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| Na osnovučlana 18. stav 1. tačka 3. Statuta, SkupštinaUdruženjainovativnihproizvođačalijekova u Bosni i Hercegovini, nasjedniciodržanoj18.12.2020. godine u Sarajevu, donijela je: | Pursuant to Article 18, paragraph 1, item 3 of the Articles of Association, the Assembly of the Association of Innovative Drug Manufacturers in Bosnia and Herzegovina, at a session held on 18 December 2020 in Sarajevo, adopted the following: |
| **KODEKS PONAŠANJA INOVATIVNIH PROIZVOĐAČA LIJEKOVA** | **CODE OF CONDUCT OF INOVATIVE PHARMACEUTICAL MANUFACTURERS** |

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| **PREAMBULA** | **PREAMBLE** |
| Udruženjeinovativnihproizvođačalijekova u Bosni i Hercegovini (dalje u tekstu: **Udruženje**) je dobrovoljno, samostalno, nestranačko, nevladino i neprofitnoudruženječijičlanovisupravnalicanakojaglasidozvola za stavljanjeinovativnihlijekova u promet u Bosni i Hercegovini (u daljemtekstu: **BiH**), a koji suregistrovani i posluju u BiH u skladusavažećimpropisima. | The Association of Innovative Pharmaceutical Manufacturers in Bosnia and Herzegovina (hereinafter: **the Association**) is a voluntary, independent, non-partisan, non-governmental and non-profit association whose members are legal entities that have been authorised to market innovative medicinesin Bosnia and Herzegovina (hereinafter: **BiH**), and registered to operate in BiH in accordance with applicable legislation. |
| Udruženje je članicaEuropskefederacijefarmaceutskeindustrije i njezinihudruženja (engl. European Federation of Pharmaceutical Industries and Associations; dalje u tekstu: **EFPIA**), jednog od vodećihtijelaistraživačkiorijentisanefarmaceutskeindustrije u Europi. | The Association is a member of the European Federation of Pharmaceutical Industries and Associations (hereinafter: **EFPIA**), one of the leading bodies of the research-oriented pharmaceutical industry in Europe. |
| Ciljevi i djelatnostiUdruženjasuutvrđeninjegovimStatutomovjerenimodstraneMinistarstvapravdeBosne i Hercegovine (u daljemtekstu: **Ministarstvo**) pod brojem UP 08-07-1-220/14 dana 02.09.2014., tenjegovimkasnijimizmjenama i dopunama, pričemu jemisijaUdruženja je poticanje i promocijatehnološkog i ekonomskograzvojaistraživačkiusmjerenihproizvođačalijekova koji djeluju u BiH otkrivanjem, razvijanjem i stavljanjem u prometnovihlijekovaradipoboljšanjakvalitetezdravljaljudi i kvalitetezdravstvenezaštite. | The Association’s objectives and business activities have been defined by the Articles of Association, number: UP 08-07-1-220/14, certified by the Ministry of Justice of BiH (hereinafter: the **Ministry**) on 2 September 2014, and its subsequent amendments, while the mission of the Association is to encourage and promote technological and economic development of the research-oriented manufacturers of medicinal products operating in the territory of Bosnia and Herzegovina, by discovering, developing and placing into circulation the new medicinal products in order to improve people’s health and healthcare. |
| EFPIA Kodeksponašanja, u skladusakojimsuse dužniponašatiUdruženje i njegovičlanovi, predstavljazbirkuetičkihpraviladogovorenihodstranečlanova EFPIA vezano za promocijulijekovazdravstvenimradnicimatesaradnjusaZdravstvenimradnicima, Zdravstvenimorganizacijama i Organizacijamapacijenata bez obziranavrstukomunikacije i saradnje (tradicionalne i digitalne), a kaojemstvo da se oveaktivnostiprovodepoštujućinajstrožijeetičkeprincipeprofesionalizma i odgovornosti. | The EFPIA Code of Practice that the Association and its members are required to comply with, constitutes a collection of ethical rules agreed by EFPIA members for the promotion of medicinal products to Healthcare Professionals and the interactions withHealthcare Professionals, Healthcare Organizations and Patient Organizations,regardless of the form of communication and interactions (traditional and digital), with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. |
| Etičnoponašanjeprilikomoglašavanjalijekova je ključno za ostvarenjenavedenemisijejer je davanjepotpunih, preciznih, objektivnih, tačnih i znanstvenoutemeljenihinformacija o lijekovimastručnojjavnosti (zdravstvenimradnicima) preduslov za uobličavanjevlastitogstava o terapijskojvrijednostilijekaprilikompropisivanjalijekovabolesnicima. | Ethical conduct in promotion of the medicinal products is essential for the implementation of the mission, because providing the professional public (healthcare professionals) with full, precise, objective, accurate and science-based information about medicinal products is a prerequisite for forming his/heropinion about a therapeutic value of a medicinal product when prescribingmedications to patients. |
| UsvajanjemovogKodeksaponašanja u postupkuoglašavanjalijekova (dalje u tekstu: **Kodeks**) premastručnojjavnosti, Udruženjeuspostavljavidljiva i jasnapravila i postupkekojihsu se Kompaniječlanicedužnipridržavati u provođenjuaktivnostioglašavanjalijekovapremaZdravstvenimradnicima, kakosuoninižedefinirani u članu.(Definicije) ovogKodeksa, nanačin koji će u najvećojmogućojmjeriosiguratiprofesionalno i etičnoponašanjekao i transparentnostzdravstvenihradnika u postupanjuradipostizanjaracionalnefarmakoterapije i osiguranjakvalitetnezdravstvenezaštiteusmjerenenadobrobitpacijenata u BiH. | By adopting this Code of Conduct concerning the procedure for promotion of medicinal products(hereinafter: the **Code**) to the professional public, the Association shall establish transparent and clear rules and procedures that the Member Companies are required to apply to the promotion of medicinal products to Healthcare Professionals in a manner as defined under Article 2(Definitions) hereof, so as to secure to the greatest extent possible the professional and ethical conduct and transparency in the activities of the Healthcare Professionals with a view to reaching a rational pharmacotherapy and providing a high quality healthcare focused on wellbeing of patients in Bosnia and Herzegovina. |
| Saradnjaizmeđuinovativnihproizvođačalijekova i Zdravstvenihradnika i Zdravstvenihorganizacija, kakosuonidefiniraniniže u članu. (Definicije) ovogKodeksa, nesumnjivoimadubinski i pozitivanučinaknakvalitetuterapijskihpostupakautemeljenihnaorijentisanostipremabolesnicima i njihovimpotrebama, ali i navrijednostbudućihistraživanja. Istovremeno, nezavisnostZdravstvenihradnika u odlučivanju o zdravstvenimpostupcima, štouključuje i odluke o farmakoterapiji, jedan je od temeljnihzahtjevasvakogzdravstvenogsistema. Upravo u svrhuotklanjanjasumnji o pristranosti/sukobuinteresaZdravstvenihradnika i Zdravstvenihorganizacija u njihovimodnosimasainovativnimproizvođačimalijekova, ovim se Kodeksom, izmeđuostalog, osiguravaprimjerenaobaviještenostjavnosti o saradnjiinovativnihproizvođačalijekova i Zdravstvenihradnika i Zdravstvenihorganizacijakojoj je svrha ne samoosiguranjetransparentnosti i jačanjeintegritetasudionika toga odnosa, nego i osiguranjeobjektivnostikodprosuđivanja o postojanjuneprimjerenogutjecajailipotencijalnogsukobainteresa. | Interactions between the innovativepharmaceutical manufactures and Healthcare Professionals and Healthcare Organisationsas defined in Article 2 (Definitions) hereunder undoubtedly has adeep and positive impact on the quality of therapeutic procedures that are focused on patients and their needs but also on values of the future researches. At the same time, independence of Healthcare Professionals in making decisions on healthcare procedures, including decisions on pharmacotherapy, is one of the basic requirements of any healthcare system. For the avoidance of doubt about partiality/conflict of interest of Healthcare Professionals and Healthcare Organisations in their interactions with the innovative pharmaceutical manufacturers, this Code shall, *inter alia*, make sure that the public is properly informed about interactions between the innovative pharmaceutical manufacturers and Healthcare Professionals and Healthcare Organisations, with a viewto securing not only transparency and enhancedintegrity of participants in such interactions, but also objectivity in assessing the existence of inappropriate influence and possible conflict of interest. |
| Udruženjepotičekonkurencijuizmeđuinovativnihproizvođačalijekova. StogasvrhaovogaKodeksanijeograničavatiiliuticatinaoglašavanjelijekovakoje se provodi u skladu s dobrimposlovnimobičajima i ne predstavljanepoštenotržišnonatjecanje. SvrhaovogKodeksa je osigurati da se Kompaniječlanice u provođenjuaktivnostioglašavanjalijekovaponašajupošteno i odgovorno, da izbjegavajupraksudovođenja u zabludu i potencijalnisukobinteresasaZdravstvenimradnicima, i da uvijekpostupaju u skladusavažećimpropisima u BiH, vodećiračuna o političkom i socijalnomokruženju u kojemdjeluju. CiljovogKodeksa je osiguratiuslove u kojimagrađanimogubitisigurni da je odabirlijekaodstraneZdravstvenogradnikaizvršennaosnovukarakteristikasvakogproizvoda i individualnihpotrebasvakogpacijenta. | The Association encourages competitiveness between the innovative pharmaceutical manufacturers. Therefore, it is not the purpose of this Code to restrict or influence promotion of medicinal productswhich is conducted in accordance with good business practice and which does not constitute an unfair market competition. The purpose of this Code is to secure that, while carrying out the medicinal product promotion activities, the Member Companies act honestly and responsibly, avoid deceptive practices and potential conflict of interest with the Healthcare Professionals, and in compliance with the applicable legislation of Bosnia and Herzegovina, taking into account the political and social environment in which they operate. This Code is aimed at securing the conditions under which the citizens may be certain that the selection of a medicinal product by a healthcare professional was made based on the properties of any product and individual needs of every individual patient. |
| Na istinačinregulisana je i saradnjaKompanijačlanicasaOrganizacijamapacijenata, kakosu one nižedefinisane u članu.(Definicije) ovogKodeksa, od kojihstičusaznanjakako je živjeti s određenimoboljenjem, kakopružitinjegu, kakooboljenjeutječenapacijente, njihovekarijere i porodice i kakolijekovi i drugitretmanimogupromijenitinjihovkvalitetživota i zadovoljitinjihovepotrebe. | In the same way, Article 2 (Definitions) of this Code provides for the interactions of Member Companies with Patient Organizations from which they acquire knowledge about how to live with a certain disease, how to provide care, how the disease affects patients, their careers and families and how medications and other treatments can change their quality of life and meet their needs. |
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| **PRVI DIO: OPĆE ODREDBE** | **PART I: GENERAL PROVISIONS** |
| 1. **PRIMJENA KODEKSA** | 1. **THE SCOPE OF APPLICATION OF THE CODE OF CONDUCT** |
| * 1. OvajKodeks se primjenjujenaoglašavanjestručnojjavnostitj. oglašavanjeLijekova koji se isključivoizdajunarecept, nakomunikacijuizmeđuZdravstvenihradnika i Proizvođačalijekovatimpovodom, nasaradnjuUdruženja i/ilinjegovihKompanijačlanicasaOrganizacijamaPacijenatanapodručjuzdravstvene i socijalnezaštite i PrenosvrijednostiizvršenodstraneKompanijačlanicapremaZdravstvenimradnicima, Zdravstvenimorganizacijama i Organizacijamapacijenata. | * 1. This Code shall apply to the promotion of medicinal products to the professional public, i.e. promotion of prescription-only-medicines(POM), including communication between the Healthcare Professionals and medicinal product manufacturers related thereto, interactions with the Association and/or its Member Companies with Patient Organizations in the field of health and social care and Transfers of Value (ToV) by Member Companies to Healthcare Professionals, Healthcare Organizations and Patient Organizations. |
| * 1. OvajKodeks se **ne primjenjuje**nadopušteneaktivnostioglašavanjalijekovaširojjavnosti u skladusaZakonom o lijekovima i medicinskimsredstvima BIH i Pravilnikom o oglašavanjulijekova i medicinskihsredstava BIH kojima se propisujunačin(i) oglašavanjaLijekova, kaoninasljedećeaktivnosti: | * 1. This Code shall **not apply** to the permitted promotion of medicinal products to the general public in accordance with the Law on Medicinal Products and Medicinal Devices of BiH and the Rulebook on Advertising the Medicinal Products and Medicinal Devices of BiH which stipulate the method(s) of advertising the medicinal products, and nor shall it apply to the following activities: |
| 1. obaveznooznačavanjeLijekova, uputstvo za pacijente i sažetakglavnihkarakteristikalijeka koji suodobreni u postupkudavanjadozvole za stavljanjeLijeka u promet, | 1. mandatory labelling onMedicinal Products, and accompanying package leaflets and summary of productcharacteristics approved under market authorisation granting procedure, |
| 1. korespondencijukojoj je pridruženmaterijal koji ne služi u promotivnesvrhe, a kojom se dajeodgovornaodređenopitanje u vezi s pojedinimLijekom, | 1. correspondence including non-promotional material, which provides replies made in response to specific enquiriesrelating to a certain Medicinal Product, |
| 1. informativneobjave o činjenicama i stručnimaterijali koji se odnose, primjerice, napromjene u pakiranju, upozorenjananeželjenadjelovanjailidrugeizmjenjenesigurnosneinformacije, trgovačkekataloge i cjenovnikeLijekova, pod uslovom da ne sadržeelementereklamiranja, | 1. informative announcements and reference material relating, for example, to pack changes, adverse reactions warnings or other altered safety information, trade catalogues and medicinal products pricelists, provided that they do not include the advertising elements, |
| 1. svakonepristrasno, objektivnoinformisanje o bolestima, prevencijitedostupnimmetodamaliječenjapričemunijedozvoljenonavoditiodređeniLijek; | 1. any unbiased, objective information about diseases, prevention and available treatment methods provided there is no reference to specificmedicines, |
| 1. nepromotivneinformacije o ljudskomzdravljuilibolestima; | 1. non-promotional information relating to human health or diseases, |
| 1. aktivnostikojesuisključivovezane za Lijekove koji se ne izdajunarecept; | 1. activitiesrelating solely to over-the-counter medicines, |
| 1. nepromotivne, općeinformacije o proizvođačimaLijekova (primjerice, obavijestinamijenjeneinvestitorimailisadašnjim/budućimzaposlenicima), uključujućifinansijskepodatke, navode o istraživačkim i razvojnimprogramima i diskusije o zakonodavnomokruženju i mjeramakojeutičunaproizvođačaLijeka i njegoveproizvode; | 1. (g)non-promotional general information relating to the Medicinal Product Manufacturers (for example, information intended for investors or present/future employees), including financial data, information concerning research and development programmes and discussions on the legislative environment and measures affecting Medicinal Product Manufacturers and their products, |
| * 1. SveKompaniječlanicedužnesu se prvenstvenopridržavatiodredabavažećihpropisa u BiH koji uređujumaterijuoglašavanja o Lijekovima koji imajuprednostpredovimKodeksom u svimslučajevimaneslaganja u vezinjegovogtumačenjailiprimjene. | * 1. AllMember Companies shall primarily comply with the provisions of the applicable regulations in Bosnia and Herzegovina governing the medicinal product advertising activities, which have precedence over this Code in the case of any dispute arising from its interpretation or application. |
| * 1. Pored važećihpropisa u BiH, ovajKodeks se temeljinanačelimautvrđenim u sljedećimpropisima: | * 1. Apart from the applicable regulations in Bosnia and Herzegovina, this Code is also based on the principles defined in the following regulations: |
| 1. Kodeksufarmaceutsketrgovačkeprakse (engl. IFPMA Code of Practice , 2019 Revision) Međunarodnefederacijeudruženjaproizvođačalijekova (engl. International Federation of Pharmaceutical Manufacturers Associations), u primjeni od 01.01.2019., tenjegovihnaknadnihizmjena i dopuna; | 1. IFPMA Code of Practice, 2019 Revision and International Federation of Pharmaceutical Manufacturers Associations, applicable as of 1 January 2019, and its subsequent amendments; |
| 1. Direktivama EU br. 2001/83/EC i 2004/27/EC o lijekovima za humanuupotrebu (engl. Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC), i njihovimnaknadimizmjenama i dopunama. | 1. EU DirectivesNo. 2001/83/EC and 2004/27/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC), and their subsequent amendments. |
| * 1. Kompaniječlanicesuprvenstvenoodgovorne za pridržavanjeodredabaovogKodeksa, pa i u slučajukadanabilo koji načinangažirajutrećeosobe (npr. stručnesaradnike, konsultante, agencije za istraživanjetržišta, agencije za oglašavanje, agencije za odnose s javnošću i sl.) da za računKompanijačlanicaobaveposloveosmišljavanja, primjeneiliprovedbeaktivnostinavedenih u ovomKodeksu. | * 1. Member Companies are primarily responsible to comply with this Code, even ifthey, in any way whatsoever,commissiona Third Party (e.g.,medical associates, consultants, market research agencies, advertising agencies, public relations agencies, and the like),to design, implement or engagein activities covered by this Code on their behalf. |
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| 1. **DEFINICIJE** | 1. **DEFINITIONS** |
| * 1. U ovomKodeksu se koristepojmovi koji imajusljedećeznačenje: | * 1. This Code includes the terms with the following meaning: |
| 1. **Donacija**:darovanje u novcu, stvarimailiuslugamaizvršenoZdravstvenimorganizacijama i Organizacijamapacijenata( usmisluniženavedenihdefinicijacitiranihpojmova) u svrhupodrškezdravstva, naučnogistraživanjailiobrazovanja bez obavezePrimateljadonacije da Donatoruzauzvratdostavinekustvarilipružiuslugu. | 1. **Donation**: donations in cash or in kindto HealthcareOrganisations and Patient Organisations (within the meaning of the definition of terms cited hereunder) for the purpose of supporting health care, scientific research or education incurring no obligation on theRecipient to provide to the Donor any good or service in return. |
| 1. **Gostoprimstvo**:dozvoljenitroškovivezaniuzsudjelovanjeZdravstvenogRadnika i predstavnikaOrganizacijepacijenatanaSastancimaštoznačiputnitroškovi, troškovihrane i pića, smještaja i kotizacije. | 1. **Hospitality:** approved costs related to attendance at meetings by Healthcare Professionals and Patient Organisation Representatives, which include travel, food and drinks,accommodation and registration fees. |
| 1. **Kompanijačlanica**:privrednadruštva i njihovepodružnicesasjedištem u Bosni i Hercegoviniučlanjena u Udruženjekojajesuilimogubitipovezana, u smisluZakona o privrednimdruštvima, sadruštvimasasjedištemizvanBosne i Hercegovine. Za potrebeovogaKodeksa, Kompaniječlanice i sva s njimapovezanadruštvapredstavljajujedinstvenisubjektna koji se primjenjujeovajKodeksodnosno EFPIA-inikodeksinaprijednavedeni. | 1. **Member Company:** companies and their subsidiaries with their registered office in Bosnia and Herzegovina that are Association members which are or may be affiliated, for the purposes of the Law on Companies, with companies that have their registered office outside Bosnia and Herzegovina. For the purposes of this Code, Member Companies and all associated companies shall constitute a single entity to which this Code or EFPIA Codes set forth above apply. |
| 1. **Lijek:**je svakasupstancailikombinacijasupstanci, namijenjena za liječenjeilisprečavanjebolestikodljudi. U lijek se ubrajasvakasupstancailikombinacijasupstancikoje se moguprimijenitinaljudimaradipostavljanjadijagnoze, obnavljanjailimodificiranjafiziološkihfunkcija, teradipostizanjadrugihmedicinskiopravdanihciljeva. | 1. **Medicinal Product:** any substance or combination of substances, intended for treating or preventingdisease in human beings. Medicinal product includes any substance or combination of substances which may be used in or administered to human beings either with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions, and for achieving other medically reasonable goals. |
| 1. **Lokacija**:geografskomjesto u kojem se Sastanakorganizira (npr. grad) | 1. **Location:**refers to geographical location where the Meeting is organized (e.g. city, town) |
| 1. **Medicinskaedukacija:**edukacija o zdravljuljudi i o bolestimatespecifičnenepromotivneedukacije o lijekovima. | 1. **Medical education:**includes education related to human health and diseases and specific non-promotional training related to Medicinal Products |
