

EFPIA Disclosure Code

2019 Disclosures

Shire Pharmaceuticals (now a
part of Takeda)

Section 1: Reporting Approach for 2019 Data:

In January 2019, Takeda acquired Shire. In accordance with guidance from the EFPIA Board, Shire will plan to disclose their 2019 ToVs in 2020, separately from Takeda, and then as one Takeda entity starting with the disclosure period of 2020 in 2021, unless local laws or regulations requires otherwise. Shire and Takeda are also working towards harmonizing their separate methodologies.

Statement for the disclosure of 2019 data during the COVID-19 pandemic in 2020

As part of the pharmaceutical industry's annual disclosure of transfers of value to HCPs, ORDMs and HCOs via the Disclosure UK platform and in order to ensure accuracy of the published data, the ABPI writes to all of the HCPs, ORDMs and HCOs named in companies' disclosure data ahead of its publication on Disclosure UK at the end of June. (Over 20,000 in June 2019.)

Given the unprecedented pressure on the NHS and health care professionals in responding to the COVID-19 pandemic, in April 2020 the ABPI and PMCPA agreed that it would not be appropriate for industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would add additional work for NHS professionals at this time. To avoid this, and in-line with guidance provided by the ABPI, Shire's 2019 transfer of value data has been published on Disclosure UK in aggregate.

Commitment to transparency

The pharmaceutical industry is committed to preserving the integrity of Disclosure UK and transparency in our interactions with HCPs, ORDMs and HCOs. The ABPI continues to explore how the full disaggregated 2019 data can be submitted to Disclosure UK in line with data from previous years.

Section 2: Scope of Disclosure:

The following EFPIA member countries are in scope for disclosure:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

Per EFPIA, the following countries have a **full or partial** exception to the Disclosure Code:

1. Belgium
2. Denmark
3. France
4. Netherlands
5. Portugal
6. Romania

- 7. Slovakia
- 8. Turkey

Iceland and Luxembourg are not formal member countries of EFPIA but are voluntarily implementing the HCP Disclosure Code.

Shire will publish data based on the local country Code template. If no template is provided by the local country, then Shire will default to the EFPIA Disclosure Code template.

Shire will publish R&D data for the Netherlands, Romania, and Slovakia in the EFPIA Disclosure template as these are not reportable under local law/code reporting.

Section 3: Decisions in Methodology:

Below captures the decisions that drive our collection, aggregation and reporting process:

Decision Point	Shire's Approach
Tax & VAT	<p>In general, Shire excludes Tax and VAT for Monetary payments/transfers of value (TOVs) and includes Tax and VAT for In Kind TOVs (except DBS or WBK donations). VAT is excluded for all R&D TOVs. Exceptions to this methodology are as follows:</p> <p>Austria: VAT is excluded for all TOVs.</p> <p>Belgium: VAT is excluded for all TOVs.</p> <p>Czech Republic and Russia: Sponsorship TOVs include VAT.</p> <p>Norway/Netherlands: Donations, Grants, Research and Sponsorship TOVs include VAT.</p> <p>Poland: For honorarium associated with services and consultancy, Shire will report the full invoice amount including withholding (personal income) tax. VAT is excluded for other Monetary payments and included for the majority of In Kind TOVs.</p> <p>Russia/Ukraine: For honorarium associated with services and consultancy, Shire will report the full invoice amount including withholding (personal income) tax. For In Kind costs related to Events (such as registration fees, travel and accommodation), Shire will report the full invoice amount including VAT.</p> <p>Spain: For honorarium associated with services and consultancy, Shire will report the full invoice amount including withholding (personal income) tax. VAT is excluded for all other payments.</p>

