

STADA ARZNEIMITTEL AG

REQUIREMENTS FOR DISCLOSURE AND TRANSPARENCY IN DEALING WITH HEALTHCARE PROFESSIONALS/ ORGANISATIONS AND PATIENT ORGANISATIONS

METHODOLOGY

STADA Arzneimittel AG and its affiliated companies support rules and regulations, which promote transparency regarding interactions with Healthcare Professionals.

This document outlines the methodology for disclosure of STADA Arzneimittel AG and its German affiliates, STADAPHARM GMBH and ALIUD PHARMA GMBH, ("STADA") according to the applicable provisions from the Medicines for Europe Code of Conduct (chapter 7 – Transparency Rules and Requirements) as well as statutory and internal regulations.

1. Transparency obligations

Any transfers of value that could potentially pose a conflict of interest to HCPs, healthcare organizations and patient organizations, which includes any transfers made direct and indirectly (via a third party).

The disclosure in the transparency report takes place in Euro.

2. Process of Disclosure

a) Transfers of value to HCPs

This includes especially consulting contracts, contracts on the membership in advisory boards and further service contracts (especially speaking contracts).

For each HCP the following data is published (in compliance with applicable data protection laws): Full name, office or practice address and (if applicable) doctor identifier number, kind of service, value/height of payments. Any expenses for accommodation and travel expenses are not published.

Furthermore, meetings organized by the company, site visits and educational support are published. Such educational events are defined as occupational or scientific meetings, congresses, conferences and similar events, which have the purpose of educating the HCP and which are organized on behalf of STADA or sponsored by STADA. In these cases, no disclosure by name of each HCP takes place.

In case of meetings organized by the company or site visits, the total amount spent is disclosed in connection with the total number of participating (and thereby supported) HCPs.

In cases of internal or external educational support, the event is named as well as the amount spent for this event including the number of HCPs, whose participation was supported.

b) Transfers of value to Healthcare Organizations

This mainly includes sponsoring contracts. Transfers of value for services and consultancy will be published as "contracted services" by naming the organization, which includes a description

of the type of value and the respective annual amount paid. Any expenses for accommodation and travel expenses are not published.

Any kind of donations are published by naming the healthcare organization and the kind of donation (in kind or financial). This includes a description of the type of donation including the total amount spent.

c) Transfers of value to patient organizations

STADA has made no transfers of value to patient organizations in 2018; therefore, nothing in this regard was disclosed.

For potential transfers of value in the future, the following methodology on disclosure applies:

Any transfers of value in the course of service contracts will be disclosed as “contracted services” by naming the patient organization, which includes a description of the type of value, the amount paid for each contracted service as well as the total amount spent.

Further financial and non-financial transfers of value that are to be disclosed by naming the organization and the kind of value (in kind or financial). In cases of non-financial transfers of value, where no certain monetary amount can be connected to, a description of the in kind benefit for the patient organization takes place.

This category includes especially financial and in kind donations to patient organizations.

3. Compliance with data protection laws

Applicable data protection laws are complied with.

For HCPs, a declaration of consent needs to be obtained. In case the HCP refuses to give consent or does not declare consent, the transfer of value will be disclosed anonymously. If several HCP do not give their consent, anonymized data can be aggregated, whereat the total number of persons will be stated.

In case of transfers of value to healthcare organizations that are organized in the form of partnerships under German law (“Personengesellschaft”) and which underlie transparency obligations (mainly medical practices, dental practices or pharmacies with at least two partners/shareholders), consent needs to be declared by all partners/shareholders. Exceptions are possible if consent is given by a shareholder, which has the right of exclusive representation. In cases of doubt whether all partners gave their consent or if nor each partner gives its consent, the transfer of value is disclosed anonymously. If the consent is withdrawn from one partner, the disclosure can only take place anonymously. If several partners do not declare their consent, anonymized data can be aggregated. The total number of persons is stated.

In case of transfers of value to patient organizations, that are organized in the form of partnerships under German law (“Personengesellschaft”), consent needs to be declared by all partners/shareholders. Exceptions are possible if consent is given by a shareholder, which has the right of exclusive representation. In cases of doubt whether all partners gave their consent

or if not each partner gives its consent, the transfer of value is disclosed anonymously. If the consent is withdrawn from one partner, the disclosure can only take place anonymously. If several partners do not declare their consent, anonymized data can be aggregated. The total number of persons is stated.