

Almirall Ltd Disclosure 2021 Methodological Note – March 2022



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1. Introduction

At Almirall we are committed to transparency in our dealings with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to instill trust and transparency, and comply with the ABPI Code of Practice requirements for the disclosure of relevant transfers of value (ToVs).

We believe that transparency is key to building and maintaining confidence and trust in us, and in our medicines. We fully endorse and support the efforts of the ABPI in improving transparency across the pharmaceutical industry.

During 2021 the impact of Covid 19 continued to disrupt our industry as well as place significant strain on the NHS, and this impacted how we engaged with our stakeholders such as HCPs and HCOs. Due to the constraints related to face to face interactions, we initiated a reduced volume of engagement activities which in turn translated in fewer engagements with HCPs and HCOs as compared to prepandemic years.

The ToVs in this report covers all the disclosable payments, to the best of our knowledge, made by Almirall in the UK for the 2021 calendar year.

2. Disclosure Methodology

During 2021, we continued to operate on a consent model basis for disclosure, in compliance with the GDPR consent provisions. ToVs to HCPs have been disclosed against the individual HCP only where the data subject consented for individual disclosure basis. Where consent has not been provided, such ToVs have been disclosed under the aggregate category.

During 2021, we revised our approach to how consent for disclosure is collected from HCPs, as a result we have seen an improvement in our overall individual disclosure rate. We are committed to continually improving in this area and by doing so being able to disclose a higher proportion of ToVs on an individual basis.

The change in consent model took place as of 1st July 2021. Where an HCP has consented to some but not all ToVs being disclosed on an individual basis, all ToVs for the 2021 reporting period have been added to the aggregate category.

ToVs made to UK HCPs, ORDMs or HCOs by Almirall Head Office (Spain) and/or other affiliates have been reported to Almirall Ltd and have been disclosed as required.

ToVs to HCPs conducting business through a limited company have been disclosed against the HCP.

Data was checked for accuracy to the best of our knowledge before publication.

Disclosure of Research and Development Transfers of Value:

Costs that are subsidiary to these activities are included in the aggregate R&D category.

Almirall discloses payments agreed with universities and research centres for pre-clinical research as well as clinical trial agreements in hospitals (either direct payments or through a third-party), fees of independent professionals to provide research and development services, and investigator's meeting expenses.

We do not disclose the payments made to companies providing services for research and development (CROs).

Fees related to retrospective study work have been disclosed under service contracts with HCPs in accordance with their consent type.

3. Categories of Transfers of Value

Disclosures for HCPs includes fees for service (including retrospective studies), travel, accommodation, and registration for third party meetings.

Disclosure for HCOs includes fees for service, sponsorships, and any grants/donation payments.

Almirall Ltd provides grants & donations to certain Patient Organisations in accordance with what is permitted under the Code. Such ToVs made to Patient Organisations will be disclosed by June 2022 and will be available on the Almirall UK website.

Almirall Ltd has not provided any benefits in kind in 2021 to HCPs, ORDMs and HCOs during 2021.

4. Disclosure Scope

Almirall Ltd promotes Prescription Only Medicines (POM) as well as products that are registered as Over the Counter (OTC) Products and / or Medical Devices. Almirall Ltd does not believe these products fall into

the excluded disclosure category and as such we have made disclosures against all ToVs for all products irrespective of their registered category.

Free stock of General Sale List (GSL) products are not included within scope for disclosure.

<u>Note:</u> Whilst Medical Devices do not generally fall into the scope of ABPI Code of Practice, Almirall Ltd has made the decision to disclose ToVs made for such products in line with the ABPI Code of Practice if / where these products can be both promoted and prescribed. For 2021 we had no medical devices related disclosures to make.

HCPs working for Almirall Ltd as employees (full or part time), contracting consultant staff, are not included in the disclosure data, as all such individual's primary occupation is not that of a practicing health professional.

5. Specific Considerations

ToVs in case of partial attendances or cancellation: There were no cases of partial attendance and therefore these have not been reported in the 2021 disclosure. ToVs that did not ultimately take place or were cancelled are not disclosed as no benefit was received by the HCP, ORDM or HCO.

Cross-border Activities: Where Almirall Global or any other Almirall affiliate provide a ToV to a UK HCP, ORDM or HCO; the respective Almirall entity obtains consent and records the ToV in the Almirall UK CRM system.

Country Unique Identifier: Almirall Ltd aims to maintain an up to date contact database which allows HCPs & ORDMs to have more than one practicing address associated with them, for example when an HCP works at different centres / hospitals etc. For the purposes of disclosure, the database utilised only recognises one address - the principle practice address.

ToVs to forums, networks etc.: Those that have no associated principle practice address have been disclosed using the address of the lead HCP or ORDM etc. for the purposes of disclosure.

Multi-year Contracts: Where agreements, sponsorships, and the like fall into more than one year, these are disclosed when any activity is performed, hence payment will be split over several years.

Compassionate Use: Almirall Ltd does not disclose a ToV for any medicines provided on request to HCPs for individual patients which come under 'Compassionate Use Supply'.

Home address: In cases where the HCP has a home address as their place of work, such ToVs have been disclosed in aggregate in an effort to protect the individual's privacy.

6. Consent Management

Consent collection: In the spirit of transparency and in compliance with GDPR requirements Almirall Ltd has provided each HCP the opportunity to confirm their consent type (individual or aggregate). As of July 2021, Almirall Ltd operates a 'universal consent model' which means HCPs provide their consent once and this is applied to all engagement following the provision of that consent. HCPs have the option to revise their consent type at any time by emailing Almirall directly. HCPs who have provided aggregate consent between July and Dec 2021, were contacted in Jan 2022 to offer them the opportunity to revise their consent type. This reflects Almirall's commitment to disclosing ToVs on an individual basis wherever possible.

Management of recipient data/consent withdrawal: The consent management system enables amendment from individual to aggregate or vice versa and consents are changed manually in the database. This is done via an email inbox specified in the consent form/agreement (tovconsentuk@almirall.com). If an HCP / ORDM requests clarification or changes to the disclosed data or consent status Almirall Ltd will

act on the request as appropriate, replying to the HCP / ORDM with the clarification requested or that the change has been implemented. The email from the HCP will serve as evidence of withdrawal / change of consent. Disputes on the value of the ToV disclosed will be resolved as quickly as possible and the disclosed data amended where possible and required.

Partial Consent: Pre / post July 2021 Almirall Ltd collected consent on a per-activity basis and as of July 2021 Almirall Ltd moved to a universal consent model (i.e., one time consent that covers all future engagements until consent is revoked).

Due to the change in consent model, we found that in some cases there was a difference in the consent type from the same HCP pre-post July 2021. Where recipients of ToVs decided to disclose on an individual basis in some activities and aggregate in others, the amount attributable to all ToVs is disclosed on an aggregate basis.

We expect that as of 2022 due to a consistent consent model operating throughout the calendar year, the issue of partial consent will cease.

7. Financial Information

Currency: All disclosed ToV data is reported in GBP. Where a ToV has been provided by Almirall Ltd or a third-party from outside the UK such ToVs are provided in the local currency and converted to GBP using the exchange rate of the payment date.

VAT: VAT is included in the disclosure data, where it applies due to country or event requirements.

Invoice payment date: All ToVs taking place in 2021 are disclosed to the best of our knowledge (any data relating to 2021 which was available up to 17th March 2022 was included in this report). For pending invoices related to events that took place during 2021, all invoices paid up to 17th March 2022 have been included in the 2021 disclosure.

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