

BioNTech SE
Germany HCP/HCO Methodological Note for the Reporting
Year 2022
Publication on 30 June 2023

This document will detail the methodology for BioNTech SE's disclosure of donations to healthcare professionals (HCPs) and healthcare organizations (HCOs) in accordance with the Germany "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) Transparency code

Version: 1

Last updated on: 30/06/2023

Introduction

BioNTech SE [“**BioNTech**”] is a member of FSA and is committed to meeting the obligations of the FSA codex in its interactions with the healthcare community (i.e., healthcare professionals, healthcare organizations and patient organizations). In line with these obligations, BioNTech has published transfers of value (ToV) made to German HCPs and HCOs for the 2022 reporting cycle. *Note:* POs will be disclosed in a separate report.

The 2022 disclosure report includes ToV made between 01 January 2022 and 31 December 2022. Any ToV not processed by 01 March 2023 will be moved into the next reporting cycle’s disclosure report (i.e., 2023).

This methodological note documents the details on how BioNTech has recorded the ToV and published them as required by the FSA codex.

Transparency Notification, Data Privacy and Consent

Agreements between BioNTech and HCPs and/or HCOs may have included a clause on Transparency, notifying them of BioNTech’s obligations to report ToV as required by legislation, regulation and/or local trade association code.

In addition, HCPs and HCOs received a data privacy notice explaining how their personal data is processed including their rights and how to exercise them in accordance with the applicable data protection laws. Besides the privacy notice, HCPs would have received a consent form requesting their explicit consent for ToV disclosure.

If HCPs have provided their consent, BioNTech has published their details in the individual disclosure section of the report. In case HCPs have not returned a signed consent form or have declined to provide consent, their ToV has been published in the aggregate section of the disclosure report.

A similar approach has been applied to small sized HCOs (i.e., general practices or medical care centres made up of up to 5 HCPs/employees).

If an HCP or HCO provided varied consent responses (i.e., one signed consent and one declined consent), BioNTech will determine this to be a declined consent. Therefore, all ToV for the HCP or HCO have been disclosed in the aggregate section of the disclosure report.

If an HCP or HCO has any queries regarding data privacy and/or consent, they can do so by contacting our Global Data Privacy team at data.privacy@biontech.de.

Pre-Disclosure

HCPs and HCOs with reportable ToV would have received a pre-disclosure letter in April 2023 including an overview of the ToV to be disclosed. BioNTech did so intending to provide the recipients with the opportunity to review the details for correctness and provide feedback prior to publication on 30 June 2023.

HCPs with Multiple Licenses

If BioNTech is aware of an HCP holding multiple licenses, the ToV is disclosed in all respective countries where the licenses are held.

Non-Duplication of ToV

Where possible, ToV is disclosed to the final HCP recipient. In case the ToV is provided through an HCO, the ToV is attributed to the HCO.

Number of HCPs/HCOs in the Aggregate Section

Each category reflects the respective amount for the HCPs or HCOs with ToV. Each HCP or HCO is counted once for the relevant category.

ToV through a Third-Party (i.e., Indirect ToV)

ToV made to a third-party vendor (TPV, e.g., professional congress organiser (PCO), agency, event organizer, etc.) have been disclosed in the name of the respective HCO.

Any Sponsorships made through a PCO, the ToV has been disclosed in the name of the HCO (“Veranstalter”) and included the name of the Organiser (“Organisator”). Where the HCO is unknown, the ToV are disclosed in the name of the Organiser (PCO).

Cross Border ToV

Applicable ToV for German HCP or HCO engagements made through BioNTech’s global affiliates have been included in the disclosure report.

HCP ToV Categories:

- i) Fee for Service and Consultancy
 - Advisory Board participation (including preparation and/or post Ad-board work)
 - Speaker fees for service at a congress, educational or scientific event (including preparation work)
 - Other Consultancy services (e.g., sample analysis, etc.)

- ii) Fee for Service and Consultancy related expenses
 - Travel (e.g., flight, taxi, train, parking, etc.)
 - Accommodation (e.g., hotel)

Note: If the fee for service included out-of-pocket expenses which cannot be separated, these are disclosed as part of the Fee for Service and Consultancy ToV.

- iii) Contribution to Cost of Events
 - Registration Fee for attendance to a congress, educational or scientific event
 - Related travel and accommodation fees (e.g., flight, taxi, train, parking, hotel, etc.)