| 1. **MedicinskiOdjel:**znanstveniodjeliliosobezadužene u okviruorganizacijskestrukturesvakeKompaniječlanice koji je zadužen za davanjeinformacija o Lijekovima, davanjesaglasnosti i vršenjenazdoranadprovođenjemNeintervencijskihispitivanjaLijekova, odobravanjepromotivnihmaterijala/aktivnosti, organizaciju i vođenjenepromotivnihsastanaka, provođenjemedicinskihedukacijaStručnihsaradnika i ostalihzaposlenika koji stupaju u kontaktsaZdravstvenimradnicima i Zdravstvenimorganizacijama; | 1. **Medical Department:**refers to a scientific service or persons entrusted within the organisational structure of any Member Company in charge of providing information about **medicinal** products, granting consents and supervising the implementation of the non-interventionalstudiesrelating to medicinal products, approving promotional materials/ activities, organising and chairing non-promotional meetings, conducting medical training for Medical Associates and other employees in contact with Healthcare Professionals and Healthcare Organisations; |
| 1. **MeđunarodniSastanak**:sastanak (u smisluniženavedenedefinicijeSastanka) koji se organizira i održavaizvanteritorijeBosne i Hercegovine. | 1. **International Meeting:** a meeting (within the meaning of the meeting definition as stated below) organised and held outside the territory of Bosnia and Herzegovina |
| 1. **Neintervencijskoispitivanjelijeka**:svakoispitivanje u kojem se ispitivaniLijekpropisuje u skladu s odobrenjem za stavljanje u promet. Uključivanjepacijenata u određeniterapijskipostupaknijeunaprijedodređenoplanomispitivanja, nego se provodi u skladusauobičajenompraksom, a propisivanjelijeka je neovisno o odluci o tome da se pacijentuključi u ispitivanje. Ne provode se dodatnidijagnostičkipostupci i postupcipraćenjapacijenata, nego se koristeepidemiološkemetode za analizuprikupljenihpodataka. | 1. **Non-interventionalstudiesinvolving medicinal products:** a study where the Medicinal Product(s) is (are) prescribed in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data |
| 1. **Oglašavanje**:svakioblikdavanjainformacija o Lijekovimaširoj i stručnojjavnostizbogpoticanjapropisivanjalijekova, njihoveopskrbe, prodaje i potrošnje u pisanom, slikovnom, zvučnom, usmenom, elektroničkomilibilokojemdrugomobliku. | 1. **Promotion:** any form of information about medicinal products provided to general or professional public which promotes the prescription, supply, sale and consumption of medicinal products, in a written, pictorial, audio, oral, electronic or any other form. |
| 1. **Organizacijapacijenata:**registrirani i neregistriranioblikorganiziranjapacijenatananeprofitnojosnovi (uključujući i krovneorganizacijekojimapripadaju) kojepredstavlja i/ilipružapodrškupacijentima i/ilinjegovateljimanapodručjuzdravstvene i socijalnezaštite u Bosni i Hercegovini, a kojadjeluju s ciljemostvarenja i zaštiteinteresasvojihčlanova koji većimdjelomčinepacijenti i/ilinjegovatelji, uključujućiudruženja i drugeformalneoblikeorganiziranjagrađana i pravnihlica koji suregistriranikodMinistarstvapravdeBosne i Hercegovine, entitetskihministarstavapravde, kantonalnihministarstvapravde, sudovailidrugih organa | 1. **Patient Organization:** a registered and unregistered form of non for profit patient organization (including umbrella organization to which it belongs) that represents and/or supports patients and/or caregivers in the field of health and social care in Bosnia and Herzegovina, operating with with the aim of achieving and protecting the interests of its members, mostly patients and/or caregivers, including associations and other formal forms of civic organizations and legal entities registered with the Ministry of Justice of Bosnia and Herzegovina, entity ministries of justice, cantonal ministries of justice, courts or other authorities |
| 1. **Osobnizdravstvenipodaci**:sveinformacijekoje se odnosenafizičko, mentalnozdravljeilinaslijeđeneilistečenegenetskekarakteristikeodređenefizičkeosobeiliosobekoju je mogućeidentificirati, uključujućipodatke o pružanjuzdravstvenihusluga, kojeotkrivajupodatke o fiziologijiilizdravstvenomstanjufizičkeosobe | 1. **Personal Health Data:** any information related to the physical, mental health or to the inherited or acquired genetic characteristics of anidentified or identifiable natural person, including the provision of health care services information, which reveal information about his or her physiology or health status |
| 1. **PredstavnikOrganizacijepacijenata:**osobakoja je ovlaštena da zastupa i izražavakolektivnestavoveOrganizacijepacijenata o određenompitanjuilipodručjubolesti. | 1. **Patient Organization Representative:** a person who is mandated to represent and express the collective views of Patient Organization on a specific issue or disease area. |
| 1. **Prenosvrijednosti:**direktniiliindirektni transfer vrijednosti, u novcu, uslugama, stvarimailinadruginačinučinjenizpromotivnihilidrugihsvrha, u vezisarazvojem i prodajomLijekova koji se izdajunareceptisključivo za upotrebukodljudi. Izravniprenosivrijednostisuoni koji kojisuizvršeniodstraneKompaniječlaniceu koristprimaoca, iliprenosivrijednostikodkoječlanvršiputemposrednika i kodkojegKompanijačlanicaznailimožeidentificiratiZdravstvenogradnikailiZdravstvenuorganizacijukojaće se ostvaritikoristodprenosavrijednosti. | 1. **Transfer of Value:** direct and indirect transfer of values, in cash, in kind or otherwise, made for promotional or other purposes, in relation to the development and sale of prescription-only **medicinal** products exclusively for human use. Direct transfers of value are those made directly by a Member for the benefit of a recipient or transfers of value made by a Member through an intermediate and whereby the Member knows or can identify the Healthcare Professional or Healthcare Organisation that will benefit from the transfer of value. |
| 1. **Prenosvrijednosti za istraživanje i razvoj**:transferivrijednostizdravstvenimradnicima i zdravstvenimorganizacijama u ciljuplaniranjailiprovođenja*(i)*nekliničkihstudija; *(ii)*kliničkaispitivanjaili*(iii)*neintervencijskihispitivanjalijeka. | 1. **Transfers of Value for research and development:** transfers of value to Health Professionals and Health Organizations for the purpose of planning or conducting (i) non-clinical **studies**; (ii) clinical trials or (iii) non-interventional studies. |
| 1. **Primatelj**:Zdravstveniradnici,ZdravstveneOrganizacije i Organizacijepacijenata (u smislunavedenihdefinicijacitiranihpojmova); | 1. **Recipient:**Healthcare Professionals and Healthcare Organisations (within the meaning of the **definitions** of terms herein provided); |
| 1. **Proizvođačlijeka**: KompanijačlanicaUdruženjainovativnihproizvođačalijekova u Bosni i Hercegovini, njegovepodružnice i sva s njimepovezanadruštva u smisluZakona o prvirednimdruštvima ("SlužbenenovineFederacijeBiH“, broj: 81/15) i njegovihkasnijihizmjena i dopuna; | 1. **Medicinal Product Manufacturer:**aMember Company of the Association of Innovative PharmaceuticalManufacturers its subsidies **and** all affiliated companies within the meaning of the Law on Companies (Official Gazette of FBiH, 81/15) and its subsequent amendments. |
| 1. **Sastanak**:stručni, promotivni, znanstveni i edukativnisastanci, kongresi, konferencije, simpoziji, manjiposlovnisastanci i drugasličnadogađanja, uključujući, ali ne ograničavajući se nasastankesavjetodavnihtijela, posjeteistraživačkimcentrimailiproizvodnimpogonimakao i planiranje i treningilisastankeispitivača koji se održavaju u okvirukliničkih i neintervencijskihispitivanjakojeorganizirailifinansiraProizvođačlijeka, ilitrećaosoba u njegovoime. | 1. **Meeting:** professional, promotional, scientific and educational meetings, congresses, conferences, symposiums, minor business meetings and other similar events including, but not **limited** to, advisory board meetings, visits to research centres or production facilities, as well as planning and training or examiners meetings held during clinical trials and non-interventionalstudies organised or financed by Medicinal Product Manufacture or a Third Party on its behalf. |
| 1. **Sponzorstvo**:novčanailinefinansijskapodrškakojuKompanijačlanicapružaZdravstvenimorganizacijama, Organizacijamapacijenatailitrećojstrani u ciljuorganiziranja, kreiranjailiizvođenjaodređeneaktivnostiuzobavezuPrimaocasponzorstva da zauzvratpružiKompanijičlaniciodređenukorist. | 1. **Sponsorship:** financial or non-financial support provided by aMember Company to Healthcare Organizations, Patient Organizations or a Third Party for the purpose of organizing, creating or performing a particular activity with the obligation of the Sponsorship Recipient to provide a benefit in return to the Company Member. |
| 1. **Stručnoadministrativnoosoblje**:osobekojevršeupravljačkefunkcije u privatnim i javnimZdravstvenimorganizacijama, kao i osobezaposlene u državnimtijelimanadležnim za primjenu i provođenjepropisafarmaceutskogsektora (naprimjer, Agencija za lijekove i medicinskasredstva, entitetska i kantonalnaministarstvazdravstva, entitetski i kantonalnizavodizdravstvenogosiguranja i sl.) i imenovane u savjetodavneorganepridržavnimtijelima i ustanovama (naprimjer, članovietičkih, stručnih i drugihpovjerenstava i sl.); | 1. **Professional Administrative Staff**: persons performing managerial functions in private and public Healthcare Organisations, including persons employed in public service bodies responsible for applying and implementing pharmaceutical regulations (e.g. Agency for Medicinal Products and Medical Devices, entity-level and cantonal-level ministries of health, entity-level and cantonal-level institutes for health insurance, and the like) and those appointed to the advisory bodies within the public servicebodies and institutions (e.g. members of ethics committees, professional and other committees, etc.); |
| 1. **Stručnisaradnik**:osobekojeobavljajuposlovepromocijeLijekova, a koji imajuvisokustručnuspremuzdravstvenogusmjerenja – uključujući i osobekojeProizvođačilijekovaangažiraju za obavljanjetihposlova, za njihovračun – kao i sviostalipredstavniciProizvođačalijekova koji stupaju u kontaktsaZdravstvenimradnicima i ZdravstvenimOrganizacijama; | 1. **Medical Associate:** personnel promoting Medicinal Products, having university healthcare degree – including persons engaged by the **Medicinal**Product Manufacturers to perform these activities on their behalf – including all other representatives of Medicinal Product Manufacturers who get into contact with Healthcare Professionals and Healthcare Organisations; |
| 1. **Uzoraklijekailimedicinskogsredstva**:uzorakmedicinskogproizvoda koji se besplatnodajekvalificiranimosobama za propisivanje/izdavanjemedicinskihproizvodakako bi se mogleupoznatisanovimmedicinskimproizvodima i stećiiskustvo u postupanjusanjima, a u skladusaPravilnikom o načinuoglašavanjalijekova i medicinskihsredstava ("SlužbeniglasnikBiH“, broj: 40/10); | 1. **Medical Sample or Medical Device Sample:** a medical sample that is provided free of charge to persons qualified to prescribe/supply medicinal products in order to get **acquainted** with new medicinal products and gain experience in handling them, in accordance with Rulebook on Advertising Medicinal Products and Medical Devices (Official Gazette of BiH, 40/10); |
| 1. **Zdravstveniradnik**:licakojaimajuobrazovanjezdravstvenogusmjerenjanamedicinskom, stomatološkom, farmaceutskomilifarmaceutsko-biohemijskomfakultetu, fakultetuzdravstvenihstudija i srednjimškolamazdravstvenogusmjerenja, a koji propisuju, prodaju, odnosnoizdajulijekove, koji vršenabavkulijekova za apoteke i drugezdravstveneustanove, odnosnoprivatnupraksuilinabilo koji druginačinutječunanabavkuiliupotrebulijekova i drugastručnalica u oblastiproizvodnje i prometalijekova i medicinskihsredstavanaveliko i malokao i osobe u organimaupravljanjazdravstvenihustanova. Zajednosastručnimosobamazaposlenim u ministarstvimazdravlja, u organizacijamazdravstvenogosiguranja i Agenciji za lijekove i medicinskasredstva BiH, tedrugiminstitucijamadržave, entiteta, kantonailinižih organa vlasti, činestručnujavnost. | 1. **Healthcare Professional –** persons with healthcare education acquired at the respective faculties of medicine, dental medicine, **pharmacy** or pharmacy-biochemistry, health sciencesor medical high schools, who prescribe, sell, supply medicinal products, and whosupply pharmacies and other healthcare institutions, including private practices, with medicinal products or who otherwise influence supply or use of medicinal products, and other professionals involved in the production and retail or wholesaleof medicinal products and medical devices, as well as persons in the healthcare institution managements, which together with professional staffin the ministries of health, in the health insurance organisations and Agency for Medicinal Products and Medical Devices of BiH, and other institutions at the state, entity, cantonal and lower levels of government, constitute the professional public. |
| 1. **ZdravstvenaOrganizacija**znači: | 1. **Healthcare Organisation** means**:** |
| * pravnaosobasasjedištem u Bosni i Hercegovinikoja je osnovana i poslujetemeljemvažećihzakona i propisa koji uređujumaterijuobavljanjazdravstvenedjelatnosti u BiH (npr. bolnice, domovizdravlja, zdravstvenicentri i institucije i slično) obrazovne i naučneorganizacijezdravstvenogusmjerenja (npr.medicinskog, stomatološkog, farmaceutsko-biokemijskog i sličnogusmjerenja) u kojima se izvodinastavni, istraživačkiiliznanstveni rad, | * a legal entity having its registered office in Bosnia and Herzegovina, established and operating based on the applicable laws and regulations governing the healthcare activities in Bosnia and Herzegovina (hospitals, healthcare centres, health centres, institutions and the like, educational and scientific healthcare organisations (e.g., in the field of medicine, dental medicine, pharmacy-biochemistry and similar field) where teaching, research or scientific activities are performed, |
| * strukovneorganizacijezdravstvenihradnika u koje se zdravstveniradniciučlanjujunaosnovupropisa o zdravstvenimprofesijama, | * vocational organisations of healthcare professionals that healthcare professionalsjoin based on the regulations on healthcare professions, |
| * udruženja i ostalioblicidobrovoljnogučlanjivanjazdravstvenihradnika,nezavisno od pravneformeorganiziranja, u svrhuostvarenjaposebnihinteresa. | * associations and other forms of voluntary membership of healthcare professionals, irrespective of the legal form of organisation, for the purpose of reaching special interests. |
| * 1. Osimakonijedrugačijenavedeno u ovomKodeksu, pojmovi koji se koriste u ovomKodeksu i pišuvelikimpočetnimslovimaimatićeznačenjekojeim je dodijeljeno u prethodnomstavku. | * 1. Unless otherwise stipulated in this Code, terms and captions in this Code shall have the meaning assigned to them in the previous paragraph. |
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| **DRUGI DIO: OSNOVNA NAČELA OGLAŠAVANJA** | **PART TWO: BASIC PRINCIPLES OF PROMOTION** |
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| 1. **ODOBRENJE ZA STAVLJANJE LIJEKA U PROMET** | 1. **MARKETING AUTHORISATION** |
| * 1. Zabranjeno je oglašavati: | * 1. It is prohibited to promote: |
| 1. Lijek koji nemadozvolu za stavljanje u promet, i | 1. medicinal productswithout marketing authorisation, and |
| 1. indikacijukojanemadozvolu za stavljanje u promet. | 1. unauthorised indications. |
| * 1. Zabranaizodredbe se ne odnosenainformiranje o gotovomLijeku koji nemaodobrenje za stavljanje u prometnastručnim i znanstvenimskupovima, te u stručnojliteraturi, uzuslov da je pokrenutpostupak za davanjeodobrenja za stavljanjeLijeka u promet, te da se koristisamouobičajenimeđunarodninezaštićeninaziv (INN) Lijeka, bez navođenjaProizvođača. Ova ograničenja se ne odnosenameđunarodneskupove koji se održavaju u Bosni i Hercegovini. | * 1. Prohibition referred to in paragraph 3.1 shall not apply to information relating to a finished medicinal product without marketing authorisation provided at the professional and scientific meetings and in the professional literature, provided that a procedure for granting marketing authorisation has been initiated, and that only a standard international non-proprietary name of the medicinal product (INN) should be used, without including the manufacturers name. These restrictions do not apply to international meetings held in Bosnia and Herzegovina |
| * 1. UkolikoProizvođačlijekaprimipitanje o neodobrenimLijekovima/indikacijama od Zdravstvenogradnika, dužan je upitproslijediti u MedicinskiOdjelradidavanjaodgovora. | * 1. If the medicinal product manufacturer receives an enquiry about the unauthorised medicinal products/indications from a Healthcare Professional, he/she shall forward the enquiry to the Medical Department for response. |
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| 1. **SADRŽAJ PROMOTIVNIH INFORMACIJA** | 1. **PROMOTIONAL INFORMATION CONTENT** |
| * 1. OglašavanjeLijeka i sav promotivnimaterijal mora sadržavatibitnepodatke o Lijekuistovjetneonimaizsažetkaglavnihkarakteristikalijeka i uputstva za pacijenteodobrenih u Bosni i Hercegovini. | * 1. Promotionof medicinal products and all promotional material must include essential data on the Medicinal Product, identical to those stated in the summary of product characteristics and patient information leaflet approved in Bosnia and Herzegovina. |
| * 1. Oglašavanje mora bititačno, uravnoteženo, pošteno, objektivno i u dovoljnojmjericjelovito da omogućiZdravstvenomradnikustvaranjevlastitogmišljenja o terapijskojvrijednostipredmetnogLijeka. Ono se mora temeljitinanajnovijojprocjenirelevantnihznanstvenihdokaza i jasnoodražavatisadržajtihdokaza. Oglašavanje ne smijedovoditi u zabluduiskrivljavanjem, pretjerivanjem, nepotrebnimnaglašavanjem, ispuštanjemilinadruginačin. | * 1. Advertising must be accurate, balanced, fair, objective and sufficiently completeso as toenable a healthcare professional to form their own opinion of the therapeutic value of the medicine. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. |
| * 1. Oglašavanje mora poticatiracionalnuupotrebuLijeka, predstavljajućiLijeknaobjektivannačin i bez pretjerivanja u opisunjegovihsvojstava. Ne smiju se iznosititvrdnjekojima se navodinapomisao da Lijekilinjegovadjelatnatvarimajunekoposebnosvojstvo, kvalitetuiliučinak, ako se takvatvrdnja ne možepotkrijepitidokazima. | * 1. Promotionmustencouragethe rationaluseofa medicinebypresentingitobjectivelyandwithout exaggerating its properties. Claims should not imply that a medicine or an active ingredient has some special merit,quality or property unless this can be substantiated. |
| * 1. Kada se u promotivnimmaterijalimanamijenjenimoglašavanjuLijekakoriste: | * 1. When the promotional material intended for advertising a Medicinal Product use: |
| 1. **objavljenestudije** - moraju se jasnonavestinjihoviizvori; | 1. **published study –** clear reference must be given; |
| 1. **navodi, tabeleilidrugagrađaizmedicinske i znanstvene literature iliizosobnekomunikacije**- morajubitivjernopreneseni (osim u slučajukada je sadržajprilagođeniliizmijenjenkaoposljedicazahtjeva za sukladnošćusabilokojimprimjenjivimzakonomilikodeksom, u kojemslučaju mora bitijasnonavedeno da je sadržajcitataprilagođen i/iliizmijenjen) i moraju se točnonavestinjihoviizvori; | 1. **Quotations, tables or other material taken from medical and scientific literature or frompersonal communications**must be faithfully reproduced (except where adaptation or modification is required in order to comply with the Code) and in such circumstances it must be clearly stated that the quotation has been adapted and/or modified and the precise source of quotation must be identified. |
| 1. **slikovniprikazi, uključujućigrafove, ilustracije, fotografije i tabelekojesupreuzeteizobjavljenihstudija** - morajuudovoljavatisljedećimzahtjevima; | 1. **pictorial presentations, including graphs, illustrations, photographs and tables** adopted **from the published research –** must satisfy the following requirements: |
| * jasno i preciznonavestiizvorslikovnogprikaza; | * the source of a pictorial presentation clearly and accurately stated |
| * bitivjernoreproducirani, a u slučajuprilagodbeiliizmjenenužno je jasnonavesti da je slikovniprikazprilagođen i/iliizmijenjenpotrebamajezika u zvaničnojupotrebi u Bosni i Hercegovini; | * be accurately reproduced and, in the case of adaptation or modification, it is necessary to state that the pictorial presentation is adapted and/or modified to meet the needs of the official languages in Bosnia and Herzegovina; |
