LILLY POSITION ON HEALTHCARE PROFESSIONAL (HCP) AND HEALTHCARE ORGANIZATION (HCO) TRANSFER OF VALUE (TOV) DISCLOSURES

BACKGROUND

The patient is at the center of everything we do at Lilly. Collaborations between HCPs, HCOs and pharmaceutical companies benefit society by promoting the discovery, development, and appropriate use of new innovative medicines that improve individual and public health. By disclosing details of our financial relationships with HCPs and HCOs, we hope to enhance patient and stakeholder trust and confidence. Despite industry-led evolution of business practices, polices for interactions, and codes of conduct, there remains a need for further education about how the industry engages with our key stakeholders, with the ultimate objective of improving patient care. In general, there continues to be a concern, among some parties, that industry relationships with HCPs and HCOs may no longer be trustworthy. This has resulted in the continued emergence of disclosure measures aimed at ensuring the maintenance of public trust and the mitigation of undue influence in financial relationships with industry. Disclosing relevant data to key stakeholders is one-step toward addressing these concerns.

The desire for greater transparency is evidenced by the action taken by trade associations and governments globally to develop transparency disclosures to meet national or regional objectives. Disclosures are now prevalent in approximately 50 countries (some of which may also have local or state/province requirements) in virtually every region of the world. Generally speaking, as the public disclosure trend has evolved, all of the following factors have grown in nature: diversity of requirements; complexity of requirements and associated impact on company processes, systems, resources, etc.; level of detail of data being disclosed; legal and privacy challenges; government legislated disclosures; disclosable party scope; media, customer, and other stakeholder expectations and scrutiny; potential for dual reporting (local trade association and government legislated requirements); third-party complexities.

GENERAL POSITION

Lilly is supportive of initiatives related to the appropriate disclosure of ToV in countries in which we operate. As determined by local officials, we support both voluntary industry-led disclosures adopted by local trade associations, as well as government legislated disclosures. Such disclosure requirements may apply at the local, state/province, region, or national levels. We support a consistent national or regional approach vs. varying disclosure requirements, which create significant operational challenges for industry, HCPs, and HCOs. These frameworks involve the public disclosure of data related to direct and indirect forms of ToV provided through engagement with HCPs and HCOs, including interactions pertaining to conducting Research and Development (R&D) activities. Lilly believes HCPs should be compensated at a fair market rate for their time and expertise whether they are scientists helping to research a potential new treatment, HCPs advising us on medical and scientific matters, or physicians conducting an educational program for us with their peers. By disclosing our financial relationships with HCPs and HCOs, patients, caregivers, and other key stakeholders can better see and understand the collaborations and interactions their own medical professionals have with us.

Transparency and disclosure efforts should focus on the low volume material value financial exchanges related to key commercial and research-related engagement activities. For HCPs, examples include, as permitted by local regulations: contracted service fees and expense reimbursement for educational, advising, and consulting, etc. activities, sponsored individual registration fees to attend professional congresses or conferences, and travel and accommodation related to executing contractual obligations or attending certain sponsored meetings/events. For HCOs, examples include, as permitted by local regulations: congress or conference sponsorships, grants and donations, and R&D (at aggregate level). Financial relationships should be disclosed publically at levels that are

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meaningful and improve the understanding of the interactions between industry and HCPs and HCOs to benefit patients. Broadly, Lilly supports disclosure frameworks that:

1. Are respectful of local laws and social/cultural norms, including intellectual property, trade secret, and competition laws, as well as privacy rights of reportable or covered recipients;
2. Have a clear and established objective that addresses a key stakeholder concern(s);
3. Are consistent with Lilly's compliance policies and industry codes of conduct;
4. Do not undermine Lilly's ability to compete effectively;
5. Ensure information shared, and associated rationale, are communicated with appropriate context and are easily understood by the public and stakeholders;
6. Provide insight into the appropriate relationship between industry, HCPs, and HCOs;
7. Offer adequate readiness time for industry to implement, including use of a pilot period to test data collection and reporting processes and systems;
8. Demonstrate the disclosure owner has strong ownership, resources, and commitment to lead and support the success of the initiative.

R&D TOV DISCLOSURE

The lifeblood of the pharmaceutical industry is bringing new solutions that meet unmet patient needs to market. Disclosing such information allows companies to demonstrate insight into innovative R&D activities. While we support the disclosure of R&D-related ToV, due to the sensitive nature of this information, the disclosure owner must take appropriate steps to ensure all applicable local intellectual property, trade secret, and competition laws are carefully considered. In addition, attribution of disclosure to a single or a group of HCPs and or HCOs may be misleading for R&D activities versus consulting or speaking activities, as funds are used to conduct clinical research. Given the above points, we support aggregate level R&D ToV disclosure. This can be comprised of pre-clinical and basic research, clinical research phases 1-4 (including observational trials and investigator-initiated trials), clinical trial start up meetings (travel & accommodation, fee for service, and miscellaneous expense reimbursements), interventional and non-interventional studies.

DISCLOSURE OWNER RESPONSIBILITIES

As catalysts for the development of frameworks, disclosure owners bear significant leadership responsibility to ensure the integrity and the success of the initiative for all stakeholders. Owners must embrace this role and fully commit to it via investing appropriate time, funding, and resources. The impact and success of the disclosure is ultimately a direct result of the actions the owner did or did not take. The owner should establish clear and meaningful disclosure objectives that are consistent with the industry compliance standards, do not undermine the ability of companies to compete effectively (applies to all pharmaceutical companies whether national, multi-national, innovative, biosimilar, or generic), and provide insight into the appropriate relationship between industry, HCPs, and HCOs. Early in the planning process, the owner should strive to gain buy-in and support from all key stakeholders – including the disclosable parties. It is key to make the construct a collective "we" initiative vs. an "us" (industry only) initiative. A formal project plan should be developed to establish realistic implementation timelines (a minimum of 18-24 month readiness period to begin data collection upon formal approval of the initiative and formal pilot testing period). The owner should utilize formal working groups comprised of industry experts and key stakeholders to develop and support the disclosure via the creation of robust plans for change management, communication, training, and stakeholder/customer/media outreach. The owner must commit to establishing clear requirements, templates, guidance, reference and training materials, FAQs, and other support resources. The owner should also develop an automated central platform for industry to submit data, allow HCPs and HCOs to preview their data prior to disclosure, efficiently process HCP and HCO inquiries/disputes, and publicly disclose data.