Note: If a registration fee includes hospitality (i.e., coffee breaks, snacks) that cannot be separated, these are included as part of the Contribution to Cost of Events ToV. Additionally, if registration fees and/or other incidental expenses are included in a fee for service and cannot be separated, these are disclosed as part of the Fee for Service and Consultancy ToV.

- iv) Research and Development (R&D)
 - Investigator Fees
 - Advisory Boards related to R&D
 - Related travel and accommodation fees (e.g., flight, taxi, train, parking, hotel, etc.)

HCO ToV Categories:

- i) Fee for Service and Consultancy
 - Advisory Board participation (including preparation or post Ad-board work)
 - Speaker fees for service at a congress, educational or scientific event (including preparation work)
 - Other Consultancy services (e.g., sample analysis, etc.)
- ii) Fee for Service and Consultancy related expenses
 - Travel (e.g., flight, taxi, train, parking, etc.)
 - Accommodation (e.g., hotel)

Note: If the fee for service included out-of-pocket expenses which cannot be separated, these are disclosed as part of the Fee for Service and Consultancy ToV.

- iii) Contribution to Cost of Events
 - Sponsorships contributing to the cost of an event organized by an HCO and/or TPV (e.g., PCO)
 - Registration Fee for attendance to a congress, educational or scientific event
 - Related travel and accommodation expenses (e.g., flight, taxi, train, parking, hotel, etc.)

Note: If a sponsorship package included other forms of funding, such as catering, logistics, registration fees, travel and accommodation, etc., that cannot be separated, these are disclosed as part of the sponsorship ToV.

- iv) Grant funding to support educational or scientific research purposes
- v) Research and Development (R&D)
 - Investigator Fees, Site Payments
 - Related Advisory Boards
 - Related travel and accommodation fees (e.g., flight, taxi, train, parking, hotel, etc.)

Research and Development

The R&D ToV disclosure includes studies that are of a Pre-Clinical (in-vitro, in-vivo, in-silico), Clinical (Phase I – IV), Investigator Initiated Trials (IITs) and Prospective Non-Interventional nature.

The total R&D amount for both HCPs and HCOs is aggregated in the disclosure report and includes ToV made by BioNTech and its global affiliates.

Clinical studies of a retrospective nature have been disclosed individually in the Fee for Service category.

ToV related to the lending of laboratory equipment to a study site for use during the clinical study have not been included in the aggregate R&D amount.

Out of Scope ToV

The disclosure report does not include ToV that are:

- i) Over the counter (OTC) medicines
- ii) Items of medical utility or medical samples
- iii) A part of ordinary course purchases and sales of Medicinal Products
- iv) Meals and/or drinks

Date Methodology

BioNTech used the following approach to determine the ToV to be included in the current reporting cycle's disclosure (i.e., occurring between 1 January 2022 and 31 December 2022):

Event Date – the date on which the activity/event occurs. This is applicable for the following expense categories:

- Fees for Service and Consultancy related expenses
- Contribution to Cost of Events: Registration Fees and related travel and accommodation expenses
- Research and Development (R&D) related travel and accommodation expenses

Invoice Date – the date of the invoice received from the HCP or HCO issued within the current reporting cycle. This is applicable for the following expense categories:

- Fees for Service and Consultancy
- Contribution to Cost of Events: Sponsorships
- Grants
- Research and Development (R&D) and related Advisory Boards

Other Terms

Value Added Tax (VAT) - Excludes, where applicable. ToV from cross border activities may or may not include VAT.

Social Benefits (i.e., social security, pension, health insurance) - Excludes, where applicable.

Withholding Taxes - ToV for services concluded outside of Germany will be disclosed as detailed in the contractual agreement, where applicable.

Currency - Disclosure amounts are in Germany.

Exchange Rate - Foreign currencies have been converted into euro using the Monthly Average exchange rate.

Amount Rounding - ToV amounts in the disclosure report have been rounded to the nearest euro. The disclosure amount for each HCP or HCO is summed up for each category.

Multi-year Agreements - ToV for Agreements that include multiple year schedules are disclosed in the reporting cycle an invoice is issued.

Post Publication Queries or Feedback

HCPs and HCOs with any queries or feedback regarding the disclosure may contact us through BioNTech.com [Connect](#) - General Inquiry webpage. BioNTech will review and investigate the details accordingly and will update the published report with any occurring changes.