



Interactions with Healthcare Professionals – Principles for Third Parties

All interactions with Healthcare Professionals (“HCPs”)¹ and Healthcare Organisations (“HCOs”)² must be ethical and compliant with Applicable Laws³ and your contract with Elvium Life Sciences (“Elvium”)

1. General Principles

- (a) Third Parties are required to implement and maintain internal policies and procedures that are designed to ensure compliance with Applicable Laws and their contract with Elvium relating to their interactions with HCPs and HCOs.
- (b) Third Parties are prohibited from providing anything of value (including but not limited to items covered in this Policy) to HCPs as an improper inducement or reward for the prescription, purchase, recommendation, supply, or use of Elvium products.
- (c) No agreements, commitments, contracts, or invitations may be entered into, or issued to any HCPs, HCOs or other External Parties⁴ prior to approval of the activity in accordance with all of the Third Party’s relevant policies and procedures.
- (d) Third Parties must promptly, accurately and completely record all product detailing calls with and Transfers of Value⁵ to HCPs or HCOs.
- (e) Where a Third Party provides Transfers of Value to HCPs and/or HCOs and unless otherwise agreed by the parties in the written agreement, the Third Party is responsible for complying with any and all applicable laws, regulations and/or industry code requirements to report such Transfers of Value.
- (f) Third Parties are required to report adverse events, product quality complaints or other safety information relating to Elvium products or services to Elvium, and/or other entity or individual as directed by Elvium, as soon as possible and no later than within 24 hours of first awareness.
- (g) Third Parties must immediately report suspected or confirmed violations of the principles

¹ **HCPs (Healthcare Professionals)** are registered or otherwise certified members of the medical, dental, pharmacy or nursing professions or any other person who is authorised to prescribe, recommend, purchase, supply, or administer a medical product or service. Also included in this definition are other healthcare providers, such as hospital administrators, who support HCPs in the fulfilment of their duties.

² **Healthcare Organisations (HCOs)** are organisations comprised of HCPs and/or that provides healthcare-related products or services or conducts healthcare research, including but not limited to a hospital, general practice surgery, or medical society.

³ **Applicable Laws** means any and all laws, rules and regulations, including any rules, guidance, guidelines and requirements of any government authorities and any industry codes of conduct or practice applicable to either party or the activities performed. For clarity, Applicable Laws include Anti-Bribery/Anti-Corruption Laws^{3a}.

^{3a} **Anti-Bribery/Anti-corruption Laws** means all Applicable Laws addressing public corruption or commercial bribery, such as the U.S. Foreign Corrupt Practices Act 1977, the UK Anti-Bribery Act 2010, the Foreign Extortion Prevention Act, and laws in place in the relevant country or place where the services are being performed and/or where the applicable Third Party is domiciled, registered and/or legally established.

⁴ An **External Party** is another entity that is not directly associated with Mundipharma or the Third Party.

⁵ A **Transfer of Value (TOV)** refers to a direct or indirect transfer of value, whether in cash, in kind or otherwise, in connection with the development or sale of medicines. Examples of transfers of value include, but are not limited to, consultancy fees paid to HCP Service Providers for services rendered, registration fees and travel costs related to HCP Sponsorships, Sponsorships of External Events, etc. Direct TOVs are those made directly by the Third Party for the benefit of the recipient HCP or HCO. Indirect TOVs are those made on behalf of the Third Party for the benefit of the recipient HCP or HCO, or those made through an External Party and where the Third Party knows or can identify the recipient HCP or HCO that will benefit from the Transfer of Value.

contained in this document. Reports should be made to the applicable Elvium representative, or the Elvium Integrity Line.

2. Product Promotion⁶

- (a) Third Parties who Promote Elvium products may only do so with prior written authorisation from Elvium (which is typically part of the written agreement between Elvium and the Third Party). The following paragraphs in this section apply to such authorised Third Parties.
- (b) Third Parties may Promote Elvium's products only:
 - i) After the product has received all required regulatory approvals in the relevant country;
 - ii) For approved product indications and for any more narrow indications as directed by Elvium; and
 - iii) To HCPs who treat or recommend products to patients who can legitimately receive the product within the indications referenced in part (ii).
- (c) Where required by Elvium, Third Parties must only use Elvium-approved materials and messages when discussing Elvium products or relevant therapy areas (for purposes in connection with Elvium products) with HCPs. In any event, information, claims, and comparisons about Elvium products or relevant therapy areas must be accurate, balanced, fair, objective, unambiguous, capable of substantiation and must clearly reflect an up-to-date evaluation of all relevant evidence. Information and materials must not be likely to mislead the recipient, misrepresent the product, or understate side-effects including the risk of abuse or addiction. Furthermore, with respect to Elvium's pain portfolio, Third Parties must comply with additional guidelines as communicated by Elvium from time to time.
- (d) Third Parties may promote Elvium products with a particular HCP only as often as reasonable and required to ensure the provision of complete and up-to-date product information, ongoing scientific developments, and to support appropriate ongoing education and awareness.
- (e) Third Parties may not solicit, initiate, or otherwise encourage off-label questions or discussions, or requests for off-label information. If an HCP makes an unsolicited request for off-label information, only appropriately qualified employees who are not part of the sales organisation (i.e. Medical Affairs) may respond to the request and may only provide information that is narrowly tailored to the request and only to the specific individual making the request.

