

Eli Lilly B-H d.o.o.

2025 EFPIA: Metodologija primjenjena u provođenju obaveza iz Kodeksa EFPIA-e o javnom objavljivanju podataka

Uvod

Ovdje su opisane metode koje se koriste kako bi se ispunile obaveze iz EFPIA Kodeksa o javnom objavljivanju podataka za zdravstvene radnike i zdravstvene organizacije.

Izvještaj se ne odnosi na udruženja pacijenata, budući da se obaveze izvještavanja u tom smislu ispunjavaju u okviru EFPIA-ina Kodeksa za udruženja pacijenata.

Izvještaj o prenosu vrijednosti objavljuje se za kalendarsku godinu, u lokalnoj valuti (BAM).

Ova metodologija odnosi se na Bosnu i Hercegovinu.

Definicije

- **Primatelji:** Definicije zdravstvenih radnika i zdravstvenih organizacija općenito slijede definicije EFPIA-e. Prije pojedinačne objave podataka primatelja potrebno je dobiti saglasnost svakog zdravstvenog radnika za javnu objavu prenosa vrijednosti, dok se u slučaju zdravstvene organizacije ti propisi ne primjenjuju. Saglasnost zdravstvenih radnika pribavlja se i u slučaju kada su oni jedini zaposlenici (ili vlasnici bez zaposlenika) u vlastitoj zdravstvenoj organizaciji.
- **Vrste prenosa vrijednosti:** donacije i bespovratna sredstva, doprinos troškovima događaja, naknade za usluge i savjetovanje, istraživanje i razvoj (I&R), ostalo.

Opseg javnog objavljivanja

- Izvještaj obuhvata prenose vrijednosti pružene zdravstvenim radnicima i zdravstvenim organizacijama u toku naznačene kalendarske godine.
- Datum u kojem se bilježi prenos vrijednosti kod naknade za uslugu jednak je datumu na dan isplate. U slučaju troškova povezanih sa sastancima, datum prenosa vrijednosti jednak je datumu (datumima) održavanja sastanka.
- Donacije zdravstvenim organizacijama, u gotovini, dobrima ili neke druge vrste (na primjer donacije proizvoda) obuhvaćene su izvještajem. Sva sponzorstva vezana za događanja koja organizuje zdravstvena organizacija ili treća strana u ime zdravstvene organizacije također su obuhvaćena.
- Podaci o prenosima vrijednosti zdravstvenim organizacijama objavljuju se pojedinačno. Ukoliko Lilly podupire zdravstvene radnike plaćanjem troškova registracije (kotizacije), prenos vrijednosti bit će objavljen u dijelu izvještaja koji obuhvaća zdravstvene radnike, a prijavljeni iznos jednak je prosječnoj objavljenoj cijeni kotizacije.
- PDV i druge porezne obaveze isključene su iz izvještaja, osim u slučaju zdravstvenih organizacija i zdravstvenih radnika, koji sami plaćaju svoje porezne obaveze, gdje ukupan plaćeni iznos sadrži i iznos poreza odnosno PDV-a.

- Ako Lilly ne naplati registraciju, ti se troškovi ne uzimaju u obzir pri izračunu prosječnih iznosa. Trošak nenaplative smještaja nije uračunat u prosječnim iznosima prenosa vrijednosti.
- Prekogranične aktivnosti: Bez obzira na to događaju li se prenosi vrijednosti u predmetnoj državi ili izvan nje, objavljivanje se vrši u državi u kojoj primatelj, zdravstveni radnik ima primarnu ordinaciju, odnosno u državi sjedišta ako je primatelj zdravstvena organizacija.
- Objavljivanje povezano sa istraživanjem i razvojem sadrži prenose vrijednosti zdravstvenim radnicima i zdravstvenim organizacijama u planiranju i provođenju: (i) nekliničkih ispitivanja (kako ih definiraju Principi dobre laboratorijske prakse OECD-a); (ii) kliničkih ispitivanja (kako ih definira Direktiva 2001/20/EC); ili (iii) neintervencijskih ispitivanja prospektivne prirode (Odjeljak 15.1 Kodeksa za zdravstvene radnike). Aktivnosti vezane uz istraživanje i razvoj vodi i koordinira kompanija Eli Lilly globalno. Podaci o prenosima vrijednosti bit će zbirno objavljeni.

