POLITIKA STROKOVNIH PRAKS (P3)

PROFESSIONAL PRACTICES POLICY (P3)

1. UVOD

Novartisova vizija je biti zaupanja vredna družba, ko gre za spreminjanje zdravstvenih praks. Skladno s to vizijo v Novartisu stremimo k visokim standardom etičnega poslovanja, kjerkoli poslujemo.
Novartis je zato sprejel enotna etična načela, ki jim sledimo pri vsakodnevnem odločanju in veljajo za vse sodelavce družbe Novartis vsakokrat, ko govorimo o interakcijah s strankami in/ali aktivnostih, ki so povezne s strokovnimi praksami, četudi te niso izrecno omenjene v tej Politiki ali z njo povezanih aktih.

2. OBSEG IN UPORABA

Ta Politika velja za vse sodelavce družbe Novartis in tudi za tiste tretje stranke, ki v imenu družbe Novartis izvajajo aktivnosti, povezane s strokovnimi praksami, kot jih določa ta Politika. Vse P3 aktivnosti se izvajajo skladno z lokalno zakonodajo, predpisi in panožnimi kodeksi.

P3 Politika služi kot osnova za P3 Smernice (v nadaljevanju: Smernice) in ostale interne postopke (v nadaljevanju: SOP), ki definirajo dodatne zahteve glede pričakovanega vedenja. Politika se zato vselej uporablja skupaj s Smernicami in drugimi akti, na katere se sklicujemo v tem dokumentu.

Politika velja od 1. novembra 2019 dalje, za vse divizije in podjetja v skupini Novartis. Nadomestila bo vse obstoječe različice Politike, ki prenehajo veljati oz. se uporabljati z dnem uveljavitve Politike.

Skrbnik Politike strokovnih praks (P3) je oddelek za Etiko, tveganja in skladnost.

3. DEFINICIJE

Neželeni dogodek - Kakršenkoli neugoden medicinski pojav pri bolniku ali preiskovancu v procesu kliničnega preskušanja, ki je uporabil zdravilo ali medicinski pripomoček, ki pa ni nujno vzročno povezan z zdravljenjem. Neželeni dogodek je torej lahko kakršenkoli neželen ali nenameren znak (vključno z neobičajnimi rezultati laboratorijskih preiskav), simptom ali bolezen, ki je časovno povezana z uporabo zdravila ali medicinskega pripomočka, ne glede na vzročno povezavo z zdravilom.

Stranka ali poslovni partner - Splošna opredelitev:
- Bolniki in organizacije bolnikov

1. INTRODUCTION

Novartis' vision is to be a trusted leader in changing the practice of medicine. Consistent with this vision, Novartis is committed to the same high standard of ethical business conduct wherever it does business. Novartis has therefore adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis Associates in any customer interaction and professional practice-related activity, including those not specifically covered by this Policy or related documents.

2. SCOPE AND APPLICABILITY

This Policy applies to all Novartis Associates as well as all professional practice-related activities conducted by third parties on behalf of Novartis. All such activities must be conducted in accordance with local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.
P3 Policy serves as the foundation for P3 Guidelines ("Guidelines") and local standard operating procedures ("SOPs") all of which provide additional requirements for expected behaviors. As a result, this Policy should be read and applied in conjunction with the Guidelines and other references included in this document.

This Policy is effective as of November 1st, 2019 and must be adopted by all Novartis affiliates. It replaces its previous versions.

The owner of this Professional Practices Policy (P3) is Ethics, Risk & Compliance.

3. DEFINITIONS

Adverse Event - An adverse event is any unfavorable medical occurrence or unintended sign (including an abnormal laboratory finding), symptom, disease or injury temporally associated with the use of a medical device, medicinal or investigational product, in patients, users, or other persons, whether or not it is considered to be related to or due to the product.

Customer - Defined broadly as:
- Patients and patient organizations

- Partnerji s področja zdravstvenega varstva, kar med drugim vključuje zdravstvene delavce, zdravstvene organizacije, plačnike, distributerje/ veletrgovce, tretje stranke, dobavitelje, posrednike
- Trgovci na drobno, ki niso zdravstveni delavci

Skrbnik - oseba, ki sodeluje pri odločanju oz. se odloča o zdravstvenih ukrepih za bolnika. Skrbniki so na primer starši ali zakoniti skrbniki, zakonci ali partnerji, odrasli otroci, sorodniki ali drugi prijatelji.

Programi za osveščanje o boleznih – nepromocijski program, namenjen izobraževanju, osveščanju in zagotavljanju informacij v zvezi z zdravjem, boleznimi in obvladovanjem bolezni javnosti, potencialnim pacientom ali zdravstvenim delavcem.

Donacija - sredstva, ki jih družba Novartis zagotovi priznanim organizacijam za altruističen in specifičen namen, pri čemer pa v zameno ne pričakuje nobenih koristi ali storitev.

Dogodek - konferenca, kongres, simpozij ali katero drugo srečanje z znanstveno, izobraževalno ali strokovno vsebino, ki ga delno ali v celoti organizira ali financira družba Novartis ali tretja stranka, z namenom posredovanja novih informacij, izpopolnitve znanja o Novartisovih izdelkih ali zagotovitve znanstvenih, izobraževalnih in drugih strokovnih informacij.

Darila - različni predmeti ali ugodnosti, ki jih ena oseba podari drugi kot znak spoštovanja ali prijateljstva brez pričakovanja, da bo prejela kar koli v zameno.

Subvencija - neodvisno zaprošen prispevek, ki je dan priznani organizaciji za jasno opredeljen namen brez dogovora ali pričakovanja vzajemne materialne (izmerljive) koristi.

Zdravstvene organizacije (HCOs) - vsaka pravna oseba (podjetje, družba ali zdravstvena ustanova) javnega ali zasebnega prava, ki ponuja/zagotavlja zdravstvene storitve bolnikom in lahko predpiše, naroča, izdaja, priporoča, kupuje, dobavlja, daje, najema in uporablja Novartisove izdelke, ter vsi člani njenega osebja ter ostala zdravstvena združenja in organizacije.

- Healthcare partners, including but not limited to, healthcare professionals, healthcare organizations, payers, third party distributors/wholesalers, suppliers, intermediaries
- Non-HCP Retailers

Caregiver - someone who participates in or makes medical decisions for a patient. Examples of caregivers include parents or legal guardians, spouses or partners, adult children, relatives, or other friends.

