL Pharma has obtained consent from HCPs on an individual basis. Consent is collected on contracts and other supporting documents on an event by event basis.

In 2021, Bial Pharma UK Ltd have not considered legitimate interest as a basis for disclosure.

Where an HCP has expressly requested that their name is not disclosed, BIAL Pharma UK Ltd have respected that decision, and consolidated those amounts into an aggregated transfer of value, indicating the No of HCPs captured in this manner.

The workplace addresses for the Healthcare Professionals has come from our inhouse CRM database, which is provided & Maintained by IQVIA, using the OneKey healthcare industry database (<https://www.onekeydata.com/onkey/overview>)

6) Cross-border activities

BIAL Pharma UK Ltd has implemented internal processes and procedures to ensure that all activities are managed in compliance with any global and local regulations. All cross-border activities where other BIAL entities have engaged a UK HCP/HCO or ORDM are included in the UK Disclosure report.

7) Research & Development

BIAL Pharma UK Ltd have captured the total value of 2021 Research and Development spend, in the indicated section of the disclosure template. The transfer of value for R&D will include BIAL commissioned research held in the UK.

Any transfer of value cost associated with investigator-initiated studies, supported by BIAL Pharma UK Ltd, have been captured under the requesting HCO.

8) Finance

VAT:

No healthcare professionals contracted or receiving transfer of value in this period have indicated they are VAT registered, therefore in this submission VAT has not been applied

TAX:

All healthcare professionals have received indicated transfer of value, with the understanding those healthcare professionals will manage any due taxation themselves.

Exchange Rates:

If transfer of value was received in Euros, this has been converted the £ Sterling using the prevailing rate at the time of payment. No other applicable financial considerations needed to be addressed in this submission.



Jason Stone

Country Manager

BIAL Pharma UK Ltd

29th March 2022