| * ne smijudovoditi u zabludu u pogleduprirodeLijeka (primjerice, da je podoban za primjenukoddjece) ili u pogledutvrdnjiiliusporedbi (primjerice, korištenjemnepotpunihilistatističkiirelevantnihinformacijailineuobičajenihkriterija). | * must not be misleading in terms of nature of Medicinal Product (for example, whether it is appropriate for use in children) or in termsof claims or comparisons (for example,by using incomplete or statistically irrelevant information or unusual scales). |
| * 1. SvakausporedbarazličitihLijekova mora se zasnivatinarelevantnim i usporedivimsvojstvimaproizvoda. Zabranjenisusvioblicinedopuštenogoglašavanja u smisluZakona o lijekovima i medicinskimsredstvima i Pravilnika o načinuoglašavanjalijekova i medicinskihsredstava. | * 1. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Any form of unpermitted advertising within the meaning of the Law on Medicinal Products and Medical Devices and the Rulebook on Advertising Medicinal Products and Medical Devices are prohibited. |
| * 1. Riječ ‘**sigurno**’ se ne smijenikadaupotrebljavatiprilikomopisivanjaLijeka bez potrebnogobrazloženja. | * 1. The word **“safe”** must never be used to describe a Medicinal Product without proper qualification. |
| * 1. Riječ**‘nov’** se ne smijeupotrebljavatiprilikomopisivanjaLijekailibilokojenjegoveindikacije za Lijek koji je dostupan i oglašavannatržištuBiHtijekomrazdobljadužeg od 1 (jedne) godine. | * 1. The word ‘**new’** must not be used to describe any medicinal product which has been generally available, or any therapeutic indication which has been promoted, for more than one year in Bosnia and Herzegovina. |
| * 1. OznačavanjeLijekakao „**lijekizbora, lijekprvelinije**” za određenuindikacijumože se koristitisamonatemeljupisanihsmjernica (konsenzusailipreporuka) kojeizdajurelevantnaudruženjazdravstvenihradnika - specijalista u BiH, a ukoliko ne postojesmjernice u BiH, natemeljusmjernicaevropskihilisvjetskihkrovnihudruženjazdravstvenihradnika – specijalistačijisučlanovibosanskorercgovačkastručnaudruženjazdravstvenihradnika. | * 1. Labelling a medicinal product as a “medicine of choice, frontline medicine” for a specific indication may only be used based on written instructions (consensus or recommendations) issued by the relevant associations of healthcare professionals – specialists in Bosnia and Herzegovina and, if there are no such instructions in Bosnia and Herzegovina, based on the instructions of the European or world umbrella associations of healthcare professionals – specialists, whose members are associations of healthcare professionals in BiH. |
| * 1. Zabranjeno je tvrditi da Lijeknemanuspojava i da nijetoksičanili da nemarizikaodstvaranjaovisnosti. | * 1. It is prohibited to claim that the Medicinal Product has no side-effectsand that it is not toxic or that there is no risk of addiction. |
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| 1. **DOKUMENTACIJA** | 1. **DOCUMENTATION** |
| * 1. Sveinformacijekoje se iznoseprilikomoglašavanjamoraju se potkrijepitidokumentacijomkoja se, kaoodgovornarazumnezahtjeveZdravstvenihradnika, mora bez odgodeuručitiZdravstvenomradniku. Zahtjev za uručivanjemdokumentacijekojom se potkrepljujupromotivnetvrdnjenijepotrebnoispuniti u slučajuonihinformacijakojesuvećsadržane u dozvoli za stavljanjeLijeka u promet, odnosnoodobrenomSažetkukarakteristikalijeka i/iliuputstvu za pacijente. | * 1. All pieces of information presented during the promotion must be supported by documentation which, in response to the reasonable requests by the healthcare professionals, must be delivered to the healthcare professional without delay. A request for delivery of the documentation corroborating the promotional claims should not be answered in the information has already been included in the marketing authorisation or in the approved Summary of Product Characteristics and/or Patient information leaflet. |
| * 1. Tvrdnje o nuspojavamakoje se iznoseprilikomoglašavanjamoraju se temeljitinadostupnimdokazimailinakliničkomiskustvu. Zahtjev za uručivanjemdokumentacijekojom se potrepljujutvrdnje o nuspojavamanijepotrebnoispuniti u slučajukada se traživerifikacijaonihelemenata koji suvećsadržani u odobrenomsažetkuglavnihkarakteristikalijeka. | * 1. Claims on side-effects presented during the promotion must be based on available evidence or clinical experience. A request for delivery of the documentation corroborating the promotional claims should not be answered if verification of the elements which have already been contained in the approved summary of product characteristics is requested. |
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| 1. **PRIMJERENOST OGLAŠAVANJA** | 1. **ACCEPTABILITY OF PROMOTION** |
| * 1. Proizvođačilijekovamoraju se u svakodobapridržavativisokihetičkihstandarda. Stogaoglašavanje: | * 1. Medicinal Product Manufacturers must maintain high ethical standards at all times. Therefore, promotion must: |
| 1. nikada ne smijenarušavatiugledilislabitipovjerenje u farmaceutskuindustriju, | 1. never be such as to bring discredit to, or reduce confidence in the pharmaceutical industry, |
| 1. uvijek mora uzimati u obzirposebnupriroduLijekova i profesionalniprofilosobakojima se obraća, | 1. be of a nature which recognises the special nature of Medicinal Products and the professional standing of the intended audience; and |
| 1. ne smijebititakvokoje bi moglouzrokovatikršenjezakona i propisanasnazi. | 1. not be likely to cause violation of the applicable laws and regulations |
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| 1. **DISTRIBUCIJA PROMOTIVNOG MATERIJALA** | 1. **DISTRIBUTION OF PROMOTIONAL MATERIAL** |
| * 1. OglašavanjeLijekova se moževršitisamopremaZdravstvenimradnicima. | * 1. Medicinal products promotion must only be directedat Healthcare Professionals. |
| * 1. Popisiadresata - Zdravstvenihradnika (tzv. mailing liste) moraju se redovitoažurirati, i voditi i održavati u skladusaodredbamaprimjenjivihpropisakojima je reguliranazaštitaličnihpodataka u BiH. ZahtjevuZdravstvenogradnika za brisanjemsapopisaadresata za primanjepromotivnogmaterijala mora se odmahudovoljiti. | * 1. Lists of addressees – Healthcare Professionals (so-called mailing lists) must be updated on a regular basis and run and maintained in accordance with the provisions of applicable regulations governing the protection of personal data in Bosnia and Herzegovina. A Healthcare Professional’s request to be deleted from the mailing list for receiving promotional materials must be complied with immediately. |
| * 1. Zabranjeno je oglašavanjeputemtelefona, telefaksa, elektronskepošte i drugihelektronskihsistemaPrenosapodataka bez prethodnogpismenogpristankaZdravstvenogradnika. | * 1. The use of phone, fax, electronic mail and other electronic data transfer systems for promotion is prohibitted except with a prior written consent of the Healthcare Professional. |
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| 1. **TRANSPARENTNOST OGLAŠAVANJA** | 1. **PROMOTION TRANSPARENCY** |
| * 1. Nijedopuštenoprikrivenooglašavanje. | * 1. Disguised promotion is prohibited. |
| * 1. Klinička i Neintervencijskaispitivanja (uključujući i onakojasu po svojojprirodiretrospektivna),teistraživanjatržišta ne smijuprikrivatioglašavanje. Navedenaispitivanja i studijemorajuimatiprimarnoznanstvenuiliobrazovnusvrhu. | * 1. Clinical trials and non-interventionalstudies (including those that are retrospective in nature) and market research activities must not be disguisedpromotion. They must be conducted with a primarily scientific and educational purpose. |
| * 1. KadaProizvođačlijekanaručuje, plaćailinadruginačinorganizira, samostalnoiliputemtrećihosoba, objavupromotivnogmaterijala u stručnimčasopisima, takavpromotivnimaterijal se ne smijeprikazivatikaonezavisanuredničkisadržaj. | * 1. When a Medicinal Product Manufacturer orders, pays for of otherwise secures or arranges, on their own or through a Third Party, the publication of the promotional material in professional journals, such material must not resembleindependent editoralmatter. |
| * 1. U materijalu koji se odnosinaLijekove i njihovuuporabu, bez obzirada li je materijalpromotivneprirodeili ne, a koji financiraProizvođačlijeka mora bitijasnonaznačeno da gafinancira taj Proizvođačlijeka. | * 1. The material pertaining to Medicinal Products and their use, promotional or not, which is funded by the Medicinal Product Manufacturer must clearly indicate that it has been sponsored by that Medicinal Product Manufacturer. |
| * 1. Promotivneinformacijekoje se prezentirajunaizložbenimštandovimaili se saopštavajuučesnicimanaMeđunarodnimsastancimamogu se odnositinaLijekove (iliupotrebu) koji nisuregistrovani u zemlji u kojoj se Sastanakodržavailiizkojedolazeučesnicisastankaodnosno koji suregistrovani pod različitimuslovima, pod uvjetom da je: (*i*) bilo koji takavpromotivnimaterijalpopraćenodgovarajućomizjavomkojaoznačavazemlje u kojima je medicinskiproizvodregistriran i jasnoukazuju da Lijekiliindikacijanisuregistriranilokalno, i (*ii*) svakitakavpromotivnimaterijal koji se odnosinainformacije o propisivanju (indikacije, upozorenjaitd.) odobren u zemljiilizemljama u kojima je medicinskiproizvodregistrovan, priložensaobrazloženjem u kojem se navodi da se usloviregistracijeLijeknameđunarodnomnivourazlikuju. | * 1. Promotional information which appears on exhibition stands or is communicated to participants at International Meetings may refer to Medicinal Products (or uses) which are not registered in the country where the Meeting takes place or from which the meeting participants come or which are registered under different conditions, as long as: (*i*) any such promotional material is accompanied by an appropriate statement indicating the countries in which the medicinal product is registered and clearly indicating that the medicinal product or indication is not registered locally, and (*ii*) any such promotional material which refers to prescribing information (indications, warnings, etc.) authorised in a country or countries where the medicinal product is registered, accompanied by an explanatory statementindicatingthat registration conditions for Medicinal Products differ internationally. |
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| 1. **OGLAŠAVANJE PREMA STANOVNIŠTVU** | 1. **PROMOTION TO THE PUBLIC** |
| * 1. Lijekovekoji se izdajunareceptzabranjeno je oglašavatipremaširojjavnosti, tj. stranovništvu. | * 1. It is prohibited to promoteprescription only medicines to the general public, that is, to the population. |
| * 1. Individualneupitegrađana za savjetom u veziosobnihzdravstvenihproblema je potrebnoodbiti, i uputitiihnasavjetovanjesaZdravstvenimradnikom. | * 1. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult a Healthcare Professional. |
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| 1. **OGLAŠAVANJE PUTEM INTERNETA** | 1. **ONLINE PROMOTION** |
| * 1. Svaka Internet stranica mora sadržavatijasnepodatke o: | * 1. Any website must contain clear data on: |
| 1. identitetu i kontaktpodatke (fizičke i elektroničke) naručiteljaizrade Internet stranice; | 1. identity and contact details (physical and electronic) of the party ordering the website development |
| 1. izvorusvihinformacijasadržanihnanjoj, datum objaveizvorakao i identitet i dokumentaciju (uključujući i datum kada je ta dokumentacijazaprimljena) o svimpojedinačnimiliinstitucionalnimautorima/izvorimainformacijakoje se objavljujunastranici; | 1. the source of all pieces of information contained on the relevant website, date of publication of the source and identity and documentation (including the date of receipt of documentation) on all individual or institutional authors/sources of information published on the website; |
| 1. kriterijima/postupkuodabirasadržaja Internet stranice, | 1. website content selection criteria/procedure, |
| 1. korisnicima Internet stranice (primjerice: zdravstveniradnici, bolesnici, stanovništvo/javnostilikombinacijamogućihkorisnika), i | 1. website users (for example, healthcare professionals, patients, population /public or a combination of potential users), and |
| 1. svrsi i cilju Internet stranice. | 1. the website purpose and aim. |
| * 1. Sadržaj Internet stranica mora se redovitoažurirati i mora nedvosmislenoprikazivati, za svakustranicu i/ilitemukoja se obrađuje, datum posljednjeizmjenenjenogsadržaja. | * 1. The website content must be updated on a regular basis and it must clearly show, with regard to any website and/or topic covered, the date of the latest revision of the relevant content. |
| * 1. Na internet stranice se primjericemoguuključitinapojedinačnuiliskupnu/zajedničku Internet stranicu: | * 1. The following data may for example be included in the individual or group/joint websites: |
| 1. **općipodaci o Proizvođačulijeka** – informacijekojesu od interesaulagačima, medijimajavnogpriopćavanja i javnostiuključujućifinancijskepodatke, opiseistraživačkih i razvojnihprograma, rasprave o regulatornimpitanjimakojeutječunaproizvođača i njegoveproizvode, informacije ozapošljavanju i slično. Sadržajovihinformacija je slobodan i nijeograničenovimKodeksomilipropisima o oglašavanjulijekova. | 1. **general informationaboutMedicinal Product Manufacturer** – information directed to investors, public release media and the public, including financial data, descriptions of research and developmental programmes, discussions on regulatory developments affecting the Manufacturer and its products, information about employment vacancies and the like. Content of these pieces of information is free and is not limited by this Code or regulations on promotion of medicines. |
| 1. **zdravstveno-obrazovneinformacije** – nepromotivneinformacije o karakteristikamabolesti, načinimanjihoveprevencije i liječenjakao i sveostaleinformacijenamijenjenepromocijizdravlja. Ove informacijemoguupućivatinaLijekove,ali pod uvjetom da je takavsadržajodmjeren i tačan. Mogubitidaneinformacije o alternativnimoblicimaliječenjauključujući, tamogdje je to prikladno, informacije o operacijama, dijetama, promjenamaživotnihnavika i drugimaktivnostimakoje ne zahtijevajuupotrebuLijekova. Internet stranicekojesadržezdravstveno-obrazovneinformacijemorajuuvijeksadržavatiuputuosobama da se, u pogledudaljihinformacija, savjetujusasvojimliječnikom. | 1. **health-educational information** – non-promotional information about the characteristics of disease, methods for their prevention and treatment, and any other health-promotion information. This information may refer to medicinal products, provided that the relevant content is balanced and accurate. Information about alternative forms of treatment may be offered, including, where appropriate, information about surgeries, diets, lifestyle changes and other activities which do not require administration of medicines. Website containing health-educational information must always include instructions for people to consult their doctor for further information. |
| 1. **informacijenamijenjeneZdravstvenimradnicimauključujući i promotivneinformacije** – ukolikosutakveinformacijepromotivnogsadržaja, njihovsadržaj i format mora bitiusklađensaodredbamaovogKodeksa i važećimpropisima u BiH o oglašavanjulijekovapremaZdravstvenimradnicima. TakveinformacijemorajujasnobitioznačenekaoinformacijenamijenjeneZdravstvenimradnicima; | 1. **Information directed atHealthcare Professionals, including promotional information**– if this information is promotional, its content and format must be harmonised with the provisions of this Code and applicable regulations in **Bosnia** and Herzegovina about promotionof medicines to Healthcare Professionals. Such information must be clearly marked as information directed atHealthcare Professionals. |
| 1. **nepromotivneinformacijenamijenjenebolesnicima i širojjavnosti**Internet stranicemogusadržavatinepromotivneinformacijenamijenjenebolesnicima i javnosti u vezi s proizvodimaProizvođačaLijekova (uključujućiinformacije o indikacijama, nuspojavama, interakcijama s drugimLijekovima, pravilnojprimjeni, izvještajima o kliničkimispitivanjima i slično) pod uvjetom da susvetakveinformacijeuravnotežene, točne i u skladu s odobrenimsažetkomglavnihkarakteristikalijeka. U odnosunasvakitakavproizvod, Internet stranica mora sadržavatipotpunitekstvažećeg i odobrenogsažetkaglavnihkarakteristikalijeka i uputstva za pacijenta. Citiranidokumentimoraju se nastranicipostavitikaosastavnidioinformacija o samomproizvoduilise nanjihtrebaupućivati u samomtekstu, stvaranjemvidljiveveze (engl.*link*) uzpreporuku da se izvršiuvid u povezanedokumente. Pored toga, Internet stranicamožesadržavativezu s potpunimtekstombilokojegdokumentakojegobjavljujeAgencija za lijekove i medicinskasredstvaBosne i Hercegovineodnosnodrugonadležnotijelo. Pored zaštićenihimenaLijekovamoraju se koristitiuobičajeninazivi (INN). Ovakve Internet stranicemogusadržavativeze s drugim Internet stranicamakojesadrževjerodostojneinformacije o Lijekovima, uključivo i Internet stranicamanadležnihtijela, istraživačkihZdravstvenihOrganizacija, Organizacijapacijenataitd. Ovakve Internet straniceuvijekmorajusadržavatisavjetkorisnicima da se za svedaljeinformacijeobrateZdravstvenimradnicima. | 1. **non-promotional information directed at patients and general public** – websites may contain non-promotional information directed at patients and the public concerning the products of the Medicinal Product Manufacturers (including information about indications, side-effects, interactions with other medicines, proper administration, clinical trial reports and the like) provided that all pieces of such information are balanced, accurate and consistent with the approved summary of product characteristics. With regard to any such product, a website must contain a complete text of the applicable and approved summary of product characteristics and patient information leaflets. The quoted documents must be posted on the website as an integral part of information about the medicinal product or a reference to them should be madein the text by including visible links, along with a recommendation to review the linked documents. In addition, a website may contain a link to a complete text of any document published by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, or by some other relevant body. In addition to the brand names, standard names (INN) must be also used. Such websites may contain links to other websites containing reliable information about the medicinal products, including the websites maintained by relevant government authorities and by research-oriented Health Organisations, Patient Organisations, etc. Such websites must always advise users to consult Healthcare Professionals for further information. |
| * 1. **Pitanjapostavljenaputemelektronskepošte**: Internet stranicamožeomogućavatikomunikacijusaZdravstvenimradnicima i stanovništvom, kada se tražedaljeinformacije o lijekovimailidrugimpitanjima (primjerice, povratneinformacije o samojstranici) putemelektronskepošte. Proizvođačlijekamožeodgovoritinaodnosnapitanjanaistinačinna koji bi odgovorionapitanjaprimljenaputempošte, telefonailidrugihmedija. U komunikaciji s bolesnicimailistanovništvom, mora se izbjećirazgovor o osobnomzdravstvenomstanju. Sveinformacije o osobnomzdravstvenomstanjukoje se otkrijutokomkomunikacijemoraju se čuvati u tajnosti. Tamogdje je to potrebno, odgovorićeuvijekupućivatikorisnike da se, u pogledudaljihinformacija, savjetujusasvojimZdravstvenimradnikom, tj. svojimljekarom, stomatologomilifarmaceutom. | * 1. **E-mail enquiries**: A website may enable communication between with Healthcare Professionals and the publicseeking further information about medicines or other issues (e.g. a feedback regarding the website) via electronic mail. A Medicinal Product Manufacturer may reply to the relevant questions in the same manner as it would reply to enquiries received by post, telephone or other means of communication. Discussion about personal medical matters must be avoided in communication with patients and population. If any information about personal medical condition is revealed in communication,it must be held confidential. Where appropriate, replies shall always refer the users to consult their doctor, dentist or pharmacist for further information. |