3. Samples⁷

- (a) Third Parties are not permitted to offer or provide Samples of Elvium products that are classified as controlled substances (such as opioids, narcotics, psychotropic drugs), or as otherwise restricted by Elvium.
- (b) Third Parties may only provide Samples of other Elvium products for the purpose of enhancing patient access or enabling HCPs to gain experience with the product to improve patient care and as permitted by Applicable Laws, which typically limit product Sampling to a specified frequency, quantity, time and purpose.

⁶ **Promotion** is any activity undertaken, organised or sponsored by Mundipharma or on its behalf (including by Third Parties) that is directed at HCPs to promote the prescription, recommendation, supply, administration, or consumption of its products. **Promote**, **Promoting** and **Promotional** shall be interpreted accordingly.

⁷ **Samples** are Mundipharma products provided free of charge to HCPs for the purpose of familiarising the HCP with the product.

4. Hospitality⁸ provided to HCPs

- (a) Unless prohibited by Applicable Laws or the contract with Elvium, Third Parties may only provide meals and refreshments to HCPs if they are:
 - i) Modest in value and appearance;
 - ii) Infrequent;
 - iii) Only provided for consumption during or directly associated with an in-person discussion regarding Elvium products, therapy areas, or related medical or business topics (collectively meetings);
 - iv) Secondary to the main purpose of the meeting; and
 - v) Only for the legitimate participants in the meeting, interaction or event and in a quantity that is proportionate to the number of reasonably expected attendees.
- (b) Third Parties may only provide travel and accommodation to HCPs if they are:
 - i) Permitted by Applicable Laws and their contract with Elvium;
 - ii) Modest in value and appearance; and
 - iii) Necessary for the HCPs' attendance at a legitimate event, or their services as an HCP Service Provider⁹.
- (c) Third Parties cannot provide, fund or facilitate Entertainment¹⁰ for HCPs.

5. Gifts, Promotional Aids¹¹, Educational Items¹² and Medical Utility Items¹³

- (a) Third Parties may not provide gifts to HCPs directly or indirectly (e.g., via business associates or family members). Gifts are items provided directly or indirectly to a recipient, including but not limited to cash, vouchers or other cash equivalents, watches, jewellery, clothing, entertainment tickets, and personal services. Education, training, or opportunities that go beyond appropriate product or therapy area training can be considered gifts where they are provided free of charge and have personal value to the recipient such as an advanced medical degree, enhanced income, legal or business advice, or similar. As such, these are also prohibited.
- (b) Third Parties may not provide Promotional Aids to HCPs related to or in connection with the Promotion of Elvium products that require a prescription in the relevant country ("Elvium prescription products").
- (c) During meetings that discuss Elvium prescription products (or related therapy areas), attendees may only be provided with inexpensive and non-product branded pens and/or notepads to facilitate notetaking in the meeting.
- (d) Unless prohibited by Applicable Laws or the contract with Elvium, Third Parties may provide Educational and Medical Utility Items to HCPs if they are:

⁸ **Hospitality** refers to food, beverages (including meals or Snacks), travel, and/or accommodation. Snacks refer to a small serving of food and/or beverages (e.g., pastry, coffee, tea, fruits, sandwiches, salad, or other similar snacks or light meals).

⁹ **HCP Service Provider** is an HCP who is contracted to provide services for which there is a legitimate business need that requires the particular skills and expertise of the HCP, including but not limited to services provided as an HCP Advisor or HCP Speaker, or the development or provision of patient case studies. An HCP Advisor is a Service Provider engaged as an advisor or consultant to provide expert advice based on their knowledge and experience. An HCP Speaker is Service Provider engaged to perform services as a speaker, chairperson, or moderator.