NON-DISCLOSABLE DATA

Whether we agree or disagree with inclusion, Lilly reports all transactions mandated by local legislation or trade association disclosures to which we are party. Various forms of public disclosure reports have emerged. Disclosure owners assess their environments and/or benchmark with other countries to design their disclosure. In some instances, disclosure owners propose reporting high volume low value engagement interactions that we do not support. Our rationale for not supporting can include one or more of the following factors: a category is an uncommon disclosable item, an item lacks relevancy to stakeholders, or disclosure of such an item presents undue

administrative and operational burden on companies, HCPs, or HCOs, which outweighs perceived stakeholder value in disclosing. In cases where we are not generally supportive, we seek to collaborate with the disclosure owner, industry colleagues, and key stakeholders to align on an optimal approach. Subject to local legal requirements or unique local circumstances, Lilly generally does not support the disclosure of value related to the following items: food and beverage, samples intended for patient use, HCP and patient education materials, items of medical utility (article reprints, information-related items, textbooks, wall charts, anatomical models, etc.), payments related to blinded market research, or meeting/event overhead expenses (costs related to production, meeting planning companies, conference room rental, audio/visual, etc.)

CROSS-BORDER REPORTING

Due to the growing global nature of our work, industry and HCP interactions may result in HCPs receiving ToV outside of their "home" country where they are licensed, practice medicine, or reside. For example, a company may decide to sponsor an HCP to attend an international medical conference that takes place outside of their "home" country. In such a situation, in the course of attending the event in a "host" country, the HCP will likely receive the benefit of indirect ToV in the form of company paid travel, transportation, and hotel accommodation. Lilly feels it is important to provide stakeholders with a comprehensive data set for disclosable parties, regardless of where the benefit of the ToV is realized, in the "home" or "host" country. This methodology ensures stakeholders have the full perspective of our relationships with disclosable parties and allows them to make informed assessments.

NOTICE AND CONSENT

We fully support and exercise great diligence in ensuring compliance with relevant local legal and privacy regulations such as the European Union General Data Protection Regulation. As a general rule, transparency notice and consent is required to be provided to HCPs (and HCOs as applicable in some counties) for non-legislated disclosures, often referred to as voluntary, industry trade association-led disclosures. Under such disclosures, in most countries (local laws may vary) HCPs have a free choice as to how they prefer their data be disclosed, at the named individual level or at an unnamed aggregate level. In some countries, where stricter legal requirements apply, transparency consent may not be required, however, transparency disclosure notice must still be provided. Transparency disclosure notice and consent apply for all activities in scope for transparency reporting. Providing notice and collecting consent for disclosure protects the legitimate privacy interests of HCPs and ensures we comply with relevant privacy laws and regulations. Typically, transparency consent refers to the written authorization obtained from HCPs that describes the signed and dated permission that an HCP grants to disclose their individual data on a disclosure report. Generally, government legislated disclosures do not afford such free choice as data is automatically disclosed at the named individual level. Transparency disclosure notice relates to written documentation provided to HCPs that describes: nature of disclosure (including name, location, timing, the duration data will remain in public domain, etc.); information on how we will collect and use data; reasons the information will be shared; where HCP data is processed, stored, and secured; HCP rights and choices; how HCPs can contact us or submit a complaint.

DISCLOSURE CYCLE

The disclosure cycle refers to the data collection and reporting readiness periods, which are mandated by disclosure requirements. Data collection periods can vary in frequency (quarterly, semi-annually, annually, etc.) from one disclosure to another, however most are annual. The reporting readiness period refers to the amount of time (three months, six months, etc.) afforded to companies to analyze, validate, and report the data. We support an annual disclosure cycle, with data collection occurring from January 1 through December 31. Disclosures that are more frequent are uncommon, present significant operational challenges for companies, HCPs, and HCOs, and have not been of interest to stakeholders. Additionally, companies should have a minimum of six months from the end of the data collection period to publicly disclose the data. This allows for adequate time to collect, consolidate, analyze, validate, and report the data. This serves to ensure all data is timely, accurate, and complete prior to disclosing, thus preserving the integrity of the disclosure.

DISCLOSURE PLATFORM/LOCATION

The disclosure platform/location plays a key role in demonstrating the credibility of the initiative to key stakeholders. As a result, it is imperative to present data in a central, organized, and easy to understand manner that clearly

demonstrates achievement of key objectives. Providing stakeholders with a centralized “one-stop shop” location to view industry data is critical for a positive stakeholder experience. The goal should be to make it as easy as possible for stakeholders to locate and assess data. This approach alleviates the need to search for data, which can create frustration. We support frameworks where the disclosure owner has responsibility for developing and owning an automated disclosure platform. In this scenario, companies simply submit their data to the disclosure owner for processing and reporting. If such an option is not viable, companies should be allowed to securely disclose data on an existing central company website via secure PDF file or on local websites in a similar manner. The owner must ensure an appropriate communication plan is in place to inform stakeholders where company data can be found. We recommend the owner place links to individual company reports on their website to facilitate stakeholder review.