Disease Awareness Programs - A non-promotional program conducted to increase awareness or education about health, disease, and their management directed to patients, general public, and healthcare professionals.

Donation - benefit granted by Novartis to a reputable legitimate institution for an altruistic and specific, non-business-related purpose, and where Novartis does not expect to receive any benefit, consideration of service in return.

Event - congress, conference, symposium and any other meeting of a scientific, educational or professional nature organized or funded partially or fully by Novartis or a third party to disseminate knowledge enhancing information, increase knowledge of Novartis products, and provide scientific, educational and/or professional information.

Gifts - Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return.

Grants - independently requested contribution conveyed to a legitimate organization for a specified purpose without agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

Healthcare Related Organizations (HCOs) - any legal entity (such as a company, partnership, or healthcare institution), whether public or private, that offer/provide Medical Services to patients and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, and use Novartis products, and all members of their office staff, and medical associations or organizations.

Primeri zdravstvenih organizacij vključujejo: zdravniška praksa, bolnišnice (vključno z univerzitetnimi kliničnimi centri), ambulantno kirurški centri, lekarne, klinike, negovalni centri, pravne ali fizične osebe za nadzorovano nego, organizacije za skupno nabavo (Group Purchasing Organizations), specializirane prodajalne, zdravstvena združenja in podjetja v lasti posameznega zdravstvenega delavca ali skupine zdravstvenih delavcev.

Examples of HCOs include physician practices, hospitals (including university hospitals), ambulatory surgical centres, and pharmacies, clinics, nursing facilities, managed care entities, group purchasing organizations (GPOs), specialty pharmacies, medical societies, and businesses owned by an individual or group of HCPs.

Zdravstveni delavec - Vsakdo, ki opravlja poklic zdravnika, zobozdravnika, očesnega zdravnika, farmacevta ali vsaka druga oseba, ki pri izvajanju svojih poklicnih dejavnosti zagotavlja zdravstvene storitve in lahko predpiše, naroča, deli, priporoča, kupuje, dobavlja, daje, najema ali uporablja zdravila in/ali medicinske tehnologije**.** Izjema so študenti medicine/ farmacije ter izvajalci negovalnega poklica, npr. medicinske sestre, za katere veljajo posebna pravila, kot to določata veljavna zakonodaja in SOP.

Healthcare Professionals (HCPs) - Any member of the medical, dental, optometry, pharmacy, or any other person, who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies. Exceptions are medical/ pharmacy students and medical caregivers, i.e. nurses, who are subject to special rules, as provided for by applicable law and SOP.

Predmeti za strokovno uporabo - predmeti, ki (1) se uporabljajo za neposredno izobraževanje zdravstvenih delavcev ali bolnikov oz. jih lahko uporabijo bolniki kot pripomoček pri odmerjanju, administriranju zdravil ali pri obvladovanju svoje bolezni, in ki so (2) uporabni kot izobraževalni pripomočki za zdravstvene delavce, zunaj njihove ordinacije pa nimajo nobene vrednosti.

Item of Medical Utility - items that (1) are intended for the direct education of HCPs or patients, or are for use by patients to assist them in the administration of their treatment or management of their conditions, and (2) do not have value to HCPs outside of the scope of their practice and educational need.

Zdravstvene storitve - izvajanje ali naročanje vseh pregledov, laboratorijskih izvidov ali postopkov za diagnosticiranje ali zdravljenje katere koli težave s področja medicine ali v zvezi z zdravjem, ter pisanje receptov za farmacevtske izdelke ali za medicinske pripomočke, ki jih bo plačala oseba (iz javnega ali zasebnega sektorja), ki ni bolnik/ potrošnik.

Medical Services - performing or ordering any examination, test, or procedure to diagnose or treat any medical or health- related issue, or filling a prescription for a pharmaceutical or device product that is eligible for payment by someone (whether payer is public or private) other than a patient/consumer.

Zdravilo brez recepta (OTC) - zdravilo, ki se sme izdajati brez zdravniškega recepta, saj ne izpolnjuje meril za razvrstitev med zdravila na recept

Over the Counter (OTC) Product - A medicine or a device sold directly to a consumer without a prescription from a healthcare professional.

Bolnik - Vsaka oseba, ki za svoje osebne potrebe lahko prejme recept in/ali se zdravi s farmacevtskim izdelkom in/ali z medicinskim pripomočkom.

Patient - any person who may receive a prescription for, and/or are treated with a pharmaceutical product and/or medical technology for his or her individual needs.

Združenje bolnikov - neodvisno združenje, ki zagotavlja neposredno podporo osebam, ki jih je prizadela bolezen, zagovarja pravice bolnikov, osvešča o bolezni in si prizadeva za informiranje bolnikov o vsaj enem terapevtskem področju. Ta združenja pogosto ustanavljajo bolniki, njihovi družinski člani in skrbniki, vendar se lahko med

Patient Organization - independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and

njihove člane združenja in vodstvo vključijo tudi zdravstveni delavci, prostovoljci in oblikovalci politike.

Program za podporo bolnikov – program vključuje neposredne in posredne stike z bolniki ali njegovimi skrbniki. Izvaja ga Novartis ali tretja stranka v imenu družbe Novartis. Primeri vključujejo pomoč bolnikom pri jemanju zdravil in upoštevanju priporočil za zdravljenje, zagotavljanje podpore pri obvladovanju bolezni ali zagotavljanje/načrtovanje finančne pomoči za bolnike, ki si ne morejo privoščiti zdravil.

Vzorci - ustrezno označeni in upravljani brezplačni izdelki, ki jih zdravstvenim delavcem dajemo z namenom, da jih z njimi seznanijo.

Javni uradnik:

- vsakdo, ki je izvoljen ali imenovan za uradnika oz. je zaposlen pri vladi, ministrstvu ali drugi državni službi oz. v podjetju, ki je v državni lasti. Za javne uradnike štejemo tudi zdravstvene delavce, ki so zaposleni pri javni zdravstveni ustanovi in lahko neposredno vplivajo na zdravstveno politiko, npr. tako da deluje v regulatornih in/ali drugih upravnih državnih organih. Za namene te politike je javni uradnik vsakdo, ki ustreza definiciji »uradnika« po Zakonu o javnih uslužbencih (ZJU-UPB3, Ur.l. RS, št. 63/2007),
- vsakdo, ki je izvoljen ali imenovan za uradnika (ali je zaposlen) v mednarodni javni organizaciji,
- vsaka oseba, ki opravlja uradne dolžnosti za in v imenu vlade, ministrstva, državne ali javne mednarodne organizacije,
- politik in kandidat za politično funkcijo.