| * 1. **Veze s drugim Internet stranicama:** Dopušteno je uspostavitiveze s Internet stranicomProizvođačalijeka s Internet stranicakojefinancirajutrećeosobe, ali bi ProizvođačilijekatrebalispriječitipovezivanjestranicanamijenjenihstanovništvunastraniceProizvođačalijekakojesunamijenjeneZdravstvenimradnicima. Na istinačinmogu se uspostavitiveze s posebnim Internet stranicama, uključujućistranicekojefinanciraProizvođačlijekailitrećeosobe. Veze bi uobičajenotrebalebitidostupne s početnestranice, tako da je korisniksvjestanidentitetaodnosne Internet stranice s kojom se vezauspostavlja. | * 1. **Links from other websites:** Links may be established to a Medicinal Product Manufacturer website from websites sponsored by Third Parties, but Medicinal Product Manufacturers should not establish links from websites designed for the general public to Medicinal Product Manufacturer websites that are designed for Healthcare Professionals. In the same manner links may be established to a separate website, including websites sponsored by a Medicinal Product Manufacturer or a Third Party. Links should commonly be available on the home page of a website so that the user is aware of the identity of the website. |
| * 1. **Znanstvenaprovjera:** Proizvođačilijekovatrebajuosigurati da se prethodnoprovjeriistinitost i usklađenost s ovimKodeksom (i važećimpropisima u Bosni i Hercegovini) znanstvenih i medicinskihinformacijapripremljenih za objavuna Internet stranicama. MedicinskiOdjelproizvođačalijekamože se zadužiti za odnosnuprovjeruili se taj zadatakmožepovjeritiprimjerenoeduciranojosobi. | * 1. **Scientific review:** Medicinal product manufacturers should make sure that scientific and medical information prepared by them for inclusion on their website is reviewed for accuracy and compliance with this Code (and applicable regulations in Bosnia and Herzegovina). The Medical Department of the Manufacturer may be entrusted with the review or such task may be entrusted to an adequately qualified person. |
| * 1. Internet stranica mora udovoljavatisvimvažećimpropisima koji uređujumaterijuzaštitetajnostipodataka i zaštiteosobnihpodataka. | * 1. The website must conform to all applicable regulations governing confidentiality and safety of personal data. |
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| **TREĆI DIO: ODNOSI IZMEĐU PROIZVOĐAČA LIJEKOVA I ZDRAVSTVENIH RADNIKA,ZDRAVSTVENIH ORGANIZACIJA I ORGANIZACIJA PACIJENATA** | **PART THREE: INTERACTIONS BETWEEN THE MEDICINAL PRODUCT MANUFACTURERS AND HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS** |
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| 1. **SASTANCI I GOSTOPRIMSTVO** | 1. **MEETINGS AND HOSPITALITY** |
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| * 1. **Sastanci** | * 1. **Meetings** |
| * + 1. Svi SastancikojeorganizirailifinanciraProizvođačlijeka, ilitrećaosoba u njegovoime, morajubitiorganiziraninaprimjerenommjestukojeodgovaraglavnojsvrsiSastanka, a Gostoprimstvo se možepružitisamoakoudovoljavakriterijimaizčlanaovogKodeksa. | * + 1. All meetings organised or financed by the medicinal product manufacturer or a third party acting on their behalf must be held in appropriate venues conducive to the main purpose of the meeting, while provision of Hospitality depends on the criteria referred to in Article 11.2 of this Code. |
| * + 1. ZapotrebeovogKodeksa, **primjerenimmjestomodržavanja**Sastanka i MeđunarodnogSastanka koji se održava u Bosni i Hercegovinismatratiće se izdvojeni, namjenskikonferencijskicentarili - ako je konferencijskicentarintegriran u smještajniobjektizskupine hotel – hotel koji premavažećimpropisima o kategorizacijismještajnihobjekataimanajviše 4 (četiri) zvjezdice i koji je uglavnompoznatzboguslugapretežitoposlovnogsadržaja, a sve u skladusapropisima o razvrstavanju, minimalnimuvjetima i kategorizacijiobjekataizskupinehotelaprimjenjivih u Bosni i Hercegovini i njenimentitetima. | * + 1. For the purposes of this Code, an **appropriate venue for holding** a Meeting and an International Meeting held in Bosnia and Herzegovina shall be a separate, designated conference centre or – if a conference centre is integrated into the accommodation facility within a group of hotels – a hotel which, according to the applicable regulations on categorisation of accommodation facilities, has no more than 4 (four) stars and which is mainly known for its predominantly business services, in accordance with the regulations on classification, minimum conditions and categorisation of the hotel group facilities applicable in Bosnia and Herzegovina and its entities. |
| * + 1. Prilikomodabirahotelaizprethodnogstavaovogčlanka, treba se prvenstvenorukovoditi time da istiimaponudupretežnoposlovnihsadržaja, s odgovarajućimkapacitetomkongresneilipremabrojusudionika, primjerenedvorane, pričemuprimjerenomjestoodržavanjaSastanaka, u svakomslučaju, nije hotel s pretežnomponudom spa, wellness ilizabavnihsadržaja. | * + 1. When selecting a hotel referred to in the previous paragraph of this Article 11.1.1, one should be primarily guided byits predominantly business-oriented facilities, having adequate assembly hall or depending on the number of participants, appropriate meeting halls, which certainly do not include a hotel with predominantly spa, wellness and entertaining facilities. |
| * + 1. U slučajusumnje u primjerenostpojedinoghotela, EtičkovijećeUdruženja je ovlaštenodatitumačenje o tome, a u skladusaodredbamačlana.ovogKodeksa. | * + 1. In the case of doubt as to the hotel appropriateness, the Ethics Committee of the Association shall be authorised to provide an interpretation thereof pursuant to Article 40 of this Code. |
| * + 1. GlavnasvrhaSastanaka mora bitirazmjenainformacijaobrazovnog, stručnogiliznanstvenogkaraktera, dokpromotivni i sviostalisadržajimorajubitipopratni u odnosunaglavnusvrhuSastanka. U tom smislu, sadržajstručnogkarakteratrebabitiprevladavajući. | * + 1. The main purpose of the Meeting shall beto exchange information of educational, professional and scientific character, while promotional and all other elements must be secondary relative to the main purpose of the Meeting. Therefore, professional elements must be prevailing. |
| * + 1. Zabranjeno je organiziratiilifinansijskipodržatiorganizacijuMeđunarodnihSastanakaosim u sljedećimslučajevima: | * + 1. It is prohibited to organise or financially support the organisation of International Meetings, unless: |
| 1. akovećinapozvanihsudionikadolaziizdrugihdržavapa je, obziromnadržaveporijeklavećinesudionika, logističkiopravdanijeodržatiSastanakizvanBiH; | 1. most of the invitees are from other countries and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Meeting outside Bosnia and Herzegovina; |
| 1. ako je, obziromnalokacijuznačajnogizvorailistručnjaka koji je predmetilitemaSastanka, logističkiopravdanijeodržatiSastanakizvanBiH. | 1. given the location of the relevant resource or expertise that is the object or subject matter of the Meeting it makes greater logistical sense to hold the Meeting outside Bosnia and Herzegovina. |
| * + 1. Činjenica da je Proizvođačlijeka(su)organizatorSastanka mora bitiobjavljena u svimdokumentima koji se odnosenaSastanakkao i u svimobjavljenimzbornicimaradova i drugimpisanimmaterijalima. Oznakaidentiteta (su)organizatoraSastanka mora bitividljivoistaknutanasvimmaterijalima i mjestimanakojima se održavaSastanak. | * + 1. The fact that a medicinal product manufacturer is a (co)host of the Meeting must be published in all documents pertaining to the Meeting, including all published Collected Works and other written materials. A logo of the (co)host of the Meeting must be visibly displayed on all materials and places at which the Meeting is to be held. |
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| * 1. **Gostoprimstvo** | * 1. **Hospitality** |
| * + 1. Za sveoblikeGostoprimstvaProizvođačilijekovasu se dužnipridržavatisljedećihkriterija: | * + 1. For all forms of Hospitality, the medicinal product manufacturers are required to comply with the following criteria: |
| 1. Gostoprimstvo se plaćaisključivo za Zdravstvenogradnika i predstavnikaOrganizacijepacijenata koji je sudionikSastanka, bilokaopredavačilislušalac, ali ne i za osobe u njegovojeventualnojpratnji (članoveobiteljiilibilokojetrećeosobe). U izuzetnimslučajevimakaoštosuutvrđenezdravstvenepotrebe (npr. invalidnostiliozljeda) troškovi za put, hranu, smještaj i kotizacijumogu se platiti i osobi u pratnjisudionikaSastanka u okviruistihparametara koji važe za učesnikeSastanka; | 1. Hospitality may only be paid for a Healthcare Professional and Patient Organisation Representative attending the Meeting, either as a lecturer or audience– not for persons who could possibly accompany him/her (family members or any other third party); In exceptional cases such as identified health needs (e.g. disability or injury) travel, food, accommodation and registration fees may also be paid to the person accompanying the Meeting participants within the same conditions that apply to the Meeting participants; |
| 1. troškoviGostoprimstva se plaćaju u visininjihovestvarnevrijednosti, temeljemispostavljenihračunadobavljača, time da se Proizvođačimalijekovaprilikomdonošenjaodluke o plaćanjuGostoprimstvapreporučapridržavatisljedećihpravila: | 1. the Hospitality costs shall be paid in the amount of their actual value, based on the invoices issued by suppliers, therefore, it is recommended to the Medicinal Product Manufacturers to comply with the following rules when rendering a decision on payment of Hospitality: |
| * troškoviputovanjamogubitiplaćenisamo za putovanjazrakoplovom u ekonomskojklasi, aiznimno u poslovnojklasi i to samo pod uvjetom da let u jednomsmjeruodprebivalištasudionikaSastanka do mjestaSastankatrajeduže od 4 sata u kontinuitetu, | * + travel costs may only be paid for the economy class flight and, exceptionally, for a business class, only if a one-way flight from the place of residence of the Meeting participant to the Meeting destination lasts longer than 4 hours in continuity, |
| * prilikomodabirasmještaja u mjestuSastankaprvenstvenoće se biratismještajnejedinicekojesvojomkvalitetomodgovarajuhotelu koji ima, premakategorizacijihotela, najviše 4 zvjezdice, i koji pretežitoimaposlovnesadržaje, odnosno, pod uvjetom da se tamoodržava i Sastanak, pobližeutvrđenomodredbom2., | * + when selecting accommodation at the Meeting venue, preference is givento accommodation unit which, by its quality matches a 4-star hotel maximum, and which predominantly offers business programmes, that is, provided that the Meeting shall be held there as well, as referred to in the provision 11.1.2., |
| * troškovismještajamogubitiplaćenisamoako je to nužnozbogtrajanjacjelokupnogSastanka (za jednonoćenjepotrebno je minimalnotrajanjeSastanka od 5 sati) ilizbogvremenapočetkailizavršetkaSastanka (npr. jutarnji i večernjiSastanci), kao i u slučajevimakada je prebivalištesudionikaodmjestaSastankaudaljenoviše od 50 km, | * + accommodation costs may only be paid if it is necessary due to the length of the entire Meeting (for one overnight stay, the Meeting should last 5 hours minimum) or due to the time of the commencement or closure of the Meeting (e.g., morning and evening Meetings), as well as in cases when the place of residence of the participants is more than 50 km away from the Meeting venue. |
| 1. Troškovihrane i pića za trajanjaSastankaplaćaju se: | 1. Food and beverage costs during the Meeting shall be paid: |
| * do maksimalnogiznosa 100 KM po osobi i obroku; i | * + up to the maximum amount of BAM 100 per person and meal; and |
| * ovajoblikGostoprimstva mora bitiograničennaosvježenje i/iliobroketijekomSastanka. | * + this form of Hospitality must be limited to refreshments and/or food and drinks during the Meeting. |
| 1. U slučajuorganizacijeMeđunarodnihSastanaka, primjenjivatiće se maksimalniiznostroškovahrane i pića koji vrijedi u državi u kojoj se MeđunarodniSastanakodržava (tj. vrijednosnikriterij „državedomaćina“). | 1. When International Meetings are organised, the maximum amount for meal costs (food and beverage)determined in the country in which the International Meeting takes place (that is, the “host country” value criteria) shall apply. |
| 1. Za vrijemeSastankanijedopuštenoorganizirati i financiratidogađajezabavnog i društvenogkaraktera i aktivnostivezaneuzrazonodu, osimskromnogoblikazabave za vrijemestanki za osvježenje i/iliobroke. | 1. During the Meeting, it is prohibited to organise or finance the entertaining and social events and activities related to entertainment, other than modest forms of entertainment during the breaks for refreshment and/or meal. |
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| 1. **ZABRANA DAVANJA POKLONA ZDRAVSTVENIM RADNICIMA, PREDSTAVNICIMA ZDRAVSTVENIH ORGANIZACIJA ILI ORGANIZACIJA PACIJENATA** | 1. **PROHIBITION ON GIFTS TO HEALTHCARE PROFESSIONALS, REPRESENTATIVES OF HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS** |
| * 1. Zabranjeno je davanje, nuđenjeiliobećanjepoklona za ličnukoristZdravstvenimradnicima, predstavnicimaZdravstvenihorganizacija i Organizacijapacijenata (direktnoiliindirektno) bez obzirananjihovuvrijednost, pa makar i simboličnu. Poklonima se, u smisluovogaKodeksa, smatranovac, stvari, prava, usluge i drugiobliciprimitaka u naravidaneZdravstvenimradnicima i predstavnicimaZdravstvenihorganizacija i Organizacijapacijenatabez naknade. | * 1. It is prohibited to give, offer or promise gifts to Healthcare Professionals, representatives of Healthcare Organisations and Patient Organisations regardless of the related value, even a symbolic one. For the purposes of this Code, gifts shall be understood to mean money, goods, rights, services and other forms of benefits given to Healthcare Professionals and representatives of Healthcare Organisations and Patient Organisations without compensation. |
| * 1. Zabranjeno je davanje i nuđenjepromocionepomoći (engl.*promotional aid*)kojapredstavljapredmetdat u promotivnesvrhe (u što ne ulazepromotivnimaterijali). | * 1. It is forbidden to give and offer promotional aid, which is an item given for promotional purposes (which does not include promotional materials). |
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| 1. **INFORMATIVNI I EDUKATIVNI MATERIJALI I PREDMETI ZA MEDICINSKU UPOTREBU** | 1. **INFORMATIONAL AND EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY** |
| * 1. Dozvoljeno je davanjeinformativnihiliedukativnihmaterijala, pod uvjetom da pojedinačnabrutonabavnavrijednosttakvihmaterijala ne prelaziiznos koji zvaničnici ne morajuprijavljivati u skladusaZakonom o sukobuinteresa u institucijamavlastiBiH i da sutakvimaterijaliznačajni za praksuZdravstvenihradnikaodnosnoZdravstvenihOrganizacija i da uključuju i dobrobitpacijenata. Davanjetakvihmaterijalaneće se smatratipoticanjempropisivanja, izdavanja, prodaje i potrošnjeLijekova. | * 1. Provision of informational or educational materials is permitted, provided that the individual gross purchase value of such materials is not higher than the amount that the officials are not required to report in accordance with the Law on Conflict of Interests in Governmental Institutions of BiH and that the referenced materials are important for the practice of the Healthcare Professionals, or Healthcare Organisations, and that they also include a patient care. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product. |
| * 1. Dozvoljeno je davanjepredmeta za medicinskuupotrebunamijenjenihneposrednoedukacijiZdravstvenihradnika, ali i dobrobitipacijenata, pod uvjetom da pojedinačnabrutonabavnavrijednosttakvihpredmeta ne prelaziiznosutvrđenvažećimZakonom o sukobuinteresa u institucijamavlasti BIH i da se davanjemtakvihpredmeta ne smanjujuuobičajenitroškoviposlovanjaPrimatelja. | * 1. The provision of itemsof medical utility is permittedif aimed directlyat education of Healthcare Professionals and patient care, provided that the individual gross purchase value of such items does not exceed the amount specified in the Law on Conflict of Interests in the Institutions of BiH and that provision of such itemsshall not decrease the standard operating costs of the Recipient. |
| * 1. Davanjepredmetaizprethodnihodredbiovogačlana po svomobimu ne smijepredstavljatizaobilaženje/izbjegavanjezabranedavanjapoklonaZdravstvenimradnicimaizčlana.ovogaKodeksa. | * 1. The scope of gifts referred to hereabove must not constitute a circumvention of the prohibition on gifts to Healthcare Professionals referred to in Article 12 of this Code. |
| * 1. Informativniiliedukativnimaterijali i predmeti za medicinskuupotrebumogusadržavatinazivKompaniječlanice, ali ne smijuimatioznakuproizvoda, osimako je nazivlijekaključan za pravilnuupotrebuInformativnihiliedukativnihmaterijala i predmeta za medicinskuupotrebuodstranepacijenata. | * 1. Informational or educational materials and items of medical utility may bear the name of the Member Company, but must not bear the product label, unless the name of the medicinal product is crucial for the proper use of informational or educational materials and items of medical utility by patients. |
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| 1. **MEDICINSKA EDUKACIJA** | 1. **MEDICAL EDUCATION** |
| * 1. Medicinskaedukacijaima za ciljpovećanjenaučnogznanja i kompetentnostiZdravstvenihradnikakako bi poboljšalimedicinskupraksu i poboljšaliishodliječenjapacijenata. | * 1. Medical education aims at increasing the scientific knowledge and competence of Healthcare Professionals in order to improve medical practice and the outcome of patient treatment. |
| * 1. Kompaniječlanicemoguorganiziratirazličitevrstemedicinskeedukacije, alitakveaktivnosti ne smijupredstavljatipromocijuilioglašavanjeLijeka. | * 1. Member Companies may organize different types of medical education, but such activities must not constitute the promotion or advertising of a drug. |
| * 1. Kadafinansirajuneovisnumedicinskuedukacijuiliorganizirajuaktivnostimedicinskeedukacijedirektnoili u saradnjisatrećimstranama, Kompaniječlanicemorajuosigurati da njihovoučešće i ulogabudujasnoprepoznati i vidljiviodsamogpočetka. | * 1. When funding independent medical education or organizing medical education activities directly or in collaboration with Third Parties, Member Companies must ensure that their involvement and role is clearly acknowledged and visible from the outset. |
| * 1. UkolikoKompaniječlaniceutičunasadržajmedicinskeedukacijedužnesuosigurati da takavsadržajbudepošten, uravnotežen i objektivan, | * 1. If Member Companies have inputin the content of medical education, they must ensure that such content is fair, balanced and objective, |
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| 1. **UPUĆIVANJE ZDRAVSTVENIH RADNIKA I PREDSTAVNIKA ORGANIZACIJA PACIJENATA NA SASTANKE I MEĐUNARODNE SASTANKE I SPONZORSTVO** | 1. **ASSIGNINGHEALTHCAREPROFESSIONALS AND REPRESENTATIVES OF PATIENT ORGANISATIONS TO MEETINGS AND INTERNATIONAL MEETINGS AND SPONSORSHIP** |
| * 1. ProizvođačilijekovamoguZdravstvenimradnicima i predstavnicimaOrganizacijepacijenataomogućitisudjelovanjenaSastancima i MeđunarodnimSastancima, bez obzira je li Proizvođačlijeka (su)organizatortakvogSastankaili ne, pod uvjetom da se prilikomoveaktivnostipridržavajusljedećihuvjeta: | * 1. Medicinal product manufacturers may enable the Healthcare Professionals and Patient Organisation representatives to take part in Meetings and International Meetings, regardless of whether the medicinal product manufacturer is (co)host of such a Meeting or not, provided that the following requirements are satisfied: |
| 1. Zdravstvenomradniku i predstavnikuOrganizacijepacijenata se ne smijeplatitinaknada za vrijemeprovedenonaSastanku, | 1. No compensation shall be paid to a Healthcare Professional and a representative of the Patients Organization for the time spent in attending the Meeting, |
| 1. upućivanjeZdravstvenogradnika i predstavnikaOrganizacijepacijenatanaSastanak ne smijeslužitikaosredstvokojim se utječenapoticanjepreporučivanja, propisivanja, kupnje, nabave, prodajeiliizdavanjaLijeka. | 1. assigning a Healthcare Professional and a representative of the Patients Organization to the Meeting shall not serve as an inducement to recommend, prescribe, buy, supply, sell or administer any Medicinal Product. |
