

Na osnovu molbe Primaoca i Pisma namjere Davaoca, u Podgorici, zaključuje se

## UGOVOR O DONACIJI

Između:

Hoffmann - La Roche Ltd, dijela stranog društva, Podgorica, registarski broj kod CRPS Podgorica 6-0007794/006, sa adresom: ulica Cetinjska br. 11, 81000 Podgorica, koga zastupa ovlašćeno lice Miloš Ičević JMBG 3003983210325, (u daljem tekstu: Roche) sa jedne strane, i

**Klinički centar Crne Gore**, Ljubljanska bb, kojeg zastupa director dr Ljiljana Radulović Eraković, (u daljem tekstu: Primalac) sa druge strane

### 1. DONACIJA

- 1.1. Predmet ovog Ugovora je donacija 20 kutija lijeka RoActemra® (tocilizumab, koncentrat za rastvor za infuziju, 400mg/20ml, bočica, 20ml) kompanije Hoffmann-La Roche, u vrijednosti od 10 961.40 EUR (bez PDV), koju će Roche pružiti Primaocu kao podršku misije i aktivnosti opisanih detaljno u molbi direktora Kliničkog centra, dr Ljiljane Radulović, od 05.02.2021. godine.
- 1.2. Primalac ima potrebu za donacijom lijeka RoActemra® (tocilizumab, koncentrat za rastvor za infuziju, 400mg/20ml, bočica, 20ml), te se obratio molbom Roche-u za obezbjeđenje donacije na datum 05.02.2021.
- 1.3. Kroz donaciju koji je predmet ovog Ugovora, opisan u stavu 1.1 Roche će obezbijediti 20 (dvadeset) bočica

Based on the request of the Receiver and the Letter of Intent of Roche, in Podgorica it is concluded

## DONATION AGREEMENT

Entered into between :

Hoffmann - La Roche Ltd, part of foreign company, Podgorica, registration number with CRCE Podgorica 6-0007794/006, with the address Cetinjska street No 11, 81000 Podgorica, represented by authorized person Milos Icevic JMBG 3003983210325, (hereinafter: Roche) on one side, and

**Clinical centre of Montenegro**, Ljubljanska bb, represented by director dr Ljiljana Radulović, (hereinafter: Recipient) on the other side

### 1. DONATION

- 1.1. Subject of this Agreement is donation of 20 packs of product RoActemra®, (tocilizumab), concentrate for solution for infusion, 400mg/20ml, vial, 20ml manufactured by Hoffmann -La Roche, a total value of EUR 10 961.40 EUR (excluding VAT), which Roche will provide to the Recipient in support of the mission and activities described in the Request of the Director of the Clinical Center, dr Ljiljana Radulović, dated 05.02.2021.
- 1.2. Recipient has the need for the donation of RoActemra®, (tocilizumab), concentrate for solution for infusion, 400mg/20ml, vial, 20ml, has filed Request to Roche dated 05.02.2021.
- 1.3. Through the Donation which is described in this Agreement, Roche will provide 20 (twenty) vials of

