Helsinn Methodological Notes

a) Introduction

Collaboration between healthcare professionals and Pharmaceutical Companies has long been a positive driver for advancements in patient care and progression of innovative medicine.

Healthcare professionals and organizations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patient outcomes and the management of diseases. This expert knowledge helps to adapt our products to better suit patients and thereby improve patient care overall.

We believe that healthcare professionals and organizations should be fairly compensated for the legitimate expertise and services they provide to us. At the same time, we acknowledge legitimate concerns that such transactions should be transparent.

The transparency requirements will protect the integrity of the industry-healthcare professional relationship, and represents a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society.

The aim of this Methodology is to provide a clear and simple explanation of how Helsinn fulfils its reporting obligation according to Transparency laws and it provides a basic framework for interpretation.

b) Disclosure criteria

As Helsinn HealthCare (HHC) is not a member of EFPIA, HHC collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs only for Countries in which Transparency laws apply.

c) Terminology and Definition

Terminology	***Definition and Helsinn approach to disclosure of TOV***
Advisory Board	ToV related to Advisory Board activity will be disclosed as 'Fee for service and consultancy'
CME – Continued Medical Education	ToV to a third party (not being an HCO) that is providing HCPs with accredited Continuous Medical Education (CME) will not be disclosed, when Helsinn has no influence on participants, programme set-up, faculty incl. fees and its programme content.
CRO (Clinical Research Organisation)	Tov to a CRO will be considered R&D related and will go into the disclosure as aggregated amounts.
Donations and Grants	Donations and Grants are provided only to HCOs. Covering the costs for an individual HCP to attend an event as delegate will be disclosed as a 'Contribution to costs of Events'.
Fees for Service and Consultancy	Fees include any remuneration for services provided, e.g. speaker engagements, provision of consultancy services and participation in advisory board meetings or symposia. Any additional compensation (e.g. travel time compensation or similar) provided to an HCP is disclosed as a 'Fee for Service and Consultancy'. The HCPs are compensated for the service based on their country of practice fair market value (FMV) determination.
Investigator Meetings	An Investigator Meeting is an event organized by/on behalf of Helsinn with the purpose of training and informing investigators and other site staff about various aspects of the clinical trial. The Investigator. ToV related to an Investigator Meeting will fall under R&D ToV.
Investigator Initiated Study	Investigator Initiated Study (IIS) will be considered R&D related and will go into the disclosure as aggregated amounts since Helsinn has no influence on the study.
Market Research Programmes (MRP)	Any ToV in connection with MRP where the participating HCPs are "blinded" or "double blinded" for the sake of methodology of the MRP and the identity of the HCP therefore cannot be revealed to Helsinn is not disclosed.
Meals and Drinks	Meals and drinks will be included in the disclosure and disclosed as 'Fees for Service and Consultancy' in accordance to HCP's country of practice threshold as set by Transparency laws.
Travel and Accomodation	If expenses for accommodation and travel are covered by Helsinn, all related expenses will be included in the disclosure e.g. room rate, flight, train and related taxes.
Events	Event activities where a delegate participates in congresses, conferences, symposia and similar external events will be disclosed as a 'Contribution to costs of Events' towards the individual delegate. The main objectives of these events are the dissemination of disease and product knowledge and to stimulate scientific exchange between HCPs.

Sponsorship agreement	Sponsorships, defined as a financial or non-financial contribution: • for a specific activity/project/event • for the purpose of healthcare related education, information, research, scientific exchange • for promotional or non-promotional purposes • where Helsinn receives a direct tangible benefit in return. Sponsorships are provided to HCOs only and will be tracked and disclosed as a 'Contribution to costs of Events' (Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event).
Registration fee	All registration and participation fees related to delegate participation in conferences, symposia, congresses or similar external events. This type of ToV will always be disclosed as a ToV to an HCP/HCO. For authors/presenters of abstract/poster connected to a Trial/Study/Project ID, the registration fee is disclosed under R&D.
Medical & Scientific publications	Support related to medical & scientific publications may include medical writing and editing, graphic support, submission and publication fees. This support was not considered as a transfer of value to the authors, for the following reasons: - Publishing results of clinical studies is a societal obligation and may require the provision of editorial support to investigators at their request. Timely dissemination of the study does ensure that HCPs treat their patients in accordance with the best and most complete available evidence. - Publication of study results benefit the whole scientific community and ultimately the patients and go well beyond the interests of the individual authors and Helsinn.
Educational material	ToV in connection with educational material distributed to HCPs will be disclosed only on national platform when required by Transparency laws that apply in the country of practice of HCP receiving the material.
Reaserch and Development ToVs	Helsinn discloses in the Aggregated R&D section, all R&D-related transfers of value to HCPs or HCOs related to the planning or conduct of the following: - non-clinical studies (as defined in OECD Principles on Good Laboratory Practice) - clinical trials (as defined in EU Directive 2001/20/EC); - non-interventional studies that require the collection of patient data specifically for the purpose of the non-interventional study

d) Data Protection

HCP acknowledges that the Transparency rules require Helsinn to publish and/or disclose information, including personal data (as defined under applicable data protection laws), to competent authorities or pharmaceutical industry associations regarding transfers of value made by or on behalf of Helsinn to individual HCPs.

At the same time, Helsinn undertakes to comply with all applicable laws and regulations related to the protection of the personal data of natural persons.

The provision of personal data by HCPs is necessary in order for Helsinn to fulfil its legal obligations and contractual commitments with HCPs and for the purposes identified herein where in the legitimate interests of Helsinn. For any additional purpose in which Helsinn is required to inform HCPs and obtain their consent, including the purposes provided for by law, Helsinn will obtain any said consent before proceeding to the processing of personal data for such purposes.

Because of Helsinn's commitment to the protection of HCPs personal data, Helsinn evaluate its privacy policies and procedures to implement improvements and refinements from time to time. Please read the Privacy and Cookies Policy carefully in order to understand our views and practices regarding personal data and how Helsinn will treat it.

e) Financial Aspect

This chapter focusses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

- **Payment dates**, ToVs are disclosed based on the date the payment has been cleared via banking system.
- **Reporting Period**, Disclosure is made on an annual basis, and each reporting period covers a full calendar year (the "Reporting Period"). The disclosure is made no later than 30 June of current year. Tracking of ToVs will follow the payment date and not the date of event.
- **Disclosure Currency**, Transfers of values is registered in the currency paid by Helsinn. Where values had to be converted, the exchange rate used was the actual Conversion Rate at the time of the transaction, according to average BID/ASK UBS Interbank foreign exchange at opening spot rate.

f) Acronyms and glossary

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose:

- **Recipient**, Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a country whose a Transparency law applies.
- **TOV (Transfer of Value)**, Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by Helsinn for the benefit of a Recipient. Indirect transfers of value are those made on behalf of Helsinn for the benefit of a Recipient, or transfers of value made through an intermediate and where Helsinn knows or can identify the HCP/HCO that benefit from the transfer of Value. All ToVs to HCPs and HCOs will be stated in gross amounts.
- **HCP (Healthcare Professional)**, Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.
- **HCO (Healthcare Organization)**, Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code).
- **CRO (Contract Research Organization)**, an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **Research and Development ToVs**, ToVs to HCPs or HCOs related to the planning or conduct of (I) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.