| * 1. U slučajuMeđunarodnihSastanaka, za zakonitostsvihplaćanjaizvršenihZdravstvenomradnikuilipredstavnikuOrganizacijepacijenataodstraneProizvođačalijekaprimijenitiće se praviladržave u kojojZdravstveniradnikobavljasvojuprofesiju, odnosnodržavečijirezident je predstavnikOrganizacijepacijenta, a nepraviladržave u kojoj se MeđunarodniSastanakodržava; | * 1. For International Meetings, all payments to a Healthcare Professional or a representative of a Patient Organization by a Manufacturer shall be subjectto the rules of the Countrywhere the Healthcare Professional practices his profession or of the Countryin which a representative of Patient Organisation holds residence, and not of the country where the meeting is held; |
| * 1. PriupućivanjuZdravstvenihradnika i predstavikaOrganizacijepacijenatanaSastankedozvoljeno je plaćanjeGostoprimstva pod uvjetimaizodredbičlanaovogaKodeksa. U slučajuMeđunarodnihSastanaka, naGostoprimstvo se primjenjujupraviladržave u kojoj se održavaMeđunarodniSastanak. | * 1. When assigning Healthcare Professionals and representatives of the Patient Organization to Meetings, it is permitted to pay for Hospitality under the conditions referred to in Article 11.2 of this Code. For International Meetings, the rules of the country in which the International Meeting is held shall apply to Hospitality. |
| * 1. KompaniječlanicesudužnezahtjevatipismenoodobrenjeodZdravstveneorganizacije i Organizacijepacijenata za upotrebulogotipailimaterijalasačinjenogodstraneZdravstveneorganizacije i Organizacijepacijenatasajasnomnaznakomsvrhe i načinana koji će se koristitilogotip i/ilizaštićenimaterijal. | * 1. Member Companies are required to request written permission from the Health Organization and the Patient Organization for the use of a logo or material created by the Healthcare Organization and the Patients Organization with a clear indication of the purpose and manner of use of the logo and/or protected material. |
| * 1. Kompaniječlanicemorajuosigurati da je SponzorstvoodobrenoZdravstvenimorganizacijama i Organizacijamapacijenatauvijekjasnopriznato i očiglednoodsamogpočetkatrećimstranama. | * 1. Member Companies must ensure that Sponsorship granted to Healthcare Organizations and Patient Organizations is always clearly acknowledged and made apparent to third parties from the outset. |
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| 1. **DONACIJE ZDRAVSTVENIM ORGANIZACIJAMA I ORGANIZACIJAMA PACIJENATA** | 1. **DONATIONS TO HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS** |
| * 1. DonacijeZdravstvenimOrganizacijama i Organizacijamapacijenatadozvoljenesusamoakosukumulativnoispunjenisljedećiuvjeti: | * 1. Donations to Healthcare Organizations and Patient Organizations are only permitted if the following conditions have been cumulatively met: |
| 1. da se daju u ciljupodrškezdravstvenojzaštitiiliistraživačkoj i obrazovnojdjelatnosti, i | 1. they are provided to support health care or research and educational activity, and |
| 1. da se vrše u pisanojformi, time da strankeobveznočuvajudokumentacijuvezanu za izvršenipravniposao; i | 1. they are made in writing, and the parties are required to keep the documents related to the performed legal transaction; and |
| 1. da ne postojiobavezanaprotuusluguZdravstveneOrganizacijetj. da Donacijanijesredstvo za poticanjepreporučivanja, propisivanja, kupnje, nabave, prodajeiliizdavanjaLijeka, i | 1. that the Healthcare Organisation is not required to do a reciprocal favour, that is, that the donation does not constitute aninducement to recommend, prescribe, buy, supply, sell or issue a medicinal product, and |
| 1. da se pribavesvaodobrenjanadležnihdržavnihtijela, ukolikosutakvaodobrenjapredviđenapremavažećimpropisima u Bosni i Hercegovini. | 1. that all approvals by the relevant public authorities are obtained, if such approvals have been foreseen in the applicable regulations of Bosnia and Herzegovina |
| * 1. Zabranjeno je darovanjepojedinačnihZdravstvenihradnikazaposlenih u ZdravstvenimOrganizacijama, pod uvjetimaizovogčlanka. Tim ZdravstvenimradnicimaProizvođačlijekamožeomogućitisamosudjelovanjenaSastancima, pod uvjetimaizčlana.ovogKodeksa. | * 1. It is prohibited to give gifts to individual Healthcare Professionals employed with the Healthcare Organisations, as provided for in this Article. The Medicinal Product Manufacturer may enable the relevant Healthcare Professionals to take part in the Meetings, under the conditions referred to in Article 15 of this Code. |
| * 1. Kompaniječlanice ne smijuzahtjevatiodZdravstvenihorganizacija i Organizacijapacijenata da budujedinidonatori i/ilisponzorinjihovihaktivnosti. | * 1. Member Companies must not require Healthcare Organizations and Patient Organizations to be the sole donors and/or sponsors of their activities. |
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| 1. **USLUGE ZDRAVSTVENIH RADNIKA, ZDRAVSTVENIH ORGANIZACIJA, ORGANIZACIJA PACIJENATA I PREDSTAVNIKA ORGANIZACIJA PACIJENATA** | 1. **SERVICES OF HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS, PATIENT ORGANIZATIONS AND PATIENT ORGANISATION REPRESENTATIVES** |
| * 1. **UslugeZdravstvenihradnika i predstavnikaOrganizacijepacijenata** | * 1. **Services of Healthcare Professionals and Patient Organisation representatives** |
| * + 1. ProizvođačilijekovamoguangažiratiZdravstveneradnike i predstavnikeOrganizacijepacijenata, biloskupnoiliinidividualno, za pružanjesljedećihvrstausluga: održavanjepredavanja/govoranaSastancima i predsjedavanjeSastancima, sudjelovanje u medicinskimi naučnimistraživanjima, kliničkimispitivanjimailitreninzima, sudjelovanjenasastancimasavjetodavnihtijela i u istraživanjutržišta, akotakvosudjelovanjeobuhvaćaisplatunaknade i/iliputnihtroškova. Za sveoblikenaručivanjaopisanihuslugaodZdravstvenihradnika i predstavnikaOrganizacijepacijenatapotrebno je, u mjeri u kojoj je to relevantno za pojedinačniodnos, rukovoditi se sljedećimkriterijima: | * + 1. Manufacturers of medicinal products may engage Healthcare Professionals and Patient Organization representatives, either collectively or individually, to provide the following types of services: lecturing / speaking at Meetings and chairing Meetings, participating in medical and scientific research, clinical trials or training, participating in advisory board meetings and market research, where such participation involves remuneration and/or travel expenses. For all forms of ordering the described services from Healthcare Professionals and Patient Organization representatives, it is necessary, to the extent relevant to the individual relationship, to apply by the following criteria: |
| 1. da se uslugepružaju u obrazovne, zdravstvene, istraživačkeilinaučnesvrhe; | 1. services are provided for educational, research or scientific purposes; |
| 1. legitimniinteresProizvođačalijeka u smislupotrebe za naručivanjemodređeneuslugeodpotencijalnogizvršitelja/pružateljauslugetrebabitiunaprijedutvrđen; | 1. legitimate interest of the Medicinal Product Manufacturer in terms of the need to order certain services from a potential implementer/service provider should be defined beforehand; |
| 1. pisanimugovorompotrebno je unaprijeddogovoritiuvjetepružanjauslugeuzopispredmeta i cijene/naknadeizizvršeni rad, | 1. by a written agreement, it is necessary to agree in advance upon the service provision requirements, along with a description of the subject matter and the price/compensation for the work performed, |
| 1. kriterijodabirapružateljauslugetrebabiti u izravnojvezi s utvrđenompotrebom za određenomuslugom, pa osobekojesuzadužene za odabirpružateljauslugatrebajuposjedovatiznanjepotrebno za procjenusposobnostiZdravstvenogradnika i predstavnikaOrganizacijepacijenata da udovoljiutvrđenojpotrebi, | 1. a service provider selection criterion should be directly connected with the established need for a certain service, therefore, persons entrusted with selection of service providers should have knowledge required for the assessment of the capacities of Healthcare Professional and Patient Organisation representative to meet the established need; |
| 1. brojZdravstvenihradnika i predstavnikaOrganizacijepacijenata koji će se angažirati za pružanjeusluga ne smijebitivećiodbroja za koji se razumnomožepretpostaviti da je dovoljan za ostvarenjeutvrđenepotrebe, | 1. the number of Healthcare Professionals and Patient organisation representatives to be engaged for service provision must not exceed the number in relation to which it is reasonable to assume that it will be sufficient for meeting the established need, |
| 1. Proizvođačlijekadužan je čuvatipisanudokumentaciju o izvršenimuslugama i istom se koristitinaprikladannačin; | 1. a Medicinal Product Manufacturer shall be required to keep written documents on services provided and use them in an appropriate manner; |
| 1. naručivanjeuslugeodZdravstvenogradnika i predstavnikaOrganizacijepacijenata ne smijebitipoticaj za preporučivanje, propisivanje, kupnju, nabavu, prodajuiliizdavanjelijeka; i | 1. ordering of services from Healthcare Professionals and Patient Organisation representatives must not constitute an inducement to recommend, prescribe, buy, supply, sell or issue a medicinal product; and |
| 1. naknada za izvršenuuslugu mora bitirazumna i odgovaratistvarnojtržišnojvrijednostipruženeusluge. U tom pogledu, ugovori o pružanjusavjetničkihusluga ne smiju se koristiti za izvršavanjeneopravdanihplaćanjaZdravstvenimradnicima i predstavnicimaOrganizacijepacijenata. | 1. a compensation for a service delivered must be reasonable and match the actual market value of the service. With that regard, agreements on consultations services must not be used for making unjustified payments to Healthcare Professionals and Patient Organisation representatives. |
| * + 1. AkoangažiraniZdravstveniradnik i predstavnikOrganizacijepacijenatabude u svojstvusavjetnikailipružateljauslugeupućennaSastanak (međunarodniilidrugi), naodgovarajućinačinće se primijenitiodredbečlana. (Sastanci i Gostoprimstvo) ovogKodeksa. | * + 1. If the engaged Healthcare Professional and the representative of the Patient Organization are assigned to the Meeting (international or the like) in the capacity of an advisor or service provider, the provisions of Article 11 (Meetings and Hospitality) of this Code shall apply accordingly. |
| * + 1. UdruženjesnažnopreporučasvojimKompanijamačlanicamada pisaniugovori o angažmanuZdravstvenihradnika, bez obziranaradno-pravni status Zdravstvenogradnika (zaposlen s punim radnimvremenom u ZdravstvenojOrganizacijiilizaposlensanepunimradnimvremenomkodKompaniječlanice , ako u ostatkuradnogvremenajošuvijekobavljaprofesionalnudjelatnost), uvijeksadržeobavezuZdravstvenogradnika da u svimsvojimobraćanjimajavnosti, pisanimiliusmenimputem, u vezisauslugamakojesupredmetugovorasaProizvođačemlijekailisapitanjimakoja se tičusamogProizvođačalijeka, navede da je angažiranodstranekonkretnogProizvođačalijeka. | * + 1. The Association strongly recommends to its members that the written agreements on hiring the Healthcare Professionals, regardless of their employment status (full-time employment with the Healthcare Organisation or part-time employment with a Member Company if, during the remaining working hours he/she still performs the professional activities), should always include an obligation of the Healthcare Professional to, whenever addressing the public, either in writing or orally, and in relation to services that are the subject matter of the agreement with the Medicinal Product Manufacturer or with regard to issues pertaining to the Medicinal Product Manufacturer he/she should always state that a specific Medicinal Product Manufacturer hired him. |
| * 1. **UslugeZdravstvenihOrganizacija i Organizacijapacijenata** | * 1. **Services of Health Organisations and Patient Organisations** |
| * + 1. UgovoriizmeđuProizvođačalijekova i ZdravstvenihOrganizacija i Organizacijapacijenata, naosnovukojihse Proizvođačulijekapružajubilokojevrsteusluga,dopuštenisu pod uvjetom da se teuslugepružaju: | * + 1. Contracts between the Medicinal Product Manufacturers and Healthcare Organisations and Patient Organisation representatives based on which the Medicinal Product Manufacturer is provided with any type of services are permittedas long as the relevant services are delivered: |
| 1. u obrazovne, zdravstvene, edukativneiliistraživačkesvrhe, i | 1. for educational, health, training or research purposes, and |
| 1. da uslugenisusredstvo za poticanjepreporučivanja, propisivanja, kupnje, nabave, prodajeiliizdavanjaLijeka. | 1. that the services are not used as an inducement to recommend, prescribe, buy, supply, sell or issue of the medicinal product. |
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| 1. **POSEBNI ZAHTJEVI VEZANO ZA ODNOS PROIZVOĐAČA LIJEKOVA I ORGANIZACIJA PACIJENATA** | 1. **SPECIAL REQUIREMENTS FOR INTERACTIONS BETWEEN MEDICINAL PRODUCT MANUFACTURERS AND PATIENT ORGANISATIONS** |
| * 1. OvajKodeks se zasnivanaprincipimakojesu EFPIA i pan-evropskeOrganizacijepacijenataprihvatili, a koji suutvrđeni EFPIA Kodeksom, i to kakoslijedi: | * 1. This Code is based on the principles thatthe EFPIA together with pan-European Patient Organizations, as set out in the EFPIA Code, have subscribed to: |
| 1. nezavisnostOrganizacijapacijenata u vezisanjihovimpolitičkimstavovima, politikama i aktivnostima, mora bitiomogućena; | 1. the independence of Patient Organisations, in terms of their political judgement, policies and activities, must be assured. |
| 1. sviodnosisaradnjeizmeđuOrganizacijapacijenata i farmaceutskeindustrije, a naročitoKompanijačlanica, ćebitizasnovaninameđusobnomuvažavanju, pričemustavovi i odlukesvakogpartneraimajuistuvrijednost; | 1. all interactions between Patient Organisations and Pharmaceutical Industry, particularly Member Companies, must be based on mutual respect, with the views and decisions of each partner having equal value; |
| 1. farmaceutskaindustrija, uključujućiKompaniječlanice, nećezahtijevati, a Organizacijepacijenatanećeprihvatatipromoviranje i/ilioglašavanjelijekova koji se izdajunarecept; | 1. pharmaceutical Industry, particularly Member Companies must not request, nor shall Patient Organisations undertake, the Promotion and/or Advertisement of a particular prescription only medicines. |
| 1. ciljevi i obimbilokojesaradnjećebitijasni i transparentni, štopodrazumijeva da ćebitijasnoiskazanasvakafinansijska i nefinansijskapodrškafarmaceutskeindustrije, uključujućipodrškuKomapnijačlanica; | 1. the objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Pharmaceutical Industry, including Member Companies must always be clearly acknowledged. |
| 1. Udruženje, Kompaniječlanice i ostatakfarmaceutskeindustrijepodržavaidejuštoširegfinansiranjaOrganizacijepacijenataizrazličitihizvora | 1. Association, Member Companies and the rest of Pharmaceutical Industry welcome broad funding of Patient Organisations from multiple sources. |
| * 1. KadaKompaniječlanicepružajufinansijskupodršku, značajnuindirektnupodršku i/iliznačajnunefinansijskupodrškuOrganizacijamapacijenata, morajuimatizaključenugovor u pismenomobliku u kojem je navedeniznosfinanciranja i svrha, opisznačajneindirektnepodrške i/iliznačajnenefinancijskepodrške. | * 1. When Member Companies provide financial support, significant indirect support and/or significant non-financial support to Patient Organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose. It must also include a description of significant indirect support and /or significant non-financial support. |
| * 1. Kompaniječlanice ne smijuuticatinasadržajsponzorisanogmaterijalapripremljenogodstraneOganizacijepacijenatakako bi bio u skladusanjihovimkomercijalniminteresima, alismijuzahtijevatiispravljanjenetačnihčinjenica, tedoprinjetiizraditekstauvažavajućipoštene i uravnoteženenaučnečinjenice. | * 1. Member Companies must not influence the text of Patient Organisations' material they sponsor in a manner favourable to their own commercial interests. This does not preclude Member Companies from correcting factual inaccuracies. In addition, Member Companies may contribute to the drafting of the text from a fair and balanced scientific perspective. |
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| 1. **NEINTERVENCIJSKA ISPITIVANJA LIJEKOVA** | 1. **NON-INTERVENTIONAL STUDIES** |
| * 1. Neintervencijskaispitivanjalijekovakojauključujuprikupljanjepodataka o bolesnicimaodpojedinačnihZdravstvenihradnikailiskupinaZdravstvenihradnika, morajuudovoljavatisljedećimkriterijima: | * 1. Non-Interventional Studies that involve the collection of patient data from or on behalf of individual, or groups of, Healthcare Professionals must comply with the following criteria: |
| 1. da se ispitivanjevrši u znanstvenesvrhe; | 1. the study is conducted for scientific purposes |
| 1. da postojepisani (i) plan ispitivanja (protokol) i (ii) ugovoriizmeđuZdravstvenihradnika i/iliOrganizacija u kojima se ispitivanjeobavlja, s jednestrane i trgovačkogdruštvakojenaručujeispitivanje, s drugestrane, u kojimaće se utvrditipredmet i cijena/naknada za obavljeneusluge; | 1. There is a written (i) study plan (protocol) and (ii) contracts between Healthcare Professionals and/or Organisations where the study is conducted, as one party and a commercial company ordering the study as the other. The subject matter and price/compensation for the services shall be determined under such contract. |
| 1. nagrada za izvršenuuslugu mora bitirazumna i odgovaratistvarnojtržišnojvrijednostipruženeusluge; | 1. a reward for the service performed must be reasonable and match the actual market value of the service; |
| 1. Proizvođačilijekovadužnisupribavitiodobrenje za provođenjeNeintervencijskihispitivanjaodstraneEtičkihodboraKliničkihcentara i bolnicagdje se provodiispitivanjeteprijavitiKomisiji za kliničkaispitivanjaAgencije za lijekove i medicinskasredstva BiH i pribavitisvaostalaodobrenja i/iliispunitisveostaleobvezepredviđenevažećimpropisima u Bosni i Hercegovini o provedbiNeintervencijskihispitivanja; | 1. Medicinal Product Manufacturers shall be required to obtain an approval for carrying out the non-interventional studies from the Ethics Committees of the Clinical Centres and hospitals where the study takes place and to report to the Clinical Trial Committee of the Agency for Medicinal Products and Medical Devices of BiH and to obtain all other approvals and/or meet all of the remaining requirements stipulated in the applicable regulations of Bosnia and Herzegovina about carrying out the non-interventional studies; |
| 1. Proizvođačilijekovadužnisu se pridržavativažećihpropisa o zaštitiosobnihpodataka; | 1. Medicinal Product Manufacturers shall comply with the applicable regulations on the protection of personal data; |
| 1. provođenjeispitivanja ne smijebitipoticaj za preporučivanje, propisivanje, kupnju, nabavu, prodajuiliizdavanjeLijeka; | 1. the study must not be inducement to recommend, prescribe, buy, supply, sell or issue a medicinal product |
| 1. plan ispitivanja mora odobriti i njegovoizvršavanjenadgledatiMedicinskiOdjelproizvođačalijeka, a u skladusačlanom. ovogKodeksa; | 1. the study plan must be approved and its implementation monitored by the Medical Department of the Medicinal Product Manufacturer (pursuant to Article 27 of this Code); |
| 1. naručiteljispitivanjailitrećaosoba mora analiziratirezultateispitivanja i pripremitiizvještaj koji je MedicinskiOdjeldužanjavnopublicirati i čuvati u razumnomroku. Proizvođačlijeka je dužanposlatisažetakizvještajasvimZdravstvenimradnicima koji susudjelovali u ispitivanju i omogućitiuvid u istisamo-regulatornimtijelimaindustrije i/ilitijelimazaduženima za nadzornadprimjenomKodeksa, nanjihovzahtjev. | 1. The study results must be analysed by or on behalf of the contracting party or Third Party and summaries thereof must be made available within a reasonable period of time to the Medical Department, which service must maintain records of such reports for a reasonable period of time.The Medicinal Product Manufacturer must send the summary report to all Healthcare Professionals that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing the Code upon their request. |
| 1. Stručnisaradnicimogubitiuključeni u ispitivanjelijekasamo za potrebeobavljanjaadministrativnihposlova, a nakonizvršeneadekvatneobuke i pod nadzoromMedicinskogOdjela, tenjihovosudjelovanje ne smijebitipovezano s promocijombilokojegLijeka. | 1. Medical Associates may only be involved in an administrative capacity and such involvement must be under the supervision of the Medical Department that will also ensure that the Medical Associates are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product |