Posebna razmatranja

- Jedinствeni identifikator države: Kategorija u kojoj se objavljuju prenosi vrijednosti određuje se na temelju saglasnosti zdravstvenog radnika za javnu objavu.
- Samostalno zaposleni zdravstveni radnik: Saglasnost zdravstvenih radnika pribavlja se i u slučaju kada su oni jedini zaposlenici (ili vlasnici bez zaposlenika) u vlastitoj zdravstvenoj organizaciji radi transparentnog izvještavanja u predlošku namijenjenom za zdravstvene radnike.
- Višegodišnji ugovori: Za prenose vrijednosti nastale na temelju naknade za usluge i one za troškove povezane sa sastancima, stvarni se iznosi odnose na isplate i/ili povrat troškova za prevoz (avion, autobus, voz, lično vozilo).
- Posebnosti države: Na troškove kotizacije za sudjelovanje, smještaj i grupni prevoz primjenjuju se prosječne vrijednosti. Troškovi nenaplative registracije ne uračunavaju se u izračun prosječnih iznosa. Trošak nenaplativog smještaja nije uračunat u prosječnim iznosima prenosa vrijednosti.
- Provjere kvalitete: Nakon objavljivanja, ispravke izvještaja, odnosno zahtjevi zdravstvenog radnika/zdravstvene organizacije za promjenom statusa saglasnosti ili ispravci podataka mogu zahtijevati ažuriranje javno dostupnih izvještaja. Nakon unosa izmjena javno dostupne izvještaje će možda trebati ažurirati kako bi odražavali te izmjene.

Pravna osnova za zaštitu podataka

- Prikupljanje saglasnosti (uklj. povlačenje saglasnosti): Prije pojedinačne objave podataka potrebno je dobiti saglasnost svakog zdravstvenog radnika. Ukoliko je zdravstveni radnik dao saglasnost, svi se prenosi vrijednosti objavljuju pod njegovim imenom i prezimenom. U slučajevima kad se saglasnost neće moći pribaviti, podaci će se objaviti zbirno, bez otkrivanja identiteta primatelja.
 - o Djelimična saglasnost: Djelimična saglasnost (objavljivanje prenosa vrijednosti od angažmana do angažmana) nije moguća.

- Legitimni interes (uklj. test uravnoteženja, pravo na prigovor): Kategorija u kojoj se objavljuju prenosi vrijednosti određuje se na temelju saglasnosti zdravstvenog radnika. Za zdravstvene organizacije saglasnost nije obavezna.

Oblik javnog objavljivanja

- Datum objave: Datum objave jednak je datumu generiranja izvještaja u internim sistemima. Uobičajeni period Objavljivanja podataka o Prenosu Vrijednosti određen je u vremenskom intervalu od 20. juna do najkasnije 30. juna svake godine, za podatke iz prethodne godine.
- Platforma za objavljivanje: [Transparent Payments to Healthcare Providers](#)
- Jezik objavljivanja: bosanski i engleski

Financijski podaci o javnom objavljivanju

- Valuta: Izvještaji se objavljuju u lokalnoj valuti (BAM).
- PDV uključen ili isključen: PDV i druge porezne obaveze isključene su iz izvještaja, osim u slučaju zdravstvenih organizacija i zdravstvenih radnika koji porezne obaveze plaćaju sami gdje ukupan plaćeni iznos sadrži i iznos poreza odnosno PDV-a.
- Pravila izračuna: Iznosi objavljeni u izvještaju nisu zaokruženi na najbliži cijeli broj, već predstavljaju stvarne troškove.
- Na troškove kotizacije, smještaja i grupnog prevoza primjenjuju se prosječne vrijednosti.

Dodatne informacije

Nakon objave izvještaja, zdravstveni radnici/zdravstvene organizacije mogu zatražiti izmjenu sadržaja ili ispravak podataka te ažuriranje javno dostupnog izvještaja. Nakon svake izmjene javno dostupni izvještaj mora biti ažuriran i mora odražavati sve promjene.

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2025 EFPIA: Methodological Note – Eli Lilly B-H d.o.o.

Introduction

This document describes the methods used to fulfil the obligations under the EFPIA Disclosure Code for healthcare professionals and healthcare organisations.

Report do not cover patient associations, as reporting obligations in this regard are fulfilled under the EFPIA Patient Organisation Code.

Report on transfers of value are published for the calendar year, in local currency (BAM). This methodological note applies to Bosnia and Herzegovina.

Definitions

- Recipients: Definitions of healthcare professionals and healthcare organisations generally follow EFPIA definitions. Prior to the individual disclosure of data of the recipient, consent must be obtained from each healthcare professional for the public disclosure of transfers of value, whereas these requirements do not apply in the case of healthcare organizations. Consent of healthcare professionals is also required when they are the sole employees (or owners without employees) in their own healthcare organisation.
- Types of transfers of value: donations and grants, contribution to costs of events, fees for services and consultancy, research and development (R&D), other.

Scope of Disclosure

- Report covers transfers of value provided to healthcare professionals and healthcare organisations during the given calendar year.
- The date recorded for a transfer of value for a fee for service is equal to the payment date. For costs related to meetings, the date of the transfer of value equals the date(s) of the event/meeting.
- Donations to healthcare organisations, in cash, in kind or otherwise (e.g. product donations), are covered by the report. All sponsorships related to events organised by a healthcare organisation or by a third party on behalf of a healthcare organisation are also covered.
- Transfers of value to healthcare organisations are disclosed individually. Where Lilly supports healthcare professionals by paying registration (registration fee) costs, the transfer of value will be disclosed in the section of the report covering healthcare professionals, and the reported amount equals the average published registration fee.
- VAT and other tax obligations are excluded from the report, except in the case of healthcare organisations and healthcare professionals who settle their own tax obligations where the total amount paid also includes the applicable tax or VAT.
- If Lilly does not charge for registration, these costs are not taken into account when calculating average amounts. The cost of complimentary accommodation is not included in average transfer of value amounts.