Raziskovalne in razvojne dejavnosti - dejavnosti, ki se izvajajo za izpopolnjevanje znanstvenega in kliničnega znanja, zaradi zdravstvenih potreb. Te dejavnosti vključujejo klinične in neklinične študije, raziskave na začetni stopnji raziskovalnih študij, srečanja raziskovalcev, študije, v katerih sodelujejo ljudje ali pa vključujejo obdelavo bolnikovih podatkov, živali ali biološki material.

Izmenjava znanstvenih informacij - zbiranje, objava, razširjanje in posredovanje znanstvenih ugotovitev (znanstvena spoznanja in znanje, ki se uporablja pri znanstvenih raziskavah in se lahko

caregivers but may also include Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership.

Patient Support Program - a program that involves direct or indirect interactions with a patient or patient's caregiver implemented by Novartis or a third party on behalf of Novartis. Examples include helping patients manage medication administration and adherence, provide disease management support, provide, or arrange for financial assistance for patients who cannot afford medications.

Pharmaceutical Samples - Free pharmaceutical products supplied to HCPs authorized to prescribe that product in order to enable HCPs and their patients to gain experience in dealing with the product.

Public Official:

- Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government. Public Officials are also individual HCPs who work at public HCIs and influence health care policy or are working at governmental institutions including Regulatory, State administrative authorities. For the purpose of this policy, a "public official" shall be understood as "uradnik" as defined by Civil Servants Act (ZJU-UPB3, Ur.l. RS, št. (Uradni list RS, št. 63/2007).
- Any elected or appointed officers or employees of public international organizations, such as the United Nations.
- Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization.
- Politicians and candidates for a political office.

Research and development activities – activities conducted to obtain scientific and clinical knowledge in order to address unmet medical needs. These activities include clinical and non-clinical studies, exploratory early stage research, investigator meetings, and studies in human subjects or involving human/patient data, and animals or biological materials.

Scientific Exchange - collection, publication, distribution and communication of scientific knowledge (knowledge related to, derived from or used in science for sharing), which may include information concerning a Novartis product.

deli z drugimi), ki lahko vključujejo informacije o Novartisovih izdelekih.

Sponzorstvo - sredstva, ki jih družba Novartis nameni sponzorirani organizaciji, ta pa ji v zameno zagotovi promocijo njene podobe, blagovnih znamk ali storitev na dogodkih, aktivnostih ali na druge primerne načine, pri čemer imata obe stranki v takšnem razmerju vzajemno korist.

3. NAČELA

BOLNIKI NA PRVEM MESTU

Naše interakcije s strankami oz. deležniki morajo koristiti bolnikom, tako da izboljšujejo standard oskrbe bolnikov, omogočijo doseganje boljše osveščenosti o boleznih in možnostih zdravljenja, oz. kako drugače prispevajo k etičnemu zagotavljanju zdravstvene nege.
Z bolnikovimi podatki smo dolžni ravnati spoštljivo, tako da varujemo zaupnost, pridobivamo soglasja za njihovo zbiranje oz. morebitno razkritje, naše interakcije z bolniki pa so transparentne in ustrezno dokumentirane.
Skrbimo za varnost bolnika. Če strokovni sodelavec izve ali opazi, da v zvezi z Novartisovim izdelkom (ki je odobren ali del študije) obstaja neko tveganje oz. če prejme pritožbo (kot je npr. neželeni dogodek/ učinek, napaka, neučinkovitost), je o tem dolžan pravočasno poročati skladno s farmakovigilančnimi pravili.

ODGOVORNO FINANCIRANJE

S subvencijami, donacijami in sponzorstvi smemo podpirati le legitimne zunanje organizacije.
Način financiranja mora ustrezati našemu ugledu, biti skladen z družbenimi pričakovanji in poslanstvom družbe Novartis odkrivati inovativne načine za boljše in daljše življenje. Enaka pravila veljajo tudi, ko gre za nedenarno podporo.

JASNI CILJI

Kot zaupanja vreden partner na področju zdravstvene oskrbe, moramo vse dejavnosti izvajati z jasnimi in transparentnimi cilji, ki so natančno opredeljeni, ustrezajo dejanskemu stanju, nimajo zavajajočih vsebin in sledijo načrtovanemu namenu.
Novartis lahko izvaja promocijske in nepromocijske aktivnosti, ki omogočajo razvijanje izdelkov glede na potrebe bolnikov, izpopolnjevanje strokovnega razumevanja bolezni, izboljševanje obvladovanja bolezni in izidov zdravljenja ter pravilno uporabo naših izdelkov.

Sponsorship - agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis' image, brands, or services and a sponsored event, activity, or organization.

3. PRINCIPLES

PUT PATIENTS FIRST

All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, or otherwise contributing to the ethical delivery of healthcare.
We will treat patient information with respect, protect confidentiality, where required obtain informed consent, and be transparent with patients at all times.
We must protect patient safety. If an Associate becomes aware of a product-related risk or complaint (e.g., adverse event, manufacturing defect or product failure) related to Novartis products (approved or investigated), it must be reported in a timely manner in accordance with pharmacovigilance rules.

FUND RESPONSIBLY

External funding (including grants, donations and sponsorships) must only be given to legitimate organizations, and provided in a way that protects our reputation, aligns with society's expectations, and is consistent with the Novartis Mission to discover new ways to improve and extend people's lives. The same rules apply for external in-kind support.

ACT WITH CLEAR INTENT

As trusted partners in healthcare, all of our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context.
Novartis may conduct promotional and non-promotional activities throughout the product lifecycle. These activities ensure that products are developed to meet the needs of patients, to advance scientific understanding of disease, including disease management and treatment outcomes, and to discuss the appropriate use of products.

Nepromocijske aktivnosti se ne smejo izvajati z namenom promocije oz. na način, ki bi lahko bil razumljen kot promocijski.

PRIMERNO SODELOVANJE

Sodelavci ne smejo ponujati, odobriti ali izročati predmetov/ stvari z namenom, da bi neprimerno vplivali na stranke oz. jih nagradili za uporabo Novartisovih izdelkov.
Novartis lahko za posamezne storitve, ki mu pomagajo pri raziskavah, razvoju in promociji izdelkov, angažira zdravstvene delavce in druge tretje stranke.
Plačamo lahko le storitve, ki so bile opravljene v dobri veri. Plačilo mora biti skladno s pošteno tržno vrednostjo, ustrezno dokumentirano in evidentirano. Po potrebi smo plačila dolžni javno razkrivati.
Predmeti, ki jih izročamo poslovnim partnerjem, morajo biti skromne vrednosti. Podarjamo jih lahko le izjemoma, zaradi tega pa ne sme nastati dejansko ali navidezno nasprotje interesov.