| * 1. U mjeri u kojoj je to mogućeprimijeniti, Kompaniječlanice bi se trebalepridržavatikriterijaizodredbe i u provođenjusvihostalihvrstaispitivanja, uključujućiepidemiološkaispitivanja i ostalaispitivanjakoja po svojojprirodiretrospektivna. U svakomslučaju se prilikomvršenjatihispitivanjaprimjenjujeodredba (UslugeZdravstvenihOrganizacija). | * 1. To the extent applicable, Member Companies are encouraged to comply with Section 19.1 for all other types of studies, including epidemiological studies and other studies that are retrospective in nature. In any case, such studies are subject to Article 17.2. (Services of Healthcare Organisations) |
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| 1. **DIJELJENJE UZORAKA** | 1. **DISTRIBUTION OF SAMPLES** |
| * 1. Zdravstvenimradnicima se smijedati, nanjihovpisanizahtjev, besplatniuzorakLijekaradiupoznavanjaZdravstvenogradnikasaLijekom i to samojednom u tokujednegodine u količini od najviše 2 (dva) najmanjaoriginalnapakovanjapridržavajući se pri tome i ostalihpravila o dijeljenjubesplatnihuzorakaLijekapredviđenih u važećimpropisima u Bosni i Hercegovini. BesplatniuzorciLijekova se ni u kojemslučaju ne smijudijelitiradipoticanjapreporučivanja, propisivanja, kupnje, nabave, prodajeiliizdavanjaLijeka. BesplatniprobniuzorakLijekamože se datisamoZdravstvenomradniku koji liječenjetimLijekommožeiniciratiili koji možepropisati taj Lijek. | * 1. Free Medical Samples are provided to Healthcare Professionals, on their written request, so that they may familiarise themselves with the Medicinal Product, only once in a year in the amount of not more than 2 (two) smallest original packs,while also adhering to other rules for distribution of free medical samples as stipulated in the applicable regulations in Bosnia and Herzegovina.Free medical samples must not be distributed at all for the purpose of inducement to recommend, prescribe, buy, supply, sell or issue medicinal product. Medical Samples can only be given to Healthcare Professionals qualified to initiate or prescribe that particular Medicinal Product. |
| * 1. Proizvođačilijekamorajuimatiprimjerenesistemenadzora i pouzdanostiuzorakakojedijelekao i svihLijekovakojimaraspolažuStručnisaradnici. | * 1. Medicinal product manufacturers must have adequate systems of control and accountability for Medical Samples they distribute and for all medicinal products handled by their Medical associates. |
| * 1. Na svakomuzorku mora bitijasnonaznačeno da se radi o uzorkuriječima „besplatniuzorak – nije za prodaju“, a uzsvaki se uzorak mora priložitiuputstvo za pacijente i odobrenisažetakglavnihkarakteristikalijeka. | * 1. Each Medical Sample must be clearly marked “free medical sample – not for sale” and must be accompanied by a copy of the patient information leaflet and summary of product characteristics. |
| * 1. Ne smiju se dijelitiuzorciLijeka koji sadržeopojnedroge i psihotropnetvaritemeljemvažećihpropisanadležnihtijela. | * 1. Medical samples containing narcotic drugs and other psychotropic substances must not be distributed, based on the applicable regulations of the relevant authorities. |
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| **ČETVRTI DIO: OBJAVLJIVANJE PODATAKA** | **PART FOUR: INFORMATION DISCLOSURE** |
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| 1. **OBAVEZA OBJAVLJIVANJA** | 1. **DISCLOSURE OBLIGATION** |
| * 1. SvakaKompanijačlanica je dužnavoditievidencije o PrenosuVrijednosti i objavljivatipodatke o PrenosuVrijednostikojeposrednoilineposrednoizvrši u koristPrimatelja u vezisaaktivnostimapobliženavedenim u članovima. i .ovogKodeksa | * 1. Each Member Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient in relation to activities described in more detail inArticle 23 and 25 of this Code. |
| * 1. Od obavezeizprethodnogstavaizuzetisuPrenosiVrijednostiizvršeni u okvirusljedećihaktivnosti: | * 1. The Transfers of Value made within the framework of the following activities +63shall not be subject to the disclosure obligation referred to in the previous paragraph: |
| 1. oglašavanja i informisanja o Lijekovima koji se izdaju bez recepta; | 1. promotion of and information on over-the-counter medicines |
| 1. kojenisunavedene u članovima. i .ovogaKodeksa, štouključuje, informativne i edukativnematerijale i predmete za medicinskuupotrebuizčlana., troškovehrane i pića u smislutačkeodredbe. ovogaKodeksa do najvišeutvrđenevrijednosti, nabavnetroškoveuzorakaizčlana.ovogaKodeksa, i | 1. ToVs not specified under Articles 23 and 25 of this Code, including informational and educational materials and items of medical utility listed under Article 13, costs of food and drinks referred to in Article 11.2. (1.c) of this Code up to the maximum value established therein, supply costs of samples referred to in Article 20 of this Code, and |
| 1. redovnekupoprodaje koji se odvijajuizmeđuProizvođačalijekova i Zdravstvenihradnika (npr. farmaceuta) odnosnoZdravstvenihOrganizacija. | 1. are part of ordinary course purchases and sales by and between a Medicinal Product Manufacturer and Healthcare Professionals (such as a pharmacist) or a Healthcare Organisation. |
| * 1. U svrhuispunjavanjaobavezeobjavljivanjaizovogačlana i obavezaizvažećegZakona o zaštitiličnihpodataka, Kompanijamačlanicamase preporučuje da u svimslučajevimaPrenosaVrijednosti, bez obziravrši li se PrenosVrijednostinaosnovupisanogugovorailineformalno, pribavesaglasnostPrimatelja za objavljivanjepodataka o PrenosuVrijednosti u smisluovogaKodeksa, bilo u okviruodgovarajućeugovorneodredbeilizasebneisprave. | * 1. For the purpose of meeting the Disclosure Obligation referred to in this Article, as well as obligations set forth by the applicable Law on the Protection of Personal Data, Member Companies are advised to obtain a Recipient’s consent relating to a specific disclosure of information in all cases of Transfers of Value referred to in this Code, regardless of whether the Transfers of Value are carried out based on a written contract or informally, either under an adequate contractual provision or a separate document. |
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| 1. **DINAMIKA, FORMA I OSTALI ZAHTJEVI OBJAVLJIVANJA PODATAKA O PRENOSU VRIJEDNOSTI** | 1. **DYNAMICS, FORM AND OTHER REQUIREMENTS FOR DISCLOSURE OF TRANSFER OF VALUE** |
| * 1. Objavljivanjepodataka o PrenosuVrijednostivršitiće se jednomgodišnje, pa će – za potrebeovogaKodeksa - razdobljeobjavljivanjabitijednakokalendarskojgodini (dalje u tekstu: „**IzvještajnoRazdoblje**“). | * 1. Disclosure of Transfers of Value shall be made once a year, and for thepurposes of this Code - the disclosure period will be equal to a calendar year (hereinafter: the “**Reporting Period**”). |
| * 1. Podaci o PrenosuVrijednostimoraju se objaviti u roku od 6 mjesecinakonistekapojedinačnogIzvještajnogRazdoblja i bitidostupni u razdoblju od najmanje 3 godineračunajućioddatumaprveobjave, osim u slučaju: (i) kraćegrazdobljadostupnostiobjavljenihpodatakapredviđenogpropisima o zaštitiličnihpodataka i drugimprimjenjivimpropisimaili (ii) Primateljevogopozivasaglasnosti za konkretnuobjavupodataka. | * 1. Disclosures must be made within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under the laws on personal data protection and other applicable laws or regulations, or (ii) in case the Recipient revokes his/her consent relating to a specific disclosure. |
| * 1. Uobičajeni period Objavljivanjapodataka o PrenosuVrijednostiodređen je u vremenskomintervalu od 20.juna do najkasnije 30. junasvakegodine, za podatkeizprethodnegodine. | * 1. The common reporting period for disclosure of ToVs is set during the time interval from 20thto 30thJune each year at the latest, for the ToVs from the previous year. |
| * 1. U svrhuosiguranjausklađenostiobjavepodataka o PrenosuVrijednostipremaZdravstvenimorganizacijama i Zdravstvenimradnicima, UpravniodborUdruženjaćepropisatiobaveznisadržajobrascasvihobjava koji će se primjenjivatinasveobjave u BiH. OvajobrazacćebitiusklađensaovimKodeksom, kao i Kodeksom EFPIA-e, teprimjenjivimpropisimanasnazi u BiH. | * 1. In order to ensure compliance with the ToVs disclosure to Healthcare Organizations and Healthcare Professionals, the Board of Directors of the Association shall prescribe the mandatory content of the disclosure form that will apply to all disclosures in BiH. This form shall be harmonized with this Code, as well as the EFPIA Code, and the applicable regulations in force in BiH. |
| * 1. Eventualnaodstupanjaodsadržaja koji propišeUpravniodborshodnočlanuovogKodeksabitićemogućasamoizuzetno, kada je odstupanjeposljedicadjelovanjaprisilnihpropisa. | * 1. Any deviations from the content prescribed by the Board of Directors pursuant to Article 22.4 of this Code shall be possible only exceptionally, when such deviation is a consequence of application of compulsory regulations. |
| * 1. Objavljivanjepodataka o PrenosuVrijednostivršitiće se nacentralnojplatformiputemposebne web stranicekojućeUdruženjeosigurati u tusvrhu i/iliputem web stranicasvakeKompaniječlanice , s pravomneograničenogpristupatojstraniciputemInterneta. Podaci koji će se objavljivatinatoj web stranicibitićeprezentirani, u mjeri u kojoj je to moguće, korištenjemstruktureobrascaizodredbe 22.4.ovogKodeksa. | * 1. ToVs disclosures shall be made on the central platform through a special website provided by the Association for this purpose and/ or through the website of each Member Company, with the right of unlimited access to that site via the Internet. The disclosures made on that website will be presented, to the extent possible, using the form structure stipulated in Article 22.4. of this Code. |
| * 1. Podaci o PrenosuVrijednostibitićeobjavljeninajednomodslužbenihjezika u BiH, stime da, premaodluciUdruženja, web stranicamožebitidizajnirana i kaodvojezičnastranicauzmogućnostpregledaobjavljenihpodatakanaengleskomjeziku. | * 1. Transfers of Value Disclosures shall be made in one of the official languages in BiH, provided that, according to the decision of the Association, the website may be also designed as a bilingual page with the possibility of viewing the disclosures in English. |
| * 1. Podaci o PrenosuVrijednostiće se objavljivati u državi u kojojPrimateljimaprijavljenoličnoiliprofesionalnoprebivališteodnosnosjedište, bez obzirana to je li PrenosVrijednosti u koristPrimateljaizvršen u državinjegovaprebivališta/sjedištaili u trećojdržavi. | * 1. Transfers of Value shall be disclosed in the country where the Recipient has a registered personal or professional residence or registered office, regardless of whether the Transfer of Value to the benefit of the Recipient took place in his/her country of residence/registered office or in a third country. |
| * 1. Evidencije o poslovnimdogađajimavezanimuzobjavljenePrenoseVrijednostiKompaniječlanicesuobaveznevoditi u skladusavažećomregulativom u BiH o vođenju i obradipodatakaizoblastiknjigovodstva i podatkečuvatinajmanje 5 godinaračunajućiodistekapojedinačnogIzvještajnogRazdoblja. 5-godišnji rokčuvanjaevidencija o PrenosuVrijednostineće se primijeniti u slučajukadaprisilnipropisiizoblastizaštiteličnihpodataka i drugipropisi o obaveznimrokovimačuvanjaposlovnedokumentacije, nalažukraćerokovečuvanjaodnosnedokumenacije. | * 1. Member Companies shall keep Records of business events related to the Transfers of Value disclosures in accordance with applicable regulations in BiH on the maintenance and processing of data in the field of accounting and shall keep data for at least 5 years from the end of each reporting period. The 5-year period of keeping records on the Transfer of Value will not apply in the case when compulsory regulations in the field of personal data protection and other regulations on mandatory deadlines for keeping business documents require shorter deadlines for keeping the relevant documentation. |
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| 1. **NAČIN OBJAVLJIVANJA** | 1. **METHOD OF DISCLOSURE** |
| * 1. **Pojedinačnoobjavljivanje** | * 1. **Individual Disclosure** |
| * + 1. OsimakodrugačijenijeizričitopredviđenoovimKodeksom, svipodaci o PrenosuVrijednostibitićeobjavljivanipojedinačno, štoznači da ćebitimogućuvid u podatke o svakomPrenosuVrijednostiizvršenom u koristjasnoidentificiranogpojedinačnogPrimatelja u vezisanekimodoblikasaradnjeiztačaka i ovogastavatokomsvakogIzvještajnogRazdoblja. OdnosniPrenosiVrijednostimogu se prikazati i kaozbirniizvještaj za svakipojedinačniobliksaradnje, alisamo pod uslovomistovremenedostupnostipojedinačnogizvještaja koji se mora predočitinazahtjev (i) odnosnogPrimatelja i (ii) nadležnihtijelajavnevlasti. | * + 1. Unless specified otherwise by this Code, all data about Value Transfer shall be disclosed individually, which means that it will be possible to review the data on each Value Transfer made in favour of a clearly identified individual Recipient related to some of the cooperation forms referred to in points 23.1.2 and 23.1.3 of this paragraph during every Reporting Period. The respective Transfers of Value may also be presented as an aggregate report for each form of cooperation, but only provided that individual report is available at the same time, which must be presented upon request of the (i) respective Recipient and (ii) competent public authorities. |
| * + 1. **PrenosVrijednosti u koristZdravstvenihOrganizacija**, obuhvaćasveisplateizvršene u vezisasljedećimaktivnostima: | * + 1. **The Transfer of Value in favour of Healthcare Organisations**, includes all payments made in relation to the following activities: |
| 1. Donacijeizčlana. ovogKodeksa; | 1. Donations referred to in Article of this Code; |
| 1. troškovi koji nastanu u veziSastanaka koji suuplaćeniizravnoZdravstvenimOrganizacijamailitrećimosobama, uključujući i troškoveizčlana. ovogKodeksa (UpućivanjeZdravstvenihRadnikanaSastanke i MeđunarodneSastanke), kaoštosunpr. : | 1. costs incurred in relation to Meetings, which are paid directly to Healthcare Organisations or third persons, including costs referred to in Article of this Code (Sending of Healthcare Professionals to Meetings and International Meetings) such as: |
| * troškoviregistracije | * registration costs |
| * troškoviGostoprimstvaizodredbeuzuvažavanjeizuzetkaiztačkeodredbeovogKodeksa, i | * Hospitality costs referred to in provision, taking into account exceptions referred to in point of provision of this Code, and |
| * iznossponzorstvaizugovora o sponzorstvuizmeđuProizvođačalijeka i ZdravstveneOrganizacijeilitrećeosobekoja u ime i za računZdravstveneOrganizacijeorganiziraSastanak; | * sponsorship amount set forth by the sponsorship contract between Pharmaceutical Manufacturer and Healthcare Organisation or a third person organising the Meeting on behalf and for the account of the Healthcare Organisation; |
| * iznosnaknada za uslugeZdravstvenihOrganizacijaizodredbeovogaKodeksaisplaćenetemeljemugovora o pružanjuuslugasaZdravstvenimOrganizacijama i iznossvihostalihprimanja koji se ne mogupodvesti pod naprijednavedenekategorijeaktivnosti. U tom će se slučajuodvojenoobjaviti | * the amount of fees for Healthcare Organisations’ services referred to in provision of this Code, paid on the basis of a service provision contract with Healthcare Organisations, and the amount of all other allowances that may not be classified under the aforementioned categories of activities. In that case, the following shall be disclosed separately: |
| 1. vrijednostisplaćenenaknade za uslugeZdravstveneorganizacije; | 1. the value of the paid fee for servicesof the Healthcare Organisation; |
| 1. vrijednostitroškovavezanihuzizvršavanjeodnosneusluge, akosuugovoreni. | 1. the value of costs related to the provision of respective service, if contracted. |
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| * + 1. **PrenosVrijednosti u koristZdravstvenihradnika**, obuhvaćasveisplateizvršene u vezisasljedećimaktivnostima: | * + 1. **The Transfers ofValue in favour of Healthcare Professionals**, includes all payments made in relation to the following activities: |
| 1. troškoviregistracije | 1. registration costs |
| 1. troškoviGostoprimstva, uzuvažavanjeizuzetkaiztačkeodredbeovogKodeksa; | 1. Hospitality costs, taking into account exceptions referred to in point of provision of this Code; |
| 1. iznosnaknada za uslugeZdravstvenihRadnikaizodredbe 17.1.1. (ako je identitetZdravstvenogradnika koji sudjeluje u aktivnostimaistraživanjatržištapoznatProizvođačulijekova) ovogaKodeksaisplaćenenaosnovuugovora o pružanjuuslugasaZdravstvenimRadnicima i iznossvihostalihprimanja koji se ne mogupodvesti pod naprijednavedenekategorijeaktivnosti. U tom će se slučajuodvojenoobjaviti | 1. the amount of fees for Healthcare Professionals’ services referred to in the provision 17.1.1. (if the identity of the Healthcare Professional who participates in market research activities is known to the Pharmaceutical Manufacturer) of this Code, paid on the basis of a service provision contract with Healthcare Professionals and the amount of all other allowances that may not be classified under the aforementioned categories of activities. In that case, the following shall be disclosed separately: |
| * vrijednostisplaćenenaknade za uslugeZdravstvenogradnika; | * the value of the paid fee for services of the Healthcare Professional; |
| * vrijednostitroškovavezanihuzizvršavanjeodnosneusluge, akosuugovoreni. | * the value of costs related to the provision of respective service, if contracted. |
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| * 1. **Zbirnoobjavljivanje** | * 1. **Aggregate disclosure** |
| * + 1. U slučajukadazbogpostojanjaodređenihpravnihpreprekapodatak o PrenosuVrijednosti - koji bi se inačemogaoobjaviti u okviruobvezepojedinačnogizvještavanjaizprethodnogstava - nijemogućeobjavitipojedinačno, takavće se podatakobjavitizbirno. Pod zbirnomobjavompodatakapodrazumijeva se objavaputemkojećebitiomogućenuvid, za svakiobliksaradnje, u: (i) ukupnibrojPrimatelja, u apsolutnomiznosu i u izraženo u postotku u odnosunasvePrimatelje, i (ii) ukupniiznosPreneseneVrijednostiizvršenetakvimPrimateljima. | * + 1. In case when, due to certain legal obstacles, information on the Value Trans-fer – that could otherwise be disclosed pursuant to individual disclosure obligation referred to in the previous paragraph – cannot be disclosed individually, it shall be disclosed in aggregate form. The aggregate disclosure of in-formation means disclosure enabling, for every form of cooperation, an in-sight into: (i) a total number of Recipients, in the absolute amount and as a percentage for all Recipients, and (ii) the total amount of the Value Transferred to such Recipients. |
| * + 1. PrenosiVrijednosti u SvrhuIstraživanja i RazvojaizvršenitokomsvakogIzvještajnogRazdobljaobjavljuju se zbirno. Svi podmirenitroškovi koji suneospornovezaniuzaktivnostiistraživanja i razvojasmiju se uključiti u zbirniizvještaj u kategoriji „PrenosVrijednosti u SvrhuIstraživanja i Razvoja“. | * + 1. The Research and Development Value Transfers made during each Reporting Period shall be disclosed in aggregate form. All paid costs unambiguously related to research and development activities may be included in the aggregate amount under the “Research and Development Value Transfer” category. |
| * + 1. U slučajuposrednogPrenosaVrijednostiizvršenogZdravstvenomRadnikuputemZdravstveneOrganizacije, obaveziobjavljivanjapodatka o takvomPrenosuVrijednostibitićeudovoljenoako se taj podatakobjavijednom, po mogućnosti, u okviruobavezepojedinačnogizvještavanja u smisluodredbeovogKodeksa. | * + 1. In case of indirect Transfer of Value to a Healthcare Professional through a Healthcare Organisation, the disclosure obligation shall be met if the information is published once, preferably pursuant to the individual disclosure obligation referred to in the provision 23.1 of this Code. |
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| 1. **METODOLOGIJA** | 1. **METHODOLOGY** |
| * 1. SvakaKompanijačlanicaćesamostalnoizraditi i objavitikratkiprikazmetodologijekojuprimjenjuje u pripremiizvještaja o PrenosuVrijednosti i načinuidentifikacijePrenosaVrijednosti za svakiodpojedinačnihoblikasaradnjeizčl. i . U tom će se prikazu.koji možesadržavatiopćipregled i sveeventualnespecifičnostivezaneuzposlovanje u Bosni i Hercegovini, opisatimetodepostupanjasaodređenimaspektimaizvještavanjakojesvakaKompanijačlanicaprimjenjuje, a trebao bi uključiti i tretmanvišegodišnjihugovora, porezno-pravneaspekte, pitanjavalutnihklauzula i kursnihrazlika i svaostalapitanjavezana za vrijemeisplate i konačniiznosPreneseneVrijednosti u svrhuizvršavanjaobavezaizovogaKodeksa. | * 1. Each Member Company shall individually develop and publish a brief overview of the methodology it uses when preparing reports on Value Transfers and the method of Value Transfer identification for each form of cooperation referred to in 23.1.2 and 23.1.3. The overview, which may include a general overview of, and all specificities pertaining to operations in Bosnia and Herzegovina, shall describe the methods of treatment of certain reporting aspects applied by each Member Company, and should also include the treatment of multiannual contracts, taxation-legal aspects, currency and exchange issues and all other issues pertaining to payment timeframe and the final amount of the Value Transfer, for the purpose of meeting the obligations set forth in this Code. |