¹⁰ **Entertainment** refers to an event, performance or activity designed primarily for amusement, such as sports or cultural events, city tours, musical or theatrical performances, etc.

¹¹ **Promotional Aids** are items branded with the Mundipharma name or logo, and/or with the names or other identifiable images of Mundipharma products.

¹² **Educational Items** are items that are directly relevant to the practice of medicine or pharmacy and enhance patient care (e.g., journal reprints, patient education materials).

¹³ **Medical Utility Items** are items that enhance the provision of medical services and patient care (e.g., anatomical models, devices intended to assist patients).

- i) Modest in value;
- ii) Provided infrequently;
- iii) Are not branded with a product name unless the product's name is essential for the correct use of the item by the patient; and
- iv) Do not have the intent or effect of funding the routine operations of an HCP/healthcare organisation (e.g., stethoscopes, weighing scales, spirometers, journal subscriptions).

6. Events

- (a) Events are structured meetings or activities, separate from Product Detailing, that are organised in advance, funded and hosted by the Third Party, that generally involve HCP Service Provider(s), and that have a legitimate medical, scientific, academic or educational objective to provide information about Elvium products or therapy areas to groups of HCPs or other selective audiences.
- (b) A digital, in person or hybrid meeting with HCPs is classified as an Event, even if part of a larger external educational or scientific event, where the Third Party organises the meeting, selects or engages HCP Speakers to present at the meeting, selects or invites the HCP attendees, and/or influences the educational content or any other aspects of the meeting.
- (c) Unless prohibited by Applicable Laws or the contract with Elvium, the Third Party may organise or conduct an Event where it:
 - i) Provides substantive information about a Elvium product or related therapy area;
 - ii) Includes as attendees only those HCPs who have a legitimate medical interest in the subject matter and for whom the content will provide new, updated, or additional information that is intended to increase their knowledge about the subject matter to support improved patient care;
 - iii) Includes the fewest number of HCP Speakers, if any, needed to effectively deliver robust educational content (note that the number of attendees is not generally considered a relevant factor to determine the number of HCP Speakers, and would require demonstrable evidence to support it as a factor);
 - iv) Includes only those HCP Speakers who have the necessary skills and expertise, who have been approved in advance, and who have been briefed prior to the Event start date on the approved indications of the relevant Elvium products, the Elvium pharmacovigilance process, the Elvium Integrity Line, and any applicable communication standards, disclosure requirements or other pertinent information;
 - v) Is disclosed to the attendees that it is an Event organised and/or funded by the Third Party or Elvium, and, where applicable, that HCP Speakers have been identified, selected and/or compensated by the Third Party or Elvium; and
 - vi) Complies with all other applicable rules in this document.

7. External Events¹⁴

- (a) Unless prohibited by Applicable Laws or the contract with Elvium, the Third Party may Sponsor an External Event where:
 - i) The hosting organisation is reputable and has relevant experience and/or expertise;

¹⁴ **External Events** are scientific or educational meetings organised by an External Party including but not limited to those organised by HCOs.

- ii) The location (e.g., city or town) where the event will be held must be logistically sensible for the majority of attendees and/or the location of the required resources or expertise and would not be reasonably seen as selected for inappropriate features such as leisure/recreation, sporting, gambling, or tourist attractions and the venue of the meeting must be 1) in or near the HCP attendees' place of business whenever possible 2) suitable for a professional meeting, including providing sufficient privacy to enable effective communication of the information 3) modest in appearance and cost; and
 - iii) A sufficiently detailed description or agenda is available in advance demonstrating that educational elements are the predominant focus of the event; and
 - iv) The event agenda and/or other educational opportunities during the event have reasonable relationship to Elvium products or therapy areas.
- (b) Third Party funding must be:
- i) Paid to the official organisation hosting the External event or its authorised suppliers (e.g., event planner, restaurant, meeting venue) and not to an individual HCP;
 - ii) For the purpose of contributing to the overall costs of the meeting (such as through a general Sponsorship), supporting educational elements, paying for advertising opportunities, or similar legitimate elements of the meeting;
 - iii) At Fair Market Value, considering relevant factors, such as the size of the booth or other advertising opportunities/services, size, duration and scope of the meeting (e.g., international, regional, local), number of attendees, and costs at equivalent External events;
 - iv) In line with costs made publicly available, such as in the event brochure, and/or an official letter of request; and
 - v) Made transparent to attendees.