UPRAVIČENE RAZISKAVE

Raziskave izvajamo le v primerih, ko bi prišli do odgovorov na upravičena medicinska ali znanstvena vprašanja, katerih cilj je boljša oskrba bolnikov. Vedno moramo spoštovati in ščititi pravice, varnost in dobro počutje naših bolnikov (oz. živali) in zagotavljati integriteto ter veljavnost pridobljenih podatkov.
Raziskovalne in razvojne aktivnosti lahko izvajajo le strokovno usposobljeni raziskovalci, ki sledijo veljavnim etičnim in znanstvenim standardom.
Raziskovalne in razvojne aktivnosti ne smejo biti namenjene promociji izdelkov.

4. P3 PRAVILA

4.1. KLINIČNE ŠTUDIJE

Klinične študije lahko izvajamo samo, če imamo za to upravičene razloge. Študije se lahko izvajajo le, če so znanstveno utemeljene in načrtovane z namenom iskanja odgovorov na ustrezna medicinska, znanstvena ali ekonomsko-zdravstvena vprašanja. Raziskovalci so dolžni upoštevati zahteve, ki so definirane v Stališčih družbe Novartis o transparentnosti klinične študije in Priročniku družbe Novartis o kakovosti.
Sodelavci Novartisa morajo na prvo mesto vedno postaviti bolnika in ščititi njegovo varnost; če sodelavec zazna, da v zvezi s katerokoli študijo ali izdelkom obstaja neželeni dogodek, mora o tem poročati skladno s standardi družbe Novartis za poročanje o neželenih dogodkih.

Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

ENGAGE APPROPRIATELY

Associates must not offer, approve, or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for the use of Novartis products.
Novartis may choose to engage healthcare professionals or other customers to provide necessary and legitimate services to help us research, develop, and/or promote our products.
Any compensation must be for a bona fide service, consistent with fair market value, properly documented and accounted for and disclosed where required.
Allowable items of value, when provided to customers, must be modest, reasonable, and infrequent, free from actual and perceived conflicts of interest.

RESEARCH FOR THE RIGHT REASON

Research and development must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients (and animals) and safeguard the integrity and validity of the data obtained.

Research and development activities must follow established ethical and scientific standards and be conducted by qualified investigators.
Research and development activities must never be promotional in nature.

4. P3 RULES

4.1. CLINICAL RESEARCH

Novartis must conduct clinical research for the right reasons. Research must be conducted only if it is scientifically valid and designed to answer relevant medical, scientific, or health economic questions. It must follow the Novartis Position on Clinical Study Transparency and the Novartis Quality Manual.
Novartis Associates must always put patients first and protect their safety; if an Associate becomes aware of an adverse event related to any study or product, he/she must report it according to Novartis Adverse Event Reporting Standard.
Novartis supports the publication of study results in a timely manner and must not withhold or suppress data. We must protect confidential and/or patentable information, and personal information. Where

Rezultati raziskav morajo biti objavljeni v razumnem roku. Podatkov ni dovoljeno zadrževati ali jih prikazovati le delno. Dolžni smo zaščititi zaupne podatke, podatke o izdelkih, ki jih je mogoče patentirati ter osebne podatke. Skladno z lokalno zakonodajo in panožnimi kodeksi družba Novartis razkriva in poroča o plačilih oz. prenosih vrednosti zdravstvenim delavcem in/ali njihovim ustanovam za raziskovalne aktivnosti. Vse objave morajo biti skladne s Smernicami družbe Novartis za objavo rezultatov raziskav, ki jih sponzorira družba Novartis.

required by local laws, regulations and/or industry codes, Novartis must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research activities. All publications must follow Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research.

4.2. DOLOČANJE CEN IN DOSTOP NA TRG

Novartis lahko pride v stik s posamezniki, vključno z zdravstvenimi delavci, ki so vključeni v pripravo zdravstvenih smernic oz. priporočil glede uporabe zdravil, v postopek razvrščanja zdravil, katerih strošek nosi zdravstvena zavarovalnica, ali ki kako drugače odločajo o nakupu zdravil oz. izdelkov družbe Novartis. Paziti moramo, da s takšnimi interakcijami ne vplivamo na neodvisno presojo teh oseb, oz. da ne delujemo na način, ki bi lahko bil razumljen kot neprimeren vpliv. S posamezniki lahko vodimo proaktivno razpravo namenjeno razumevanju potreb državne oz. javne uprave, plačnikov in javnih zdravstvenih organizacij (npr. vpliv novih načinov zdravljenja na proračun) in odgovarjamo na vprašanja oz. posredujemo podatke (npr. ekonomski podatki ali informacije o razvojnih projektih, ki so v javni domeni). Vsi ti pogovori morajo biti verodostojni in točni. Pri stiku z javnimi uslužbenci upoštevamo tudi posebne zakonodajne zahteve.
Če za izvajanje strokovnih storitev angažiramo zdravstvene delavce, ki so hkrati člani državnih/javnih organov (npr. člani komisije za razvrščanje zdravi ipd.), se morajo takšne interakcije razkriti skladno z veljavno zakonodajo.
Popusti, rabati in druga plačila morajo biti natančno in ustrezno zapisani v naših računovodskih izkazih in povezanih evidencah.

4.2. PRICING AND MARKET ACCESS

Novartis may interact with individuals, including HCPs, involved in recommending or deciding product reimbursement or purchase of Novartis products. However, these interactions must not interfere with their independent judgment or be perceived as improperly influencing them. Interactions may include proactive discussions to understand the needs of governments, payers and public health organizations (e.g., budgetary impact of new therapies) or responding to specific request for information (e.g., providing economic data or pipeline information that is in the public domain). All such discussions must be truthful and accurate. If these interactions are with public officials, they may be subject to additional laws, regulations and industry codes.
Engagement of HCPs for professional services who are formulary committee members must be disclosed according to relevant laws and regulations.
Discounts, rebates and other payments must be accurately and appropriately recorded in our books and records.