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| 1. **OBJAVLJIVANJE PODATAKA O PRENOSU VRIJEDNOSTI ORGANIZACIJAMA PACIJENATA** | 1. **DISCLOSURE OF TRANSFERS OF VALUE TO PATIENT ORGANISATIONS** |
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| * 1. SvakaKompanijačlanica mora javnostavitinaraspolaganjeotkrivanjepopisaOrganizacijapacijenatakojimapružafinansijskupodrškui/iliznačajnuindirektnu/nefinansijskupodrškuilisakojima se angažovala za pružanjeugovorenihusluga za tukompanijučlanicu. | * 1. Every Member Company shall publicly disclose the list of Patient Organisations receiving financial support and/or significant indirect/non-financial support from it, or which have been engaged to provide contracted services for the Member Company. |
| * 1. Objavljivanjepodataka mora sadržavatiopisprirodepodrškeilipruženihusluga koji je dovoljnopotpun da omogućiprosječnomčitaocu da shvatiprirodupodrškeilipruženihusluga bez potrebe za otkrivanjempovjerljivihinformacija. | * 1. The data disclosure shall include the description of the nature of support or provided services which is complete enough to enable an average reader to understand the nature of the support or provided services, without the need for disclosure of confidential information. |
| * 1. Pored nazivaOrganizacijepacijenata u Podatke o prenosuvrijednostimoraju se uključiti i sljedećeinformacije: | * 1. In addition to the Patient Organisation’s name, the Data on Value Transfer shall also include the following information: |
| 1. za podrškuOrganizacijepacijenata : | 1. for a support to a Patient Organisation: |
| * novčanavrijednostfinansijskepodrške i fakturisanihtroškova. | * monetary value of the financial support and invoiced costs. |
| * nenovčanakoristkojuOrganizacijapacijentadobijakada se nefinansijskapodrška ne možeizraziti u značajnojnovčanojvrijednosti. | * non-monetary benefit received by the Patient Organisation when a non-financial support cannot be expressed in a significant monetary value. |
| 1. za ugovoreneuslugeOrganizacijepacijenata :ukupaniznosplaćenOrganizacijipacijenata u izvještajnomperiodu. | 1. for contracted services of a Patient Organisation: the total amount paid to the Patient Organisation in the reporting period. |
| * 1. Objavljivanjepodataka za Organizacijepacijenatavrši se u skladusačlanovima. (Dinamika, forma i ostalizahtjeviobjavljivanjapodataka o PrenosuVrijednosti) i (Načinobjavljivanja). | * 1. Data for Patient Organisations shall be disclosed pursuant to Articles 22 (Dynamics, Form and Other requirements for Value Transfer Data Disclosure) and 23 (Method of Disclosure). |
| * 1. SvakaKompanijačlanicaćesamostalnoizraditi i objavitikratkiprikazmetodologijekojuprimjenjuje u pripremiizvještaja o PrenosuVrijednosti za Organizacijepacijenata i načinuidentifikacijePrenosaVrijednosti za svakiodpojedinačnihoblikasaradnje (podrške i pruženihusluga). | * 1. Each Member Company shall individually develop and publish a brief overview of the methodology it uses when preparing reports on Value Transfers for Patient Organisations and the method of Value Transfer identification for each form of cooperation (support and provided services). |
| * 1. U svrhuosiguranjausklađenostiobjavepodataka o PrenosuVrijednostipremaOrganizacijamaPacijenata, UpravniodborUdruženjaćepropisatiobrazacobjavepodataka o Prenosuvrijednosti, a koji ćebitiusklađensaovimKodeksom, kao i Kodeksom EFPIA-e, teprimjenjivimpropisimanasnazi u BiH. | * 1. In order to ensure uniformity of Value Transfer data disclosure to Patient Organisations, the Association Board shall prescribe the Value Transfer data disclosure template, which will be aligned with this Code, the EFPIA Code and existing applicable legislation in BiH. |
| * 1. Eventualnaodstupanjaodsadržaja koji propišeUpravniodborshodnočlanuovogKodeksabitićemogućasamoizuzetno, kada je odstupanjeposljedicadjelovanjaprisilnihpropisa. | * 1. Any deviations from the contents prescribed by the Board pursuant to Article 25.6 of this Code may be made only in exceptional cases, when the deviation results from application of forced regulations. |
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| **PETI DIO: ORGANIZACIJA SLUŽBE ZA OGLAŠAVANJE** | **PART FIVE: ADVERTISING SERVICE ORGANISATION** |
| 1. **STRUČNI SARADNICI** | 1. **MEDICAL ASSOCIATES** |
| * 1. Svi Proizvođačilijekovamorajuosigurati da Stručnisaradnici – uključujući i podugovarače (osobekojeProizvođačilijekovaangažiraju za obavljanjetihposlovatemeljemugovora) - buduupoznatisasadržajemovogKodeksa i svihvažećihpropisa u Bosni i Hercegovini, pravilnoosposobljeni za obavljanjetihposlova i da imajudovoljnostručnoznanje o Lijekovimakojepromovirajuradipružanjatočnih i potpunihinformacija. | * 1. All Pharmaceutical Manufacturers must make sure that Medical Associates – including subcontractors (persons hired Pharmaceutical Manufacturers to perform those activities based on a contract) – familiarise themselves with the content of this Code and all applicable regulations in Bosnia and Herzegovina, to be adequately trained to perform these activities, and to possess sufficient professional knowledge about the Medicinal Products they promote for the purpose of providing accurate and complete information. |
| * 1. Stručnisaradnicimorajuobavljatisvojezadatkeodgovorno i etično. | * 1. Medical associates must perform their tasks in a responsible and ethical manner. |
| * 1. StručnisaradnicisudužniprilikomsvakogposjetaZdravstvenomRadnikuuručitizadnjiodobrenisažetakglavnihkarakteristikalijeka za svelijekovekojepredstavljaju u tom posjetu. | * 1. At every visit to a Healthcare Professional, Medical Associates shall deliver the latest approved summary of the main properties of the medicinal product for all medicinal products they present during the visit. |
| * 1. StručnisaradnicimorajuProizvođačulijekaproslijeditipovratneinformacijekojedobiju u vezi s korištenjemLijeka, aosobitoizvješća o nuspojavama. Stručnisaradnicimorajusveupite o Lijeku koji suizvanodobrenogsažetkaglavnihkarakteristikaLijekaproslijediti u MedicinskiOdjel. | * 1. Medical associates shall provide the Pharmaceutical Manufacturer with a feedback they receive concerning the use of the Medicinal Product, which referring to side-effects. Medical Associates must forward to the Medicine Department all inquiries about the Medicinal Product which go beyond the approved summary of the main properties of the Medicinal Product. |
| * 1. Stručnisaradnicimorajuvoditiračuna da dinamika, vrijeme i trajanjenjihovihposjetaZdravstvenimradnicima i ZdravstvenimOrganizacijama, kao i načinna koji obavljajuposjete, ne ometajuuobičajeniradniprocesposjećenihfizičkih i pravnihosoba. | * 1. Medical Associates must make sure that the dynamics, time and duration of their visits to Healthcare Professionals and Healthcare Organisations, and the manner in which they pay visits, do not disturb the standard work process of the visited natural and legal persons. |
| * 1. Stručnisaradnici ne smijukoristitinikakvepoticajeiliprevarnemetoderadidobivanja termina posjetaZdravstvenomradniku. TijekomrazgovorasaZdravstvenimradnikomiliprilikomdogovaranja termina posjeta, Stručnisaradnici se morajuodsamogpočetkarazgovorapobrinuti da Zdravstvenogradnika ne dovedu u zabludukako u vezivlastitogidentitetatako i identitetaProizvođačalijekakojegzastupaju. | * 1. Medical Associates must not use any incentives or fraudulent methods to secure the term for paying a visit to a Healthcare Professional. While talking to a Healthcare Professional or negotiating the time for the visit, Medical Associates must make sure from the very beginning of the conversation that they do not mislead the Healthcare Professional regarding their identity and the identity of the Pharmaceutical Manufacturer they represent. |
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| 1. **MEDICINSKI ODJEL** | 1. **MEDICAL DEPARTMENT** |
| * 1. Svi ProzvođačilijekovamorajuimatiMedicinskiOdjel. Pri tome Proizvođačilijekovaimajudiskrecijskopravoodlučiti o organizacijskomustrojuMedicinskogodjela, uzimajući u obzirstvarneorganizacijske i ljudskepotencijalekojimaraspolažu. MedicinskiOdjel mora imatizaposlenogbaremjednogdoktora medicine, stomatologijeilifarmaceuta, aostalizaposleniciMedicinskogOdjelamorajuimatizavršenfakultetzdravstvenogusmjerenja. MedicinskiOdjelodobravakonačnuverzijupromotivnogmaterijala i potvrđuje da je isti u skladusazahtjevimaovogaKodeksa i bilokojegprimjenjivogpropisa, u skladu s odobrenimsažetkomkarakteristikaLijeka i da je objektivan i istinitprikazčinjenica o Lijeku. Pored toga, MedicinskiOdjelodgovoran je za provođenjesvihvrstakliničkihispitivanjaLijekova, uključujući i pregledsvihobavezakojeproizlazeizobavljanjatakvihistraživanja. | * 1. All Pharmaceutical Manufacturers shall have a Medical Department. However, the Pharmaceutical Manufacturers shall have discretion to decide on the organisational structure of the Medical Department, taking into account the available organisational and human resources. The Medical Department shall employ at least one medical doctor, dentist or pharmacist, while the remaining staff of the Medical Department shall have a degree in the field of healthcare. The Medical Department shall approve the final version of the promotional material and verify that it is consistent with the requirements of this Code and any other applicable regulation, in accordance with the approved summary of the Medicinal Product properties, and that it objectively and truthfully presents the facts about the Medicinal Product. Besides, the Medical Department shall be responsible for the implementation of all sorts of clinical trials involving the Medical Product, including an overview of all obligations arising from such trials. |
| * 1. SvakiProizvođačlijeka mora imenovatinajmanjejednogzaposlenogradnika s relevantnimiskustvom koji ćebitizadužen za nadzorProizvođačalijeka u pogleduprimjeneodredbiovogKodeksa, tekopijutakveodluke i svakenjeneizmjenedostavitiUdruženju. | * 1. Every Pharmaceutical Manufacturer shall appoint at least one relevantly experienced employee to be tasked with supervising the implementation of the provisions of this Code by the Pharmaceutical Manufacturer, and shall provide the Association with a copy of such decision and any amendments thereof. |
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| **ŠESTI DIO: POSTUPAK U SLUČAJU POVREDE KODEKSA** | **PART SIX: PROCEDURE IN THE CASE OF VIOLATION OF THE CODE** |
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| 1. **DVOSTEPENI POSTUPAK** | 1. **TWO-INSTANCE PROCEDURE** |
| * 1. Kompaniječlanicesusvjesni da je za javnopovjerenje u integritetKompanijačlanicaključnopridržavanjepravilaovogKodeksa. Daljnjimodredbama, propisan je dvostupenipostupak koji provodi: | * 1. Member Companies are aware that compliance with the rules of this Code is crucial for public confidence in their integrity. The provisions below regulate a two-instance procedure to be conducted by: |
| 1. Etičkovijeće u prvomstepenu, i | 1. The Ethics Committee in the first-instance, and |
| 1. Skupštinaudruženja u drugomstepenu | 1. Assembly of the Association in the second instance |
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| 1. **IMENOVANJE ETIČKOG VIJEĆA** | 1. **APPOINTMENT OF THE ETHICS COMMITTEE** |
| * 1. Etičkovijećesastoji se od tri člana, predsjednika i 2 članavijeća. PredsjednikEtičkogvijeća se imenuje u skladusaodredbom, dok se preostaladvačlanaimenujuna*ad hoc*osnovi za svakipojedinipredmet koji buderazmatranpredEtičkimvijećem u skladusaodredbomčlana. | * 1. The Ethics Committee shall consist of three members: a chair and 2 members. The Chair of the Ethics Committee shall be appointed pursuant to provision 29.2, whereas the remaining two members shall be appointed on an ad hoc basis for each case before the Ethics Committee, in accordance with the provision set out by Article 29.3. |
| * 1. PredsjednikEtičkogvijeća ne možebiti u radnomodnosusabilokojomKompanijomčlanicom ,Udruženjemilisabilokojimtrećimlicemkoje se baviproizvodnjom, uvozomiliprodajomLijekova, a imenujegaSkupštinaUdruženjana period oddvijegodine. | * 1. The Chair of the Ethics Committee shall not be employed by any Member Company, the Association or any other third party dealing with manufacturing, imports or sale of Medicinal Products, and shall be appointed by the Association Assembly for a two-year term. |
| * 1. PredsjednikEtičkogvijeća, po prijemuprijave o povrediimenujepreostaladvačlanaEtičkogvijeća, i to: | * 1. Upon receiving a report on violation, the Chair of the Ethics Committee shall appoint the remaining two members of the Ethics Committee: |
| 1. jednogčlanaizRadnegrupe za pravneposlove i usklađenost po abecednomilidrugomredu, pazećinapotencijalnisukobinteresa u konkretnomslučaju; | 1. one member from the Working Group for Legal Affairs and Compliance, in alphabetic or other order, being mindful of potential conflict of interest in the particular case; |
| 1. jednogčlanakaopredstavnikaZdravstvenihradnika, Organizacijepacijenatailidrugihzainteresovanihstrana u zavisnostiodokolnostislučaja. | 1. one member as a representative of the HCP’s, Patient Organisation or other stakeholders, depending on the circumstances of the case. |
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| 1. **PRIJAVA ZBOG POVREDE ODREDABA KODEKSA** | 1. **REPORT OF VIOLATIONS OF THE CODE** |
| * 1. **Pravonapodnošenje:** SveKompaniječlanice i trećalicaimajupravonapodnošenjeprijavezbogkršenjaodredbiovogKodeksa. | * 1. **The right to submission:** All Member Companies and third parties are entitled to submit a report on violation of the provisions of this Code. |
| * 1. **Prihvaćanjeprijave:** Moguće je podnijetiprijavuprotivKompaniječlanice ,samovezano za navodnepovredekojesupočinjeneodtrenutkastupanjanasnagu i početkaprimjeneKodeksaponašanjaodstraneKompanijačlanica . | * 1. **Report acceptance:** A report against a Member Company may be filed only with regard to alleged violations committed as of the date of the entry into force of this Code of Conduct and of the commencement of its application by Member Companies. |
| * 1. **Zastara:** Postupak za utvrđivanjeodgovornostiKompaniječlaniceradipovredeodredabaKodeksamože se pokrenuti u roku od 1 (jedne) godineračunajući od dana kršenjaKodeksa do datumapodnošenjaprijave. Apsolutnazastaranastupaprotekom 3 (tri) godineodkonkretnogdogađajapovredeKodeksa. | * 1. **Statute of limitations:** A procedure for the establishment of a Member Company’s responsibility for violation of the provisions of the Code may be instigated within 1 (one) year of the date of the Code violation. Absolute statute of limitations shall take effect 3 (three) years of the Code violation date. |
| * 1. **Sadržaj i oblikprijave:** PostupakzbogpovredeKodeksapokreće se pisanomprijavomupućenomDirektoruUdruženjanaadresusjedištaUdruženjailiputem e-mail adresePredsjednikaEtičkogvijećakojaćeredovnobitiažurirananastraniciUdruženja. Prijavatrebasadržavati, po mogućnosti, štovišepodataka o podnositeljuprijave i Kompanijičlanicinakoju se prijavaodnosi, činjeničniopisrazloga za prijavusadokazimakojima se tinavodipotkrepljuju, činjeničnenavode i odredbeKodeksakojesu, po mišljenjupodnosiocaprijave, povrijeđeneradnjamaKompaniječlanicenakoju se odnosiprijava. | * 1. **Content and form of the report:** A procedure for violation of the Code shall be instigated by a written report addressed to the Director of the Association at the address of the Association’s registered office, or by e-mail to the Chair of the Ethics Committee, whose email details shall be updated on a regular basis at the Association’s website. The report should contain as many details as possible about the reporting party and the reported Member Company, a factual description of reasons for the report, and evidence supporting the allegations, factual allegations, and provisions of the Code that the reporting party believes were violated by actions of the reported Member Company. |
| 1. **PRETHODNO ISPITIVANJE PRIJAVE** | 1. **PRELIMINARY EXAMINATION OF THE REPORT** |
| * 1. DirektorUdruženjaprovodiprethodnoispitivanjeprijaveteako je prijavauredna, potpuna i blagovremenaprosljeđuje je PredsjednikuEtičkogvijećanadaljnjepostupanje. | * 1. The Director of the Association shall perform preliminary examination of the report and, if the report is orderly, complete and filed in a timely manner, forward it to the Chair of the Ethics Committee for further action. |
| * 1. AkoDirektorudruženjautvrdi da prijava ne sadržavanitiminimalnukoličinupodatakaizodredbe, pisanimputemćeodpodnosiocazatražitidopunuprijave i za to mu odreditirok od 15 (petnaest dana) računajućiodprijemazahtjeva za dopunuprijave. U slučajupropuštanjapodnosiocaprijave da udovoljizahtjevu za dopunu i uređenjeprijave u ostavljenomroku, DirektorUdruženjaćeprijavudostavitiPredsjednikuEtičkogvijećanadaljnjepostupanje. | * 1. If the Director of the Association finds that the Report does not contain even the minimum data referred to in the provision 30.4, he/she shall send a written request to the reporting party asking them to supplement the Report within 15 (fifteen) days of the date of receipt of the request. If the reporting party fails to comply with the request for amendment of the report within the given deadline, the Director of the Association shall forward the report to the Chair of the Ethics Committee for further action. |
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| 1. **PRVOSTEPENI POSTUPAK – PRVI DIO** | 1. **FIRST INSTANCE PROCEDURE – PART ONE** |
| * 1. PredsjednikEtičkogvijećamožeodbacitiprijavukaonedopuštenuako se ne odnosinapovredeKodeksailiako je očito da se prijavomozbiljnozloupotrebljavamogućnostiprijavljivanja po ovomKodeksu. | * 1. The Chair of the Ethics Committee may dismiss the report as inadmissible if it does not refer to violations of the Code or if it is evident that the report severely abuses the reporting possibility provided by this Code. |
| * 1. Ukoliko ne odbaciprijavu, PredsjednikEtičkogvijeća u roku 8 (osam) dana pozvatićeprijavljenuKompanijučlanicunadostavupismenogizjašnjenja o okolnostimakoje mu se prijavomstavljajunateret. | * 1. If the Chair the Ethics Committee decides not to dismiss the Report, he/she shall invite the reported Member Company within 8 (eight) days to provide a written response regarding the circumstances they are accused of. |
| * 1. PrijavljenaKompanijačlanicadužna je u roku od 15 (petnaest) dana od datumaprimitkapozivanaizjašnjenje, poslatisvojepismenoizjašnjenjePredsjednikuEtičkogvijećanaadresusjedištaUdruženja. Pismenoizjašnjenjemožesadržavati: | * 1. The reported Member Company shall submit its written response to the Chair of the Ethics Committee at the address of the Association’s registered office within 15 (fifteen) days of the date of receipt of the invitation to respond. The written response may contain: |
| 1. izjavu o priznanjupovrede s preuzimanjemobaveze da odmahprekineradnjekojepredstavljajukršenje i da se suzdržiodaktivnostikojemogudovesti do ponavljanjapovrede, uzpotpisivanjeizjave o prestankukršenjaKodeksa (dalje u tekstu: **Izjava o prestanku**); | 1. statement admitting the violation and assuming the obligation to immediately discontinue the actions that constitute the violation and to refrain from activities that could lead to the repeated violation, and signed statement on discontinuation of the Code violation (hereinafter: **Statement of Discontinuation**; |
| 1. izjavu o pobijanjuneosnovaneprijave o navodnojpovrediKodeksa, navodećirazlogetakvogstava. | 1. a statement challenging the ill-founded report of the alleged violation of the Code, stating the reasons behind such position. |
| * 1. UkolikoPredsjednikEtičkogvijećazaključi da je izjava o pobijanjuneosnovaneprijave o navodnojpovrediutemeljena, o tome ćedonijetizaključak koji ćedostavitipodnosiocuprijave i Kompanijičlanicinakoju se odnosiprijava. | * 1. If the Chair of the Ethics Committee concludes that the statement challenging the ill-founded report of the alleged violation is grounded, he/she shall render a conclusion accordingly and submit it to the reporting party and the reported Member Company. |