<p>Transfer of Value Dates</p>	<p>Shire used the payment date for monetary payments/TOVs for activities within the reporting period and applied the event date for In Kind TOVs (except DBS or WBK donations).</p> <p>For contracts with services that span multiple periods, Shire used the date of payment as the TOV date.</p> <p>For Italy, Greece and Belgium, based on guidance from the local association, Shire used payment date for all TOVs.</p>
<p>Disclosure Currency</p>	<p>All payments and TOVs will be disclosed in local currency per guidance from EFPIA, with the exception of Ukraine which is disclosed in EUR. If a payment is captured in another currency, it will be converted into local country currency based on the date at which the TOV occurred and corresponding daily exchange rate.</p>
<p>Reconciliation of the Data</p>	<p>On an annual basis, Shire will complete a full year reconciliation to identify any transactions that were submitted post data validation or post publication and update the reports accordingly to support the principles of full transparency.</p>
<p>Cancellation of events or contracts including when an HCP does not participate</p>	<p>Shire will only attribute the TOVs that are incurred and can be reasonably associated to the HCP based on supporting documentation. In the circumstances when a flight or accommodation is booked but the event is cancelled or HCP does not attend, no TOV will be attributed to that HCP.</p>
<p>Disclosure of Cross-Border TOVs</p>	<p>Shire will disclose based on the <u>principal practice</u> address of the recipient, regardless of where payment is made.</p> <p>Shire relies on IQVIA (previously IMS Health & Quintiles) as a recognized industry leader in data management to determine the principal practice address of the Healthcare Professional (HCP) and Healthcare Organisation (HCO) to be consistent across the EFPIA countries. <i>This may not match with the address collected on the contract, in our finance system of payment or in our other supporting documentation.</i></p>
<p>Disclosure Language</p>	<p>All disclosures will be made available in English and in the language(s) prescribed in the national codes.</p>
<p>Disclosure of Local Identifiers</p>	<p>To support the principles of privacy, Shire will disclose the “Country Unique Identifier” for HCPs and/or HCOs where this is required based on the local code.</p>

Payment made to Institution for the benefit of HCPs	<p>Shire decided:</p> <ol style="list-style-type: none"> 1. If a payment was made to an HCO for the benefit of HCPs and the identity of the HCP was attainable, Shire disclosed only once, and on an individual basis against the relevant HCPs and obtained the appropriate consent. 2. If a payment was made to the HCO and the identity of the HCP was unknown; Shire disclosed the TOV against the HCO.
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Section 4: Consent Management:

Shire is collecting consent for individual disclosures for each engagement with an HCP (and HCOs where applicable) based on local requirements.

These are the decisions made to avoid the “cherry picking” of transactions for individual disclosure:

- If consent is given for all engagements, by an HCP, Shire will disclose TOVs to the HCP under the individual section of the applicable Disclosure report.
- If Shire does not receive consent for all engagements, from an HCP, we will default all TOVs, to the HCP, to the aggregate section of the applicable Disclosure report.
- If the consent form is not returned to Shire, by an HCP, we will default all TOVs, to the HCP, to the aggregate section of the applicable Disclosure report.

These are the decisions made for the revoking of individual consent:

- If an HCP or HCO revokes consent prior to publication of the data, Shire will update the data and include the TOVs, to the HCP, in the aggregate section of the applicable Disclosure report.
- If an HCP or HCO revokes consent after publication of the data, Shire will update the information retrospectively or prospectively based on local requirements at the first reasonable time.

Other Considerations:

For Greece, in accordance with Opinion n. 5/2016 of the Hellenic Data Protection Authority (HDPa) regarding the processing of personal data relating to HCPs, TOVs are disclosed on an aggregate basis irrespective on actual consent status.

Section 5: Submission Approach for 2019 Data:

<p>The Disclosure Method for 2019 Data</p>	<p>A. Shire will publish the disclosure file on our Takeda.com website for the following countries:</p> <p>Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands (R&D), Norway, Poland, Romania (R&D), Russia, Serbia, Slovakia (R&D), Slovenia, Switzerland and Ukraine</p> <p>B. Shire will publish a link and/or the report on the local Shire website for the following countries:</p> <p>Italy and Spain</p> <p>C. Shire will publish on the central registry for the following countries:</p> <p>Belgium, Ireland, Sweden, UK and Czech Republic</p>
<p>The Timing of Disclosures for 2019 Data</p>	<p>Shire will publish data for the prior period on or before June 30 unless the local Association sets a specific date.</p> <p>Other dates include:</p> <p>A. The UK will be submitted by March 30 B. Baltics and Nordics will be published by June 1 C. Belgium Sunshine will be published by May 31</p>
<p>Disclosure Period</p>	<p>Each reporting period shall cover a full calendar year of the prior year.</p>
<p>Public Disclosure and Retention Period</p>	<p>Per the guidance from EFPIA, Shire will ensure that the information disclosed shall be required to remain in the public domain for a minimum of 3 years or longer after such information is disclosed in accordance with the disclosure method unless, in each case:</p> <ul style="list-style-type: none"> ▪ A shorter or longer period is required under applicable national data privacy or other laws or regulations; or ▪ The recipient’s consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. (Section 2.02)

Documentation and Records Retention	Per the guidance from EFPIA, Shire will ensure that all the TOVs required to be disclosed must be documented and retained for a minimum of 5 years or longer after the end of the relevant reporting period, unless a shorter or longer period is required under applicable national data privacy or other laws or regulations. (Section 2.07)
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Section 6: Categories for Disclosure as Defined within the Code:

Description	Types of TOV Included Per Shire interpretation
Donations and Grants to Healthcare Organisations	<p>Donations and Grants to HCO’s that support healthcare including donations, grants and benefits In Kind to institutions, organizations or associations that are comprised of HCP’s and/or that provide healthcare.</p> <p>Donation of diagnostic testing services either in the form of Blood Sample Collection Kits (e.g. Dry Blood Spot Kits) or Whole Blood Testing for rare diseases including costs of testing kits, management and delivery of kits to HCOs are disclosed in the Donations & Grants spend category.</p>
Contribution to costs of Events: Sponsorship agreements	<p>Events include all scientific professional meetings, congresses, conferences, symposia and other similar events.</p> <p>Sponsorships with HCOs/third party appointed by an HCO to manage an Event (for example, PCO).</p> <p>Registrations fees related to attending a Congress or Symposia paid to an HCO on behalf of an HCP disclosed on an individual basis (in the name of the HCO).</p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Rental of booth space at an event • Advertisement space • Satellite symposia at a Congress • Sponsoring of speakers/faculty
Contribution to cost of Events: Registration Fees	Registrations fees related to an HCP attending a Congress or Symposia.

<p>Contribution to costs of Events: Travel & Accommodation</p>	<ol style="list-style-type: none"> 1. Travel expenses related to attending a Congress or Symposia. 2. Accommodation expenses related to attending a Congress or Symposia. <p><u>Example:</u></p> <ul style="list-style-type: none"> • Fees for airfare, train, boat or ferry (incl. booking fees) • Car rental, car services, taxi transfers • Parking fees • Gas/Petrol costs • Road tolls or fees • Hotel Lodging
<p>Fee for service and consultancy: Fees</p>	<p>TOVs resulting from or related to contracts between Shire and institutions, organisations, associations or HCPs under which such institutions, organisation, association or HCPs provide any type of services to Shire or any other type of funding not covered in the previous categories.</p> <p>TOVs related to R&D related activities but when they do not follow within the definition of R&D TOVs as defined by EFPIA are disclosed under this category.</p> <p><u>Examples include:</u></p> <ul style="list-style-type: none"> • Speaker fees • Speaker training • Data analysis • Development of education materials • General Consulting/Advising • Shire initiated Non-Interventional Studies (Retrospective)
<p>Research & Development (to be published in the aggregate section of the disclosure template)</p>	<p>R&D TOVs to HCPs/HCOs associated with:</p> <ul style="list-style-type: none"> • Shire initiated Non-clinical (Good Laboratory Practice (GLP)) • Shire initiated Clinical trials in Phase I to Phase IV (Interventional and Non-Interventional Prospective) • Investigator initiated and sponsored Studies • Collaborative initiated Research studies

Section 7: Other Definitions:

<p>Blood Sample Collection Kit</p>	<p>Any type of material, device or kit used to collect biological samples (e.g. Blood, plasma, etc.) for the purpose to collect, store and transport the biological material necessary for the performance of a diagnostic test.</p>
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<p>Dry Blood Spot Kits (DBS Kits)</p>	<p>Dry blood spot collection kits used for the collection of blood samples needed for testing for LSDs and other diseases. Dry blood spot kits are classified as an in-vitro diagnostic medical device.</p>
<p>Professional Congress Organizer (PCO)</p>	<p>A company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events. Commercial companies involved in the organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered PCOs.</p>
<p>Transfers of Value</p>	<p>Direct and indirect transfers of value, whether in cash (Monetary), In Kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use.</p> <p>HOW</p> <ul style="list-style-type: none"> • <u>Direct transfers of value</u> - are those made directly by Shire to, and for the benefit of an HCP/HCO/Third Party Intermediary (where identity of HCP/HCO cannot be identified) Recipient. • <u>Indirect transfers of value</u> - are those made through an intermediary (Third Party/PCO) on behalf of Shire for the benefit of an HCP/HCO Recipient, where the identity of Shire is known to or can be identified by the Recipient and where Shire can identify the HCP/HCO that benefits from the TOV. (For example, single-blinded or double-blinded market research are excluded). <p>WHAT</p> <ul style="list-style-type: none"> • <u>In Kind</u> – DBS or WBK Donations, Lodging, Transportation, Registration Fees and Meals (where applicable) • <u>Monetary</u> – Grant, Sponsorship, Donation, Research and Fee for Service payments
<p>Whole Blood Kit (WBK) Testing</p>	<p>Testing service provided by Shire for testing of rare diseases using whole blood samples.</p>