8. HCP Sponsorship¹⁵ to an External Event

- (a) Unless prohibited by Applicable Laws or the contract with Elvium, Third Parties may provide funding to support an HCP's attendance at an External Event if:
- i) It is not prohibited by Applicable Laws in the HCP's country of practice and the HCP's employer's policies;
 - ii) Provided in response to an unsolicited written request from an HCP through an official channel (e.g. a professional hospital email account), that provides a legitimate rationale for the request (e.g. description of the educational need), details of the requested support, and confirmation that they are not receiving duplicative funding;
 - iii) The attendee is selected based on the legitimate medical / scientific reason to attend the meeting and not for any improper reason;
 - iv) The event is relevant to Elvium therapy areas;
 - v) The hosting organisation is a reputable organisation with previous demonstrable experience organising legitimate scientific events;
 - vi) A detailed agenda is available in advance, demonstrating that the event has clear and robust content which is relevant to the attending HCP;
 - vii) The event is held in a modest venue and location that are appropriate to facilitate the event (e.g., venues and locations that do not focus on or have a reputation primarily as a touristic or recreational destination);

¹⁵ **HCP Sponsorship** refers to funding provided to support the attendance of individual HCPs at an event, such as through the payment of registration fees.

- viii) Funding is limited to the Sponsored HCP and that HCP has a legitimate medical interest in the subject matter of the event, i.e. the content is new or useful to the HCP and increases their knowledge about the subject matter to support improved patient care, and the Third Party has not Sponsored the HCP to attend an event in the same calendar year or the same Third Party Event in the prior calendar year;
- ix) Funding is limited to the support deemed necessary for attendance (e.g. payment of registration fees) and not compensated through other sources and documented in advance in writing, and any notifications, approvals or other requirements from the HCP's employer are satisfied;
- x) Payments are made directly to the relevant vendors (e.g., travel agents, meeting organisers) and not to the attending HCP; and
- xi) The Sponsored HCP acknowledges in writing that they will fully participate in the educational, scientific or academic sessions of the event.

9. HCP Service Providers

- (a) Unless prohibited by Applicable Laws or the contract with Elvium, Third Parties may engage an HCP as an HCP Service Provider when:
 - i) There is a legitimate and documented business need that requires the experience and expertise of an HCP;
 - ii) The HCP is recommended and selected solely on the basis of their skills and qualifications in relation to the legitimate business need;
 - iii) The HCP has not been engaged as an HCP Service Provider by the Third Party so frequently that it interferes with their independent medical judgement or responsibilities to their employer or patients, or that creates an actual or perceived conflict of interest;
 - iv) The HCP has all required medical licenses and is in good standing with the relevant licensing authorities, has not been sanctioned, fined or otherwise found liable for violating laws or applicable medical codes of ethics;
 - v) The services to be performed by the HCP Service Provider are not within their normal employment duties, and are not otherwise compensated by their employer, insurance providers or other means;
 - vi) Where the services relate to Patient Personal Data, the HCP is adequately briefed (e.g. on collecting and maintaining informed consent, anonymization of Personal Data) and contractually obligated to adhere to applicable data privacy regulations; and
 - vii) Where the services relate to opioids or pain management, the HCP is not registered to practice medicine in the United States of America.
- (b) Third Parties may compensate HCP Service Providers for their services where the payment is:
 - i) Aligned with the fair market value for the service(s) provided;
 - ii) In accordance with a previously executed written agreement between the Third Party and the HCP Service Provider that specifies the agreed hours and/or fees;
 - iii) In no event more than the actual time spent performing the required services, reasonable and actual preparation and briefing time, reasonable and necessary travel time, where such travel time is capped at 50% of the hourly service fee, and/or reasonable and necessary expenses as documented in the written agreement;
 - iv) After the services have been performed, and an invoice or other document confirming performance of the services and the time spent is received from the HCP Service Provider;

- v) Paid only to the party named in the written agreement with the Third Party, which may only be the HCP performing the services or a corporate entity lawfully organised and entitled to receive such payments on behalf of the HCP performing the services;
- vi) Paid in the HCP's Home Country, or the country in which the contracting corporate entity is legally established, and in the currency of that country; and
- vii) Via wire transfers or bank cheque.

10. Accurate Books and Records

- (a) Third Parties must make timely, accurate and reasonably detailed records in their books, accounts and records for all payments, transactions and items provided to HCPs by the Third Party in connection with Elvium products or services performed for or on behalf of Elvium.
- (b) Where applicable, Third Parties must provide all the necessary details relating to transfers of value in a timely manner to Elvium for transparency reporting.
- (c) To the extent required by Applicable Laws, Third Parties must publicly disclose applicable transfers of value to HCPs and healthcare organisations.