- Cross-border activities: Regardless of whether transfers of value occur in or outside the country in question, disclosure is made in the country where the recipient healthcare professional has their primary practice address, or in the country of the registered seat if the recipient is a healthcare organisation.
- R&D disclosure includes transfers of value to healthcare professionals and healthcare organisations in the planning and conduct of: (i) non-clinical studies (as defined by OECD Principles of Good Laboratory Practice); (ii) clinical trials (as defined by Directive 2001/20/EC); or (iii) non-interventional studies of a prospective nature (Section 15.1 of the Healthcare Professional Code). R&D activities are managed and coordinated by Eli Lilly globally. Transfers of value data will be disclosed in aggregate.

Specific Considerations

- Country unique identifier: The category in which transfers of value are disclosed is determined on the basis of the healthcare professional's consent for public disclosure.
- Self-incorporated healthcare professional: Consent of healthcare professionals is also required when they are the sole employees (or owners without employees) in their own healthcare organisation, for the purpose of transparent reporting in the template designed for healthcare professionals.
- Multi-year agreements: For transfers of value arising from fees for services and those for costs related to meetings, actual amounts relate to payments and/or reimbursement of transport costs (air, bus, train, private vehicle).
- Country specificities: Average values apply to registration fees, accommodation and group transport. Complimentary registration costs are not taken into account when calculating average amounts. The cost of complimentary accommodation is not included in average transfer of value amounts.
- Quality checks: After publication, report corrections or requests by healthcare professionals/healthcare organisations for a change of consent status or data corrections may require updates to publicly available reports. Once revisions are made, the publicly available reports may need to be updated to reflect the changes.

Legal Basis for Data Protection

- Consent collection (incl. consent withdrawal): Prior to individual publication of data, consent must be obtained from each healthcare professional. If the healthcare professional has given consent, all transfers of value are published under their name and surname. In cases where consent cannot be obtained, the data will be published in aggregate, without disclosing the identity of the recipient.
 - o Partial consent: Partial consent (disclosure of transfers of value on an engagement-by-engagement basis) is not possible.
- Legitimate interest (incl. balancing test, right to object): The category in which transfers of value are disclosed is determined on the basis of the healthcare professional's consent. Consent is not required for healthcare organizations.

Form of Disclosure

- Date of publication: The publication date is equal to the date the report is generated via internal systems. The common reporting period for disclosure of ToVs is set during the time interval from 20th to 30th June each year at the latest, for the ToVs from the previous year.
- Disclosure platform: Transparent Payments to Healthcare Providers (<https://www.lilly.com/eu/transparent-payments-to-healthcare-providers>)
- Disclosure language: Bosnian and English.

Disclosure Financial Data

- Currency: Reports are published in local currency (BAM).
- VAT included or excluded: VAT and other tax obligations are excluded from the report, except in the case of healthcare organisations and healthcare professionals who settle their own tax obligations where the total amount paid also includes the applicable tax or VAT.
- Calculation rules: The amounts disclosed in the report are not rounded to the nearest whole number, but reflect the actual costs incurred.
- Average values apply to registration fees, accommodation and group transport.

Additional Information

After the publication of the report, healthcare professionals/healthcare organisations may request a change of content or correction of data and an update to the publicly available report. After each amendment, the publicly available report must be updated and must reflect all changes.

ANNEX A - STANDARDISED DISCLOSURE TEMPLATE											Date of publication:	
	Full Name	HCP: City of Principal Practice HCO: city where registered	Country of Principal Practice	Principal Practice Address	Unique country Identifier OPTIONAL	Contribution to costs of Events			Fee for service and consultancy		TOTAL OPTIONAL	
						Donations and Grants to HCOs	Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees		Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract
INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up. Information should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
HCPs	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
Aggregate amount attributable to transfers of value to such Recipients						N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Optional
Number of Recipients in aggregate disclosure						N/A	N/A	number	number	number	number	Optional
% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed						N/A	N/A	%	%	%	%	N/A
INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up. Information should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
HCOs	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
Aggregate amount attributable to transfers of value to such Recipients						Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Optional
Number of Recipients in aggregate disclosure						number	number	number	number	number	number	Optional
% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed						%	%	%	%	%	%	N/A
AGGREGATE DISCLOSURE												
ROAD	Transfers of Value re Research & Development as defined in the EFPIA Code of Practice										TOTAL AMOUNT	OPTIONAL

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