4.3. KOMUNIKACIJA IN ZNANSTVENA IZMENJAVA

Izdelke lahko promoviramo samo skladno z odobrenimi informacijami o zdravilu (SMPC, PIL, ovojnina).
Novartis podpira pravico znanstvene skupnosti in javnosti do informiranosti o razvoju na področju znanosti in medicine. Zato lahko znanstvene informacije izmenjujemo povsod, kjer to dovoljujejo zakonodaja in panožni kodeksi. Sem spada

4.3. PRE-APPROVAL COMMUNICATION AND SCIENTIFIC EXCHANGE

Products must only be promoted consistent with approved labelling (SMPC, PIL, packaging).

Novartis supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Novartis may exchange scientific information. This may

komunikacija na znanstvenih dogodkih, javno razkritje informacij delničarjem, javnemu sektorju, zdravstveni zavarovalnici ali njihovim članom in organizacijam javnega zdravstvenega varstva.

Novartis lahko s strani zdravstvenih delavcev, združenja bolnikov ali drugih deležnikov prejme zahtevo za posredovanje informacij o neodobrenih zdravilih ali indikacijah. Te informacije lahko poda le Medicinski oddelek. Strokovni sodelavci, ki takšno zahtevo prejmejo, le-to posredujejo Medicinskemu oddelku. Odgovor, ki ga ta zagotovi, vključno s priloženim gradivom, mora biti natančen, ne sme biti zavajajoč, ne sme promovirati izdelkov in mora odgovoriti samo na tisto vprašanje, ki je navedeno v zahtevi, skladno z veljavno zakonodajo in panožnimi kodeksi. Medicinski oddelek takšne zahteve in odgovore hrani na primeren način. Oddelek za Znanstvene zveze na področju medicine družbe Novartis lahko sodeluje z zdravstvenimi delavci z namenom izmenjave znanstvenih informacij glede določenega izdelka, razlog za takšno sodelovanje pa ne sme biti promocija. Vsake komunikacije mora imeti jasen namen in transparentni cilj.

4.4. PROMOCIJSKE INTERAKCIJE

Po pridobitvi dovoljenja za promet za določen izdelek/ zdravilo, lahko družba Novartis vzpostavi stike s strankami, bodisi neposredno ali prek tretje stranke, z namenom izvajanja promocije Novartisovih izdelkov. Za vsako interakcijo s strankami moramo imeti jasno opredeljen namen in transparentne cilje, pri čemer pa ne smemo vplivati na neodvisnost strank.
Promocija zdravila mora biti skladna z odobrenimi informacijami o zdravilu (SMPC, PIL, ovojnina), ki jih odobri regulatorni organ. Vsakdo, ki promovira Novartisove izdelke, mora biti za to usposobljen in z zadostnim znanjem o izdelku, tako da lahko posreduje popolne in natančne informacije.
Gradivo, ki se uporablja pri interakciji s strankami, mora biti odobreno skladno s Smernico o promocijskih materialih, veljavno zakonodajo in panožnimi kodeksi.

4.5. PROMOCIJSKE VSEBINE

Novartis lahko pripravi in distribuira vsebino (v tiskani oz. elektronski obliki ali ustno), ki je namenjena informiranju, izobraževanju ali promociji izdelkov. Takšno besedilo mora biti natančno, uravnoteženo in resnično. Podane informacije ne smejo biti zavajajoče. Navedbe morajo biti ustrezne

include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

Novartis may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical function may provide such information in response to these requests. Novartis Associates who receive unsolicited requests for off- label information must forward such requests to the Medical function. The response provided by the Medical function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the request, and in compliance with laws, regulations and industry codes. The Medical function should maintain written documentation of unsolicited requests and responses. Novartis Medical Scientific Liaisons (MSLs) may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. Interactions must not be promotional in any way and must have clear intent and transparent objectives.

4.4. PROMOTIONAL INTERACTIONS

Upon receipt of marketing authorization, Novartis may interact with customers, either directly or via a third party, to promote Novartis products, related features, and benefits. All interactions must have clear intent, transparent objectives, and must not interfere with the independence of customers. Products must only be promoted consistent with approved labelling (SMPC, PIL, packaging), as approved by the local regulatory authorities. Anyone promoting a Novartis product must be trained and have sufficient knowledge of the product to provide full and accurate product information.
Any materials used for purposes of the interaction must be approved in accordance with the P3 Guideline on Promotional Content and local laws, regulations and industry codes.

4.5. PROMOTIONAL CONTENT

Novartis may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content must be accurate, fair, balanced, truthful and not misleading, based on adequate substantiation and consistent with the scope of the relevant product’s marketing

in skladne z vsebino dovoljenja za promet s takšnim zdravilom. Besedilo mora biti pregledano, odobreno in skladno s Smernico o promocijskih materialih, veljavno zakonodajo in panožnimi kodeksi.

4.6. PREDMETI ZA STROKOVNO UPORABO

S strankami sodelujemo na primeren način. Zdravstvenim delavcem lahko ponudimo le strokovne predmete, ki se lahko uporabljajo izključno za zdravstvene namene in so koristni za bolnike, skladno s Smernico za podporo zdravstvene oskrbe.
Dajanje daril v kakršnikoli obliki (vključno z osebnimi in vljudnostnimi darili ali promocijskimi pripomočki) z blagovno znamko ali brez nje, zdravstvenim delavcem oz. njihovim družinskim članom, ni dovoljeno. Enako velja za darila v obliki denarnega plačila ali enakovrednih predmetov (npr. boni). Predmeti, ki jih zdravstveni delavci lahko prejmejo na dogodkih, ki jih organizira družba Novartis (npr. pisala in bloki za pisanje), pa ne smejo vsebovati imen izdelkov ali blagovnih znamk družbe Novartis.
Prav tako velja, da strokovni sodelavci za namen dajanja takšnih predmetov ne smejo uporabiti svojih finančnih sredstev.

4.7. VZORCI IN MEDICINSKI PRIPOMOČKI

Zdravstvenim delavcem lahko pod pogoji, ki jih določa veljavna zakonodaja, ponudimo brezplačne vzorce Novartisovih izdelkov, z namenom izboljšanja oskrbe bolnika ali seznanitve z uporabo izdelka. Vzorci morajo biti kot takšni trajno označeni. Zagotovljen mora biti sistem nadzora in sledljivosti. Vzorci se ne smejo (pre)prodajati ali kako drugače neustrezno uporabljati.
Vzorcev zdravil ni dovoljeno dajati javnosti. To je dovoljeno izključno za medicinske pripomočke, namenjene javnosti in prehranska dopolnila. Medicinski pripomočki se lahko brezplačno zagotovijo zdravstvenemu delavcu ali zdravstveni organizaciji za omejen in pogodbeno določen čas ter izključno za vnaprej predviden namen. Takšne naprave morajo biti ustrezno označene in se ne smejo izročiti uporabnikom, dokler se zanje ne izda dovoljenje za promet. Družba Novartis obdrži lastninsko pravico na takšnih napravah za celotno obdobje. Po izteku tega obdobja se morajo naprave odstraniti iz prostorov zdravstvenega delavca ali zdravstvene organizacije.

authorization. Content must be reviewed, approved, and updated, as required in accordance with the P3 Guideline on Promotional Content and local laws, regulations and industry codes.

