

EFPIA Disclosure Code
2016 Disclosures
Shire Pharmaceuticals
(including Baxalta US Inc.)

Section 1: Reporting Approach for 2016 Data:

On June 3rd, 2016, Shire acquired Baxalta. Due to the complexity of integration between the two companies, Shire has made the decision to disclose as two separate entities for the disclosure period of 2016.

As such, Shire would like to highlight the key differences in methodology between the two companies.

Shire will disclose based on a consistent methodology where possible for data collected in 2017 and published in 2018.

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, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine and the United Kingdom.

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

1. Denmark
2. France
3. Netherlands
4. Portugal
5. Slovakia
6. Turkey

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.

Section 3: Key Decisions & Differences in Methodology:

Below captures the decisions that drive our collection, aggregation and reporting process and identifies where there are differences between Shire and Baxalta for 2016 data:

Decision Point	Shire's Approach	Baxalta's Approach
Tax & VAT	Austria: VAT is excluded for direct payments and included for in kind transfers of value. Belgium: VAT is excluded for direct payments including sponsorships and	Austria: VAT is excluded. Belgium: VAT is excluded for honorarium associated with consultancy payments and sponsorships and included for in kind

<p>included for in kind transfers of value.</p> <p>Bulgaria: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Croatia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Cyprus: Follows local guidance.</p> <p>Czech Republic: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Estonia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Finland: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Germany: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Greece: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Hungary: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Iceland: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Ireland: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Italy: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Latvia: VAT is excluded for direct payments and included for in kind</p>	<p>transfers of value.</p> <p>Bulgaria: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Croatia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Czech Republic: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Estonia: VAT is included.</p> <p>Finland: VAT is excluded.</p> <p>Germany: VAT is excluded.</p> <p>Greece: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Hungary: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Ireland: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Italy: VAT is excluded for direct payments and included for in kind transfers of value. VAT is included for transfers of value not approved by Italian Medicines Agency (AIFA).</p> <p>Lithuania: VAT is included.</p> <p>The Netherlands: VAT is excluded for direct payments including sponsorships and included for in kind transfers of value.</p> <p>Norway: VAT is excluded.</p> <p>Poland: VAT is excluded for direct payments and included for in kind transfers of value excepting for</p>
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<p>transfers of value.</p> <p>Lithuania: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Luxembourg: VAT is excluded for direct payments including sponsorships and included for in kind transfers of value.</p> <p>Malta: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>The Netherlands: VAT is excluded for direct payments including sponsorships and included for in kind transfers of value.</p> <p>Norway: VAT is excluded for direct payments and included for in kind transfers of value.</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 direct payments and included for the majority of in kind transfers of value.</p> <p>Romania: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Russia: For honorarium associated with services and consultancy, Shire will report the full invoice amount including withholding (personal income) tax. For costs related to Events (such as registration fees, travel and accommodation), Shire will report the full invoice amount including VAT.</p> <p>Serbia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Slovakia: VAT is excluded for direct</p>	<p>Registration Fees.</p> <p>Romania: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Serbia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Slovakia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Slovenia: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Spain: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Sweden: VAT is excluded.</p> <p>Switzerland: VAT is excluded.</p> <p>Ukraine: For services and Consultancy, VAT is excluded unless local Code or Law explicitly requires otherwise. For costs related to Events (such as registration fees, travel and accommodation), VAT is included. Where there is a withholding tax, Shire will report the full invoice amount.</p> <p>United Kingdom: VAT is excluded for direct payments and included for in kind transfers of value.</p>
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	<p>payments and included for in kind transfers of value.</p> <p>Slovenia: VAT is excluded for direct payments and included for in kind transfers of value.</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>Sweden: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Switzerland: VAT is excluded for direct payments and included for in kind transfers of value.</p> <p>Ukraine: For honorarium associated with services and consultancy, Shire will report the full invoice amount including withholding (personal income) tax. For costs related to Events (such as registration fees, travel and accommodation), Shire will report the full invoice amount including VAT.</p> <p>United Kingdom: VAT is excluded for direct payments and included for in kind transfers of value.</p>	
<p>Disclosure Currency</p>	<p>All payments and transfers of value will be disclosed in local currency per guidance from EFPIA with the exception of Ukraine which is reported in Euros. If a payment is captured in another currency, it will be converted into local country currency based on the date at which the transfer of value occurred and corresponding daily exchange rate.</p>	<p>No difference.</p>
<p>Transfer of</p>	<p>Shire used the payment date for direct</p>	<p>Baxalta used the payment date for</p>

Value Dates	<p>Fee For Service and other payments for activities within the reporting period and applied the event date for all other transfers of values like Travel & Lodging.</p> <p>For contracts with services that span multiple periods, Shire used the date of payment as the transfer of value date.</p> <p>For Italy, based on guidance from the local association, Shire used payment date for all transfers of value.</p>	<p>direct Fee For Service and other payments for activities within the reporting period and applied the event date for all other transfers of value like Travel & Lodging.</p> <p>For a minority of reportable transactions, where event dates were not available, the payment date has been applied for transfers of value like Travel & Lodging.</p> <p>For contracts with services that span multiple periods, Baxalta used the date of payment as the transfer of value date.</p>
Reconciliation of the Data	<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>As Baxalta is now part of Shire, all transfers of value for the 2016 reporting period will be part of the annual reconciliation of data process.</p>
Cancellation of events or contracts including when a HCP does not participate	<p>Shire will only attribute the transfers of value 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 transfer of value will be attributed to that HCP.</p>	<p>No difference.</p>
Disclosure of Cross-Border Transfers of Value	<p>Shire will disclose based on the <u>principal practice</u> address of the recipient.</p> <p>Shire relies on IMS as a recognized industry leader in data management to determine the principal practice address of the HCP and HCO to be consistent across the EFPIA countries. <i>This may not match with the address</i></p>	<p>No difference.</p>