| * 1. ZaključkomizodredbePredsjednikEtičkogvijećaćepozvatipodnosiocaprijave da se izjasni o stavuPredsjednikaEtičkogvijeća o nepostojanjupovrede u roku od 7 dana računajućiodprimitkatakvogzaključka. | * 1. By the conclusion referred to in the provision , the Chair of the Ethics Committee shall call on the reporting party to respond to the conclusion of the Chair of the Ethics Committee that the violation does not exist within 7 days of the receipt of such Conclusion. |
| * 1. PredsjednikEtičkogvijećasazivasjednicuEtičkogvijeća u sljedećimslučajevima: | * 1. The Chair of the Ethics Committee shall convene a session of the Ethics Committee in the following cases: |
| 1. ako se prijavljenaKompanijačlanicane odazovepozivunadostavuizjašnjenja o podnesenojprijavipovredeKodeksashodnoodredbi; ili | 1. if the reported Member Company fails to react to the invitation to respond to the filed report of the Code violation pursuant to the provision ; or |
| 1. akozaključi da je izjava o pobijanjuneosnovaneprijave o navodnojpovredineosnovana; ili | 1. if he/she concludes that the statement challenging the ill-founded report of the alleged violation is ungrounded; or |
| 1. ako se podnosilacprijave u svomizjašnjenjuizodredbi i usprotivizaključkuPredsjednikaEtičkogvijeća o nepostojanjupovrede. | 1. if the reporting party objects the conclusion of the Chair of the Ethics Committee in their response referred to in the provisions and . |
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| 1. **PRVOSTEPENI POSTUPAK – DRUGI DIO** | 1. **FIRST-INSTANCE PROCEDURE - PART TWO** |
| * 1. PredsjednikEtičkogvijećačlanovimaEtičkogvijećadostavljaprijavu, tedokumentacijudostavljenuodstraneprijavitelja i prijavljeneKompaniječlanice, najkasnije 8 (osam) dana prije same sjedniceEtičkogvijeća. | * 1. The Chair of the Ethics Committee shall provide members of the Ethics Committee with copies of the report and documents provided by the reporting party and the reported Member Company, not later than 8 (eight) days before the session of the Ethics Committee. |
| * 1. Etičkovijećeprovodipostupakutvrđivanjačinjenicanaosnovuzaprimljene i prikupljenedokumentacije i tokompostupkaodlučuje o potrebidostavedodatnihizjašnjenjastranaka u postupku i izvođenjadrugihdokaza (npr. saslušanjemstranaka, svjedoka, pregledomisprava i slično) u ciljupotpunogutvrđivanjačinjeničnogstanja i odgovoranapitanje da li je u konkretnomslučajudošlo do povredeKodeksa. | * 1. The Ethics Committee shall conduct a procedure for the establishment of facts based on the received and collected documentation and decide during the procedure on the need for submission of additional contributions by the parties and presentation of other evidence (e.g., through hearing of the parties and witnesses, review of documents etc.) in order to fully establish the state of facts and whether the Code was violated in that case. |
| * 1. U slučajupotrebe za provedbomsaslušanjastranakailitrećihosoba, sjednicaEtičkogvijećanakojojće se provestisaslušanjeodržatiće se u roku od najkasnije 45 (četrdesetpet) dana od odluke o sazivanjuEtičkogvijeća. Etičkovijećeuputitićepravovremenostrankama u sporu i osobamakojenamjeravasaslušatipozive za saslušanje u kojimaćeodrediti datum, mjesto i vrijemesaslušanjatemogućnost da se pismenoizjasne u slučajunemogućnostidolaskanasaslušanje. Ako se prijavljenaKompanijačlanicane odazovepozivu za saslušanje bez opravdanograzloga, Etičkovijećećedonijetiodlukunatemeljustanja u spisu. | * 1. If it is necessary to interview the parties or third parties, a session of the Ethics Committee during which the hearing will take place shall be held within 45 (forty-five) days of the date of the decision on convening the Ethics Committee. The Ethics Committee shall send the hearing invitations to the parties and other persons it intends to hear in a timely manner, specifying the date, venue and time of the hearing, and allowing them to make a written statement thereof if they are unable to appear at the hearing. If the reported Member Company fails to respond to the hearing invitation without a proper excuse, the Ethics Committee shall render a decision based on the information in the case file. |
| * 1. Ako u tokupostupkaEtičkovijećenađe da je prijavaočitoopravdana, ono možepozvatiprijavljenuKompanijučlanicuda dostaviIzjavu o prestanku u skladusatačkomodredbeKodeksa. | * 1. If, during the procedure, the Ethics Committee finds that the report is evidently reasonable, it may invite the reported Member Company to submit the Statement of Discontinuation in accordance with point of the provision of the Code. |
| * 1. Etičkovijećedužno je provestiprvostepenipostupak i donijetiodluku o prijavištoprije, a najkasnije u roku od 120 dana računajućiodzaprimanjaprijaveodstraneDirektoraudruženja. AkoEtičkovijeće ne doneseodluku i dostavigastranci u navedenomroku, Direktorudruženja mora u roku od 8 dana od proteka 120. dana, pisanimputemobavijestitipredsjednikaEtičkogvijeća, da vraticjelokupnispispredmetaDirektoruUdruženja. | * 1. The Ethics Committee shall conduct the first instance procedure and render a decision concerning the report as soon as possible, and not later than within 120 days of the date of receipt of the report by the Director of the Association. If the Ethics Committee fails to render a decision and deliver it to the party within the given deadline, the Director of the Association shall send a written notice to the Chair of the Ethics Committee within 8 days following the expiration of 120 days, asking them to return the entire case file to the Association Director. |
| * 1. Direktorudruženja se obavezuje o navednomizvijestitiKompaniječlanice ,kako bi se odlučivanje o predmetustavilonadnevni red prveslijedećesjedniceSkupštineUdruženja, kojaćeodlučiti o odgovornostiprijavljeneKompaniječlanice (prijavljenaKompanijačlanica i Kompanijačlanicapodnositeljicasuisključeniodglasanjanatojsjednici po tojtačkidnevnogreda). | * 1. The Director of the Association undertakes to inform the Member Companies accordingly, in order to have the decision making on the case included on the agenda of the following session of the Association, which shall decide on accountability of the reported Member Company (the reported Member Company and reporting Member Company shall be excluded from voting on that item of the agenda). |
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| 1. **ODLUKE ETIČKOG VIJEĆA** | 1. **DECISIONS OF THE ETHICS COMMITTEE** |
| * 1. Etičkovijećemožedonijetisljedećeodluke: | * 1. The Ethics Committee may take the following decisions: |
| 1. odlukukojom se prijavaodbijakaoneosnovana, akoradnjakoja je predmetprijavenijepovredaKodeksailipostojeokolnostikojeisključujuodgovornostprijavljeneKompaniječlaniceiliakonemadokaza da je prijavljenipovreduizvršioili se utvrdi da povredunijeučinio, | 1. decision to dismiss the report as ungrounded, if the reported action does not constitute a Code violation, or if there are circumstances which exclude the responsibility of the reported Member Company, or if there is no evidence that the reported party committed the violation, or if it is established that the reported party did not commit the violation, |
| 1. odlukukojom se prijavljenaKompanijačlanicaproglašavakrivim za povreduKodeksa, | 1. a decision finding the reported Member Company guilty of the violation of the Code, |
| 1. odluku o obustavipostupkaakoutvrdi da nemadovoljnodokaza da je prijavljenaKompanijačlanicaosnovanosumnjiv da je počiniopovreduKodeksakoja je predmetprijave. | 1. a decision on suspension of the procedure, if it is established that there is no sufficient evidence to prove that there are grounds for suspicion that the reported Member Company committed the Code violation at issue. |
| * 1. OdlukaEtičkogvijećadonosi se većinomglasovasvihčlanova. | * 1. A decision of the Ethics Committee shall be rendered by majority vote of all members. |
| * 1. ObrazloženapisanaodlukaEtičkogvijećadostavlja se podnosiocuprijave i prijavljenojKompanijičlanicii obaveznosadržipouku o pravnomlijeku – pravunapodnošenježalbe. | * 1. A reasoned written decision of the Ethics Committee shall be delivered to the reporting party and the reported Member Company, and shall include information on the legal remedy – the right to appeal. |
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| 1. **PRAVO ŽALBE** | 1. **RIGHT TO APPEAL** |
| * 1. ProtivodlukeEtičkogvijećadonesenog u prvostepenompostupkupravožalbeimaju: | * 1. An appeal may be filed against a decision of the Ethics Committee rendered in the first instance procedure by: |
| 1. podnositeljprijavesamo u slučajuodluke o odbijanjuprijavekaoneosnovane, s time da žalbapodnositeljaprijaveprotivizrečenihsankcija (vrste i opsega) nijedopuštena i | 1. the reporting party only if the report is dismissed as ungrounded, but the reporting party may not appeal against imposed sanctions (type and scope), and |
| 1. okrivljenaKompanijačlanica. | 1. the accused Member Company. |
| * 1. Žalba se podnosi u roku od 15 dana računajući od dana primitkapisanogotpravkaodlukeEtičkogvijeća. | * 1. An appeal shall be filed within 15 days of the date of receipt of a written copy of the Ethics Committee’s decision. |
| * 1. Žalba se dostavljaDirektoruUdruženja, koji će, nakonštoutvrdi je li žalbapodnesena u roku od stranežalitelja, pripremitispisepredmeta za sjednicuSkupštineUdruženja i o tome obavijestitiKompaniječlanice . | * 1. An appeal shall be submitted to the Director of the Association who, having verified if the appeal was filed by the appellant in a timely manner, shall prepare the case file for the session of the Association Assembly and notify Member Companies thereof. |
| * 1. Ukolikožalbanijedostavljena u roku, DirektorUdruženjaćedostavitižalbupredsjednikuEtičkogvijećakako bi donioodluku o odbacivanjužalbe. | * 1. If the appeal has not been filed in a timely manner, the Director of the Association shall forward the appeal to the Chair of the Ethics Committee to render a decision on dismissal of the appeal. |
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| 1. **DRUGOSTEPENI POSTUPAK – ODLUČIVANJE O ŽALBI** | 1. **SECOND INSTANCE PROCEDURE – DECIDING ON THE APPEAL** |
| * 1. Ukoliko je žalbapodnesena u roku, DirektorUdruženjaćecjelokupnispispredmetadostavitiPredsjednikuSkupštineUdruženja, kako bi se predmetstavionadnevni red prvesljedećesjedniceSkupštineUdruženja. Na tojsjedniciSkupštineUdruženja, PredsjednikEtičkogvijećailijedanodčlanovabitićeizvjestilac o predmetu, nakončegaće se pristupitiraspravi i glasanju o žalbi. | * 1. If the appeal is filed within the set deadline, the Director of the Association shall forward the entire case file to the Chair of the Association Assembly, in order to put the case on the agenda of the following session of the Assembly. At this session of the Association Assembly, the Chair of the Ethics Committee or one of the members shall be the case rapporteur, which shall be followed by a discussion and voting on the appeal. |
| * 1. SkupštinaUdruženjamožedonijetisljedećeodluke: | * 1. The Assembly of the Association may decide as follows: |
| 1. odbitižalbukaoneosnovanu i potvrditiodlukuEtičkogvijeća; | 1. dismiss the appeal as ungrounded and confirm the decision of the Ethics Committee; |
| 1. ukinuti i izmijeniti, u cijelostiilidjelomično, odlukuEtičkogvijeća u odnosunasamuodlukuiliizrečenesankcije. | 1. abolish and modify the decision of the Ethics Committee, in its entirety or in part, relative to the decision itself or the imposed sanctions. |
| * 1. SkupštinadonosiodlukenatpolovičnomvećinomsvihprisutnihčlanovaSkupštine koji glasaju. | * 1. The Assembly shall render decisions with simple majority vote of all present voting members of the Assembly. |
| * 1. OdlukaSkupštine po žalbi je konačna i naistu se nijemogućežaliti. | * 1. A decision of the Assembly upon appeal is final, and no further appeal is allowed. |
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| 1. **SANKCIJE** | 1. **SANCTIONS** |
| * 1. Etičkovijeće i SkupštinaUdruženjaizričusljedećesankcije u svojimodlukamakojimaproglašavajuprijavljenuKompanijučlanicukrivom: | * 1. The Ethics Committee and the Association Assembly impose the following sanctions in their decisions finding the reported Member Company guilty: |
| 1. opomenu; | 1. admonition; |
| 1. obavještavanjedruštvaosnivačaKompaniječlaniceo pravosnažnojodluciUdruženjakojom se ta Kompanijačlanicaproglašavakrivom za povreduKodeksa; | 1. notification to the founder company of the Member Company about the Association’s final decision finding the Member Company guilty of the Code violation; |
| 1. objavuodlukeEtičkogvijeća i SkupštineUdruženjana internet straniciUdruženja i sažetkaodlukenaengleskomjeziku; | 1. publication of the decision of the Ethics Committee and the Association Assembly on the Association’s website, and the decision summary in English language; |
| 1. isključenjeKompaniječlaniceizUdruženja. | 1. exclusion of the Member Company from the Association. |
| * 1. SankcijepredviđeneovimKodeksommogu se i kumulirati. | * 1. Sanctions foreseen by the Code may also be combined. |
| * 1. Priutvrđivanju i odmjeravanjukaznipotrebno je uzeti u obzirsljedećeaspekte: | * 1. When establishing and weighing sanctions, the following aspects should be taken into account: |
| 1. ozbiljnostpovrede, | 1. severity of the violation, |
| 1. potencijalniučinakpovredenapercepcijujavnosti o integritetuKompanijačlanica , | 1. potential effect of the violation on the public perception of integrity of Member Companies, |
| 1. radi li se o jednokratnomiliponovljenomkršenjuKodeksaodstraneKompaniječlanice , | 1. is it isolated violation incident, or repeated violations of the Code by the Member Company, |
| 1. posljedicama za Kompanijučlanicuizrečenomkaznom, | 1. consequences of the imposed sanction for the Member Company, |
| 1. u kojoj se mjeriokrivljenaKompanijačlanicapokušala u svojojorganizacijisuprotstavitipovredamaKodeksa; | 1. to which extent the accused Member Company endeavoured to fight against the Code violations within its organisation; |
| 1. interne kazne i organizacijskemjerekoje je poduzela i provelaokrivljenaKompanijačlanica ,iliih je imaonaumukaoreakcijunapovredunakoju se prijavaodnosi, općenito i u ovompojedinačnomslučaju; | 1. internal sanctions and organisational measures taken and implemented, or conceived by the accused Member Company as a reaction to the reported violation, in general and in the specific case. |
| 1. cjelokupnodržanje i saradnjuokrivljeneKompaniječlanicetokompostupkapredUdruženjem. | 1. overall behaviour and cooperation of the accused Member Company during the procedure before the Association. |
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| 1. **OBAVEZA ČUVANJA TAJNOSTI O TEKUĆIM POSTUPCIMA** | 1. **OBLIGATION TO KEEP ONGOING PROCEDURES SECRET** |
| * 1. Svi oni koji suuključeni u postupak, članoviEtičkogvijeća, članoviRadnegrupe za pravneposlove i usklađenost i Regulatornegrupe, Upravniodbor i osobekojesunabilo koji načinupoznatesapostupkom i povezanesaradomUdruženja, imajuobavezučuvatitajnostpodataka o svimaktivnostima i informacijamakojedoznaju. | * 1. All those involved in the procedure, members of the Ethics Committee, members of the Working Group for Legal Affairs and Compliance and of the Regulatory Group, the Board and persons who are familiar with the procedure in any way and connected with the work of the Association, shall be obligated to keep the secrecy of data on all activities and information they obtain. |
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| 1. **IZVJEŠTAVANJE NADLEŽNIH ORGANA** | 1. **REPORTING TO RELEVANT AUTHORITIES** |
| * 1. Ovisno o prirodipočinjenepovrede, pogotovoukolikopostojiosnovanasumnja da je povredomKodeksaizvršena i povredavažećihpropisa o lijekovima i medicinskimsredstvima i njihovomoglašavanjutedrugihpropisa, Etičkovijećemože o takvojpovrediizvijestitinadležnatijela: Agenciju za lijekove i medicinskasredstva BIH, Ministarstvozdravstva FBIH i RS, Odjel za zdravstvoBrčkoDistriktaBosne i Hercegovine, odnosnoistražneorgane u vezisadjelima za koja je propisanaprekršajnailikrivičnaodgovornost. | * 1. Depending on the nature of the committed violation, especially if there is a founded suspicion that the Code violation also constitutes violation of existing legislation on medicinal products and medical devices and their advertising and other regulations, the Ethics Committee may report such violation to the relevant authorities: the Agency for Medicinal Products and Medical Devices of BiH, Ministries of Health of FBiH and RS, the Health Department of the Brčko District of Bosnia and Herzegovina, and investigation bodies in relation to activities that are subject to minor offence or criminal sanctions. |
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| 1. **MIŠLJENJE ETIČKOG VIJEĆA** | 1. **OPINION OF THE ETHICS COMMITTEE** |
| * 1. U skladusaodredbomčlana, kao i u drugimslučajevimasumnje o tumačenjuodredbiovogKodeksa, Kompaniječlanice se moguobratitiUdruženjusazahtjevom za davanjemišljenjaEtičkogvijeća, pod uslovimapropisanimovimčlanom. | * 1. Pursuant to provisions of Article , and in other cases involving doubts about interpretation of the provisions of this Code, Member Companies may address the Association and request the opinion of the Ethics Committee, under the conditions laid down in this Article . |
| * 1. Zahtjev se podnosi u pismenojformi, te mora jasnoodrediti u vezi s čim se tražimišljenje, kao i odredbeovogKodeksa u vezisakojima se tražimišljenje, aako se odnosinaodređenukonkretnusituaciju, onda mora sadržavati i svečinjeničnenavode koji supotrebni za donošenjeMišljenja. | * 1. The request shall be submitted in writing, and it shall clearly define what the opinion is sought about, and specify the provisions of this Code for which the opinion is requested. If it relates to a specific situation, it shall include all factual allegations needed for issuance of the Opinion. |
| * 1. Po prijemuzahtjeva za davanjeMišljenja, direktorudruženjaprijavuprosljeđujePredsjednikuEtičkogvijeća. | * 1. Upon receiving the request for issuance of an Opinion, the Association Director shall forward the report to the Chair of the Ethics Committee. |
| * 1. MišljenjeEtičkogvijeća se donosi u pismenojformi, a primjenjuje se postupakpropisančlanovima., . i . ovogKodeksa, s tim da rok za donošenjeMišljenja ne možebitiduži od 30 dana od dana prijemazahtjeva za davanjemišljenja. | * 1. The opinion of the Ethics Committee shall be issued in the written form, and the procedure prescribed in Articles , and of this Code shall apply, but the deadline for issuance of the Opinion may not be longer than 30 days of the date of receiving the request for issuance of the Opinion. |
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| **SEDMI DIO: ZAVRŠNE ODREDBE** | **PART SEVEN: FINAL PROVISIONS** |
| 1. **ZAVRŠNE ODREDBE** | 1. **FINAL PROVISIONS** |
| * 1. Ovajkodeks je sačinjennajednomodzvaničnihjezika u BiH (***BiH jezik***) i engleskomjeziku. U slučajurazlikaizmeđutekstakodeksana BiH jeziku i engleskomjeziku, tekstna BiH jeziku je preovladavajući. | * 1. This Code has been executed in one of the official languages in BiH (BiH language) and in English. In case of discrepancies between BiH language and English versions of the text, the BiH language version shall prevail. |
| * 1. StupanjemnasnaguovogKodeksa, stavlja se van snage i prestaje da važiKodeksponašanjainovativnihproizvođačalijekova od 22.06.2018. i KodeksponašanjačlanovaUdruženjaInovativnihproizvođačalijekova u Bosni i Hercegovini u odnosimasaOrganizacijamapacijentabroj 01/17 od 06.04.2017. godine. | * 1. Upon the entry into force of this Code, the Code of Conduct of Innovative Pharmaceutical Manufacturers of 22 June 2018 and the Code of Conduct of the Association of Innovative Pharmaceutical Manufacturers in Bosnia and Herzegovina in Relations with Patient Organisations no.: 01/17 of 6 April 2017 shall cease to have effect. |
| * 1. OvajKodeks stupa nasnagudanomdonošenja i od toga dana obavezujesveKompaniječlanice . | * 1. This Code shall enter into force on the date of adoption and shall be binding for all Member Companies as of that date. |
| \* \* \* | \* \* \* |
| Broj: 12/20 | Number: 12/20 |
| U Sarajevu, 18.12.2020. godine. | In Sarajevo, 18 December 2020 |
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