4.6. ITEMS OF MEDICAL UTILITY

Novartis must engage appropriately with all customers. Items of medical utility may be offered or provided to HCPs, if such items are modest, reasonable in value, offered on an occasional basis and according to the P3 Guideline on Items of Medical Utility.
Gifts of any kind (including personal gifts, cultural acknowledgements, or promotional aids, etc.) whether branded or unbranded, must not be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates). Items made available to HCPs for use during Novartis meetings (such as pens and note pads) must not include any Novartis product or company branding.
Novartis Associates must not use their own personal funds to provide gifts of any kind.

4.7 SAMPLES, DEMONSTRATION AND EVALUATION DEVICES

In accordance with valid laws and regulations, free samples of Novartis pharmaceutical products may be provided to HCPs authorized to prescribe that product in order to enhance patient care or provide experience with the product. Pharmaceutical samples must be permanently labelled as samples and managed with systems of control and accountability. They must never be resold or otherwise misused. Product samples should not be distributed among lay public. This is allowed only for medical devices and food supplements. Demonstration and evaluation devices may be provided free of charge to an HCP or HCO for a limited and agreed-upon duration. Devices provided must be labelled appropriately and must not be provided prior to receipt of marketing authorization for their intended use in that market. Title to the device must remain with Novartis for the entire duration of the evaluation and devices must not be stored at any HCP or HCO facility when not under evaluation.

4.8 DOGODKI

Z namenom širjenja znanstvenih informacij in izobraževanja strank o izdelkih in boleznih, lahko Novartis organizira dogodke oz. zagotovi finančna sredstva za izvedbo takšnih dogodkov, ki jih nato organizira tretja stranka. Dogodki morajo biti organizirani z jasnimi cilji, skladno z načelom odgovornega financiranja in Novartisovim poslanstvom ter na način, ki zadošča družbenim pričakovanjem.
Dogodke izvajamo na transparenten način in z jasnim namenom. Pri nepromocijskih dogodkih ni dovoljeno uporabljati materialov, ki vsebujejo oblike ali barve blagovne znamke oz. logotipe izdelkov, niti kakršnihkoli drugih promocijskih vsebin.
Prepovedana je tudi kakršnakoli oblika prikrite promocije.

Novartis lahko organizira oz. financira naslednje vrste dogodkov:
- Promocijski dogodki z govorcem, ki so namenjeni izobraževanju zdravstvenih delavcev o Novartisovih izdelkih in boleznih, ki so v obsegu delovanja zdravila. Pri tem smejo promocijske vsebine predstavljati izključno Novartisovi sodelavci, v okvirih, ki jih določajo ta Politika in povezani akti.
- Znanstvena srečanja, ki so namenjena vodenju legitimnih znanstvenih razprav, pridobivanju ali posredovanju strokovnih informacij s področja znanosti ali medicine.
- Programi za osveščanje o bolezni, ki so namenjeni izpopolnitvi znanja o boleznih in njihovem obvladovanju.
- Srečanja raziskovalcev ob začetku, spremembi ali zaključku raziskav, ki jih sponzorira ali podpira Novartis. Ta srečanja je potrebno načrtovati v skladu z zahtevami ustrezne raziskave.
- Organizirani obiski lokacije družbe Novartis. Ti obiski se morajo usklajevati z lokalnim vodstvom.
- Kongres ali simpozij tretje stranke, namenjen izobraževanju s področja zdravstvenih praks.

Pri organiziranju dogodkov morajo strokovni sodelavci upoštevati Smernice o dogodkih in strokovnih srečanjih.

4.9 LOKACIJA, POTOVANJA IN GOSTOLJUBJE NA DOGODKIH

Dogodki ali srečanja se organizirajo na lokacijah, ki so primerne za izvedbo znanstvenih ali izobraževalnih vsebin. Pri tem je potrebno vselej upoštevati določbe veljavne zakonodaje in panožnih kodeksov. Lokacije, ki bi lahko dajale vtis

4.8. EVENTS

Novartis may organize events or fund events organized by third parties throughout the product lifecycle with the objective to provide scientific information or educate customers about our products or applicable disease areas. All events must have clear objectives, be funded responsibly and aligned with Novartis' mission, in a way that meets societal expectations.

Events must have clear purpose and be transparently conducted. If the purpose of the event is non-promotional we must not use materials with brand colours and logos or any promotional content, and avoid any perceptions of disguised promotion.

Common types of events organized or funded by Novartis are:
- Promotional speaker programs to educate HCPs on Novartis products or applicable disease areas. In this context, promotional content may only be represented by Novartis associates within the frameworks set by this Policy and related acts.
- Scientific meetings to facilitate legitimate scientific debate, gain or provide scientific or medical educational information.
- Disease awareness programs to increase knowledge and education about diseases and their management.
- Investigator meetings to initiate, update, or close-out Novartis sponsored or supported studies. Such meetings must be managed in accordance with the requirements of the relevant investigator study.
- Novartis site visits. Such visits must be coordinated with the local site management.
- Third party congress or symposia to provide medical education.

Novartis Associates should organize events in accordance with the P3 Guideline on Events and Professional Meetings.