	<i>collected on the contract, in our finance system of payment or in our other supporting documentation.</i>	
Disclosure Language	All disclosures will be made available in English on our public website (Shire.com) but primarily made in the language(s) prescribed in the national codes.	No difference.
Disclosure of Local Identifiers	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.	No difference.
Charitable Contributions	Shire followed the EFPIA guidance on the following: <ul style="list-style-type: none"> • A donation or grant to a HCO will be disclosed as a Transfer of Value under the Donation/Grant section of the applicable Disclosure report. • Sponsorships of a HCO will be disclosed as a Transfer of Value, under the Costs related to Events section of the applicable Disclosure report. 	No difference.
Payment made to Institution (as an travel grant) and the HCO sends a HCP to an event	Shire decided: <ol style="list-style-type: none"> 1. If a payment was made to a 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 transfer of value against the HCO under Costs related to Events. 	No difference.

Country in which to report Research Payments	Shire determined that the transfers of value would be disclosed based on the principal address of the recipient regardless of where the payment is made.	No difference.
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Section 4: Consent Management at Shire & Baxalta

Shire	Baxalta
<p>Shire is collecting consent for each engagement with all HCPs (and HCOs where applicable) based on local requirements with the following exceptions:</p> <p>Spain has collected consent at the profile level for 2016 data.</p> <p>These are the decisions made to avoid the “cherry picking” of transactions for individual disclosure:</p> <ul style="list-style-type: none"> • If consent is given for all engagements, Shire will disclose transfers of value to the HCP under the individual section of the applicable Disclosure report. • If Shire does not receive consent for all engagements, we will default all transfers of values to the aggregate section of the applicable Disclosure report with the exception of Italy where based on local Code guidance, we must report based on the consent provided for each specific engagement. • If the consent form is not returned to Shire, we will default all transfers of value to the aggregate section of the applicable Disclosure report. <p>These are the decisions made for the revoking of individual consent:</p> <ul style="list-style-type: none"> • If a HCP or HCO revokes consent prior to publication of the data, Shire will 	<p>Baxalta is collecting consent for each engagement with all HCPs and HCOs (where applicable) based on local requirements with the following exceptions:</p> <ol style="list-style-type: none"> 1. For Germany and Austria, consent is collected at the profile level once every 3 years. 2. For Estonia, Latvia and Lithuania, if no consent was given to disclose at an individual level, then Baxalta did not engage the HCP. <p>There is no difference for the other points.</p>

<p>update the data and include the transfers of value in the aggregate section of the applicable Disclosure report.</p> <ul style="list-style-type: none"> • If a HCP or HCO revokes consent after publication of the data, Shire will update the information at the first reasonable time. <p>Other Considerations for Belgium:</p> <p>For HCP’s who do not have a RIZIV/INAMI number, all transfers of value will be reported in the aggregate.</p> <p>For HCO’s who do not have an enterprise number, Shire has decided to declare the transfers of value at an aggregate level.</p>	
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Section 5: Submission Approach for 2016 Data

<p>The Disclosure Method for 2016 Data</p>	<p>A. Shire will publish the disclosure file on our Shire.com website for the following countries:</p> <p>Bulgaria, Croatia, Estonia, Finland, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden 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>Austria, Bulgaria, Germany, Italy, Latvia, Lithuania, Norway, Romania, Russia, Serbia, Spain, Sweden, Switzerland, Ukraine</p> <p>C. Shire will publish on the central registry for the following countries:</p> <p>Czech Republic, Ireland, UK and Belgium</p> <p>D. The report for Cyprus will be published by the distributor and not by Shire.</p> <p>E. Shire will not publish an EFPIA Disclosure report for Turkey until further guidance is provided by EFPIA and the Turkish</p>
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	authorities
The Timing of Disclosures for 2016 Data	<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> <ul style="list-style-type: none"> A. The UK will be submitted by March 31 B. Belgium will be submitted by April 30 C. Estonia will be published by June 1

Section 6: Categories for Disclosure as Defined within the Code:

Description	Types of Transfer of Value Included Per EFPIA
Donations and Grants to Healthcare Organisations	Donations and Grants to HCO's that support healthcare including donations, grants and benefits in kind.
Research & Development (to be published in the aggregate section of the disclosure template)	<p>Research and Development transfer of values to HCPs/HCOs associated with:</p> <ul style="list-style-type: none"> • Non-clinical (Good Laboratory Practice (GLP)) • Clinical trials in Phase I to Phase IV • Investigator sponsored studies • Non-interventional studies
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.</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 attending a Congress or Symposia.
Contribution to costs of	1. Travel expenses related to attending a Congress or

Events: Travel & Accommodation	<p>Symposia.</p> <p>2. Accommodation expenses related to attending a Congress or Symposia.</p> <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
Fee for service and consultancy: Fees	<p>Transfers of value resulting from or related to contracts between Member Companies and institutions, organisations, associations or HCPs under which such institutions, organisation, association or HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories.</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
Fee for service and consultancy: Related expenses agreed in the fee for service or consultancy contract	<p>Related expenses agreed in the fee for service or consultancy contract:</p> <p><u>Examples include:</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