4.9. VENUE, TRAVEL, AND HOSPITALITY

All events, meetings, or activities must be held in a venue appropriate for scientific or educational exchange and in accordance with local laws, regulations, and industry codes. Novartis must avoid venues that may be perceived as extravagant or

potratnosti ali veljale za poskus neprimernega vplivanja na udeležence, niso dovoljene. Na Novartisovih dogodkih se udeležencem lahko ponudijo prigrizki in/ali obroki, ni pa dovoljeno organizirati (ali plačati za organizacijo) zabave oz. drugih dejavnosti, ki sodijo v prosti čas (družabne aktivnosti). Ko gre za interakcijo z javnimi uslužbenci je potrebno upoštevati še dodatne omejitve, ki jih določa veljavna zakonodaja na tem področju in panožni kodeksi ter Novartisova Politika preprečevanja podkupovanja.
Novartis lahko zdravstvenim delavcem omogoči udeležbo na znanstveno-strokovnih srečanjih in/ ali mednarodnih kongresih v sosednjih državah (npr. s katerimi ima skupno mejo, ali tistih, ki so v neposredni bližini) in ko potreba po znanju ne more biti zadovoljena lokalno. Onkraj teh držav pa v primeru, da zdravstveni delavec Novartisu zagotavlja strokovno storitev oz. ima aktivno vlogo pri tem.Financiranje takšne udeležbe je mogoče le takrat, ko Novartis zdravstvene delavce angažira za zagotavljanje strokovnih storitev.Takšno financiranje udeležbe na dogodku v nobenem primeru ne sme vplivati na neodvisnost zdravstvenega delavca.

applying inappropriate influence. For Novartis-organized events, refreshments and/or meals incidental to the main purpose of the event may be provided, however no entertainment or other leisure/social activities should be provided or paid for by Novartis. Interactions with public officials may be subject to additional laws, regulations and industry codes.
Novartis may fund HCPs to attend Scientific Standalone Meetings and/or International Congresses in neighboring countries (i.e. bordering or close proximity) where the educational need cannot be addressed locally and beyond neighboring countries if they provide a service by playing an active role for Novartis. International travel may be funded under certain circumstances where HCPs are engaged by Novartis to provide professional services. In all instances, we must ensure that event funding does not interfere with HCP independence.

4.10 HONORAR ZA STORITVE

Novartis lahko zdravstvene delavce ali zdravstvene organizacije angažira neposredno ali prek tretje stranke. Angažira jih lahko kot predavatelje na promocijskih dogodkih (pri čemer zdravstveni delavci nikoli ne smejo promovirati izdelkov), na znanstvenih ali drugih dogodkih, za svetovanje, sodelovanje na strokovnih posvetih in/ali pri marketinških raziskavah. Ne glede na to, ali je pogodbeno razmerje sklenjeno neposredno z Novartisom ali s tretjo stranko, ki deluje v imenu družbe Novartis, je za primernost sodelovanja vedno odgovoren Novartis, ki je dolžan preprečiti vsako obliko neprimernega vplivanja na odločanje zdravstvenih delavcev ali zdravstvenih organizacij o uporabi naših izdelkov.
Vsa pogodbena razmerja morajo temeljiti na upravičeni in utemeljeno izraženi potrebi. Vsak zdravstveni delavec ali zdravstvena organizacija, ki jo Novartis angažira, mora imeti zahtevane izkušnje in/ali zmogljivosti za realizacijo storitev. Pogodbeno razmerje mora biti urejeno v pogodbi, ki je zavezujoča zaobe pogodbeni stranki in jo podpišeta še pred začetkom izvajanja storitve.

Plačilo mora biti razumno in ovrednoteno glede na pošteno tržno vrednost. Pogodbena razmerja z zdravstvenimi delavci, ki so hkrati javni uslužbenci,

4.10. FEES FOR SERVICE

Novartis may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as speakers for promotional speaking programs (but keep in mind any promotion on behalf of HCP is strictly prohibited), scientific standalones, or other events, consulting engagements, advisory boards and/or market research. Irrespective of direct engagement or via a third party, Novartis is responsible for engaging appropriately and without the intent, perception or consequence of inappropriately influencing HCPs or HCOs for the use of our products.

All engagements must be based on a legitimate need for the service. Any HCP or HCO engaged by Novartis must have the necessary experience and/or capabilities to provide the services. The engagement must be documented in a written agreement that is executed and binding on all relevant parties before services commence.

Compensation for services must be reasonable and at fair market value in relation to the services rendered. Engagement of HCPs who are public

morajo biti skladna z zahtevami zakonodaje, ki to področje ureja in panožnimi kodeksi, ter Novartisovo Politiko preprečevanja podkupovanja.

Sodelovanje z zdravstvenimi delavci iz drugih držav, mora najprej odobriti za to pristojni Novartisov sodelavec v državi, kjer zdravstveni delavec opravlja svojo prakso, z namenom potrditve skladnosti takšnega sodelovanja z lokalno zakonodajo in lokalnimi panožnimi kodeksi. Plačilo za storitve mora biti plačano v državi, kjer zdravstveni delavec izvaja svojo prakso. Novartisovi sodelavci morajo pri tem upoštevati določila Smernic o sodelovanju z zdravstvenimi delavci in zdravstvenimi organizacijami.

officials may be subject to additional laws, regulations and industry codes.

Cross-country engagements of HCPs must be approved by qualified Novartis Associates from the HCP's practicing country for compliance with local laws, regulations and industry codes. Compensation for services must be paid into the HCP's practicing country.
Novartis Associates must follow the P3 Guideline on HCP and HCO Engagement.

4.11 SODELOVANJE Z BOLNIKI IN Z ZDRUŽENJI BOLNIKOV

Novartis lahko z bolniki, njihovimi skrbniki ali združenji bolnikov sodeluje z namenom boljšega razumevanja njihovih stališč oz. posredovanja znanja o posamezni bolezni, zdravljenju ali negi. Takšne interakcije morajo biti etične, transparentne, nepromocijske ter skladne z Novartisovim poslanstvom, ob spoštovanju neodvisnosti bolnikov ter njihovih združenj.

Novartis z osebnimi podatki bolnikov ravna spoštljivo in zaupno. Osebne podatke bolnikov zbiramo le na podlagi njihovega izrecnega soglasja.

Interakcije z bolniki so nepromocijske aktivnosti. Bolnikom oz. laični javnosti ni dovoljeno promovirati izdelkov, ki se izdajajo na recept.

Novartis lahko bolnike, njihove skrbnike ali združenja bolnikov angažira za udeležbo na strokovnem posvetu bolnikov. Takšno pogodbeno razmerje mora temeljiti na upravičeni potrebi in mora biti urejeno s pisno pogodbo, ki jo podpišeta obe pogodbeni stranki pred začetkom izvajanja storitve. Plačilo mora biti razumno in ovrednoteno glede na pošteno tržno vrednost.

Novartis lahko bolnike ali združenja bolnikov podpira s finančnimi sredstvi ali v kakšni drugi obliki, kot je npr. Program za podporo bolnikov, Program za pomoč bolnikom ipd. Strokovni sodelavci morajo upoštevati določila Smernic o sodelovanju z bolniki in združenji bolnikov.

4.11. INTERACTIONS WITH PATIENTS AND PATIENT ORGANIZATIONS

Novartis may interact with patients, caregivers, and patient organizations to understand their perspective and provide knowledge regarding diseases, treatments, and its care. All interactions must be ethical, transparent, non-promotional, and consistent with Novartis' mission and maintain the independence of the patient and patient organizations.

Novartis must treat patient information with respect and protect confidentiality. Personal information can be gathered only upon provided explicit consent.

Interactions with patients are non-promotional activities. Promotion of prescription-only products to patients is not allowed.

Novartis may engage with patients or patient organization for services, such as participation in patient advisory boards. All engagements must be based on a legitimate need for the service and confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable in relation to the services rendered.

Novartis may also provide financial and other support to patients and patient organizations. Such support may be in the form of Patient Support Programs ("PSPs"), Patient Assistance Programs (PAPs), funding to support/establish patient organizations, etc. Novartis Associates must follow the P3 Guideline on Interactions with Patients and Patient Organizations.

4.12 ZUNANJE FINANCIRANJE

Novartis lahko finančna sredstva ali drugačno podporo prispeva tudi drugim zunanjim organizacijam. Sem spadajo subvencije, sponzorstva, donacije in finančna sredstva za strokovna izobraževanja zdravstvenih delavcev s področja medicine.
Financiranje mora biti odgovorno, ustrezno našemu ugledu in skladno z našim poslanstvom odkrivanja novih načinov za boljše in daljše življenje. S tem izpopolnjujemo znanje s področja medicine in znanosti ter podpiramo skupnosti, kjer živijo in delajo Novartisovi sodelavci.

Takšno financiranje je dovoljeno le za ugledne organizacije in nikoli za posameznike. Izvaja se v skladu z določili Smernic o zunanjem financiranju. Namen takšnega financiranja mora biti jasno opredeljen. Finančna sredstva morajo biti razumno ovrednotena in upravičena glede na dejavnost, za katero so namenjena. Vrednosti se morajo ustrezno spremljati, dokumentirati in vnašati v finančna poročila ter računovodske izkaze skladno z zahtevami veljavne zakonodaje in panožnih kodeksov ter Novartisove Politike preprečevanja podkupovanja.

4.12. EXTERNAL FUNDING

Novartis may provide funding or other support to external organizations. This includes grants, donations, funding for medical education such as preceptorship programs, and sponsorships.
We must fund responsibly, in a manner that maintains our reputation, aligns with our mission to discover new ways to improve and extend people's lives, advance medical or scientific knowledge, and supports communities where Novartis Associates live and work.

External funding or support must only be given to legitimate organizations, never to individuals, and in accordance with the P3 Guideline on External Funding. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations, industry codes, and Novartis Anti-Bribery Policy.

5. IMPLEMENTACIJA

USPOSABLJANJE
Sodelavci se morajo seznaniti s Politiko in z vsemi Smernicami, ki se uporabljajo skupaj s Politiko. Usposabljanja se morajo udeležiti skladno z načrtom usposabljanja s področja skladnosti za družbo Novartis. Dodatne zahteve za usposabljanje sodelavcev in tretjih strank, ki poslujejo v imenu družbe Novartis, so opredeljene v SOP-ju.

TRETJE STRANKE
Od tretjih strank, ki so vključene v izvajanje aktivnosti po tej Politiki, in ki delujejo v imenu družbe Novartis, se pričakuje, da delujejo v skladu s to Politiko in veljavnimi zakoni ter sledijo etičnim poslovnim praksam. Sodelavci družbe Novartis, ki sklenejo pogodbo s tretjimi strankami, so odgovorni za delo, ki je opravljeno v imenu družbe Novartis.

KRŠITEV POLITIKE
Sankcije za kršitev Politike segajo od disciplinskega ukrepa do strožjih ukrepov, vključno s prenehanjem delovnega razmerja.

5. IMPLEMENTATION

TRAINING
Associates must familiarize themselves with this Policy and the relevant Guidelines referred to in this Policy. Associates must be trained in line with the Novartis-wide compliance training curriculum. Additional training requirements for Associates and third parties conducting business on behalf of Novartis may be defined in SOP.

THIRD PARTIES
Third parties involved in conducting activities covered by this Policy and on behalf of Novartis are expected to comply with this Policy, applicable laws and to adhere to ethical business practices. Novartis Associates contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Novartis.

BREACH OF THIS POLICY
Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

PRIJAVA SUMA KRŠITVE in PREPOVED UPORABE POVRAČILNIH UKREPOV
Vsak sodelavec, ki opazi kršitev, je to dolžan takoj prijaviti v skladu s postopkom za prijavo neprimernih ravnanj (SpeakUp postopek). Sodelavci, ki v dobri veri poročajo o kršitvi ali sumu kršitev, posredujejo relevantne informacije, ali kako drugače pomagajo pri poizvedbi ali pri preiskavi, so zaščiteni pred morebitnimi povračilnimi ukrepi.

IZJEME
Vselej je potrebno spoštovati veljavno zakonodajo in povezane predpise ali panožne kodekse. Vodstvo področja Etike, tveganj in skladnosti je pristojno za pregled in odobritev morebitnih izjem, ki so povezane s to Politiko.

ODGOVORNOST
Vsak Novartisov vodja je odgovoren za dosledno izvajanje Politike na področju, za katerega je pristojen. Pri tem vodi z zgledom in usmerja svoje sodelavce. Vsi sodelavci so odgovorni za dosledno izvajanje Politike.

6. KONČNE DOLOČBE

Ta Pravila se uporabljajo od 1. novembra 2019, potem ko jih je potrdila Uprava Lek d.d. in direktor podružnice Novartis Pharma Services Inc. v Sloveniji.

REPORTING POTENTIAL MISCONDUCT and NON-RETALIATION
Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the SpeakUp process. Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

EXCEPTIONS
Compliance with applicable laws, regulations, and industry codes must be maintained at all times. The Ethics, Risk & Compliance Leadership Team (ERC LT) will review and approve exceptions related to this Policy.

RESPONSIBILITIES
It is the responsibility of every Novartis Manager to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. All Associates are responsible for adhering to this Policy.

6. FINAL PROVISIONS

These rules are applicable as of November 1st, 2019, after approval by the Management Board and Head Novartis Pharma Services Inc. in Slovenia.