<p>lijeka RoActemra® (tocilizumab), koncentrat za rastvor za infuziju, 400mg/20ml, bočica, 20ml, za pacijente sa COVID-19 infekcijom koji se liječe u Kliničkom centru Crne Gore, u skladu sa kriterijumima koji to određuju.</p> <p>1.4. Donacija 20 kutija lijeka RoActemra® (tocilizumab, koncentrat za rastvor za infuziju, 400mg/20ml, bočica, 20ml) je u vrijednosti od 10 961.40 EUR, koje će ROCHE donirati posredstvom distributera Glosarij doo, Vojislavljevića 76, 81000 Podgorica, najkasnije do 28.02.2021.</p> <p>1.5. Primalac se obavezuje da će pružena podrška biti iskorišćena samo u sklopu opisane donacije koja je predmet ovog Ugovora, u svrhe liječenja pacijenata, po odluci Kliničkog centra Crne Gore.</p> <p>1.6. Po osnovu učinjene donacije Primalac donacije nema nikakvih obaveza prema Roche-u, osim onoga što je ovim ugovorom izričito predviđeno.</p> <p>1.7. U slučaju da bilo koji dio namijenjene količine lijeka ne bude korišten u svrhe Donacije opisane u stavu 1.1, Primalac se obavezuje da će o istom obavijestiti Roche.</p> <p>1.8. Na zahtjev Roche-a, Primalac donacije obavezuje se da Roche-u pruži odgovarajuće dokaze o tome na koji način se koriste, odnosno na koji način su iskorišćena donirana sredstva.</p> <p>1.9. Primalac oslobađa Roche od odgovornosti za bilo kakav gubitak, trošak (uključujući i advokatske troškove), odgovornost, štetu ili</p>	<p>RoActemra® (tocilizumab), concentrate for solution for infusion, 400mg/20ml, vial, 20ml, for patients with COVID-19 infection treated at the Clinical Center of Montenegro, in accordance with the criteria that determine it.</p> <p>1.4. Donation of 20 packs of RoActemra® (tocilizumab, concentrate for solution for infusion, 400mg / 20ml, bottle, 20ml) is worth 10 961.40 EUR, which will be donated by ROCHE through the distributor Glosarij doo, Vojislavljevića 76, 81000 Podgorica, by 28.02.2021.</p> <p>1.5. Recipient agrees that the support give through this program will be used only as part of Donation described for purpose of treating patients, upon decision of Clinical Center of Montenegro.</p> <p>1.6. Based on the donation made, the Recipient of the grant has no obligations to Roche, except as expressly provided in this contract.</p> <p>1.7. In case of any remaining unused quantity of the product tocilizumab used for the purpose of the Donation described in paragraph 1.1, Recipient is obliged to immediately inform Roche.</p> <p>1.8. At the request of Roche, the donation Recipient undertakes to provide Roche with appropriate evidence as to how it was used or how the donated funds were used.</p> <p>1.9. Recipient releases Roche from any liability for loss, expense, cost (including attorney's fees), liability, damage or claim incurred by it arising</p>
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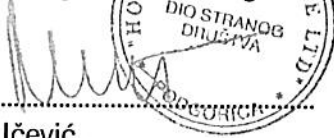
<p>potraživanje nastale prilikom sprovođenja ove Donacije.</p>	<p>out of the incurred in the implementation of this Donation.</p>
<p><b>2. SVRHA I USKLAĐENOST SA ZAKONIMA</b></p>	<p><b>2. PURPOSE AND COMPLIANCE WITH LAWS</b></p>
<p>2.1. Primalac shvata da Roche putem obezbijeđenog lijeka u sklopu navedene Donacije, nema namjeru da izazove, utiče na postojeće i nagradi ranije, sadašnje niti buduće propisivanje, snadbijevanje, nabavku, niti da preporuči upotrebu Roche proizvoda.</p>	<p>2.1. Recipient acknowledges that Roche with this Donation does not have any intention to induce, influence or reward the past, present or future prescribing, supply, purchasing, recommending or use of any Roche product (including formulary recommendations</p>
<p>2.2. Obezbjedenje lijeka u sklopu Donacije koji je predmet ovog Ugovora je:</p> <ul style="list-style-type: none"> <li>a) U skladu sa svim primjenljivim zakonima i regulativom.</li> <li>b) Nema svrhu promocije bilo kog od Roche proizvoda.</li> <li>c) Nije u vezi sa nabavkom, snadbijevanjem niti preporukom Roche proizvoda.</li> <li>d) Nije namijenjen ličnoj koristi ili upotrebi</li> <li>e) Namijenjen je da omogući Primaocu da zadovolji svoje aktivnosti čija je krajnja svrha obezbjedenje pomoći pacijentu i unapređenje javnog zdravlja.</li> </ul>	<p>2.2. Providing the product as part of this Donation which is subject of this Agreement is:</p> <ul style="list-style-type: none"> <li>a) consistent with any applicable laws and regulations;</li> <li>b) not for the purpose of promoting any Roche product or service ;</li> <li>c) not contingent on the purchase, supply or recommendation of any Roche products;</li> <li>d) not intended for personal benefit or use; and</li> <li>e) Intended to allow Recipient to supplement its activities ultimately leading to enhanced patient care and/ or benefiting public health.</li> </ul>
<p>2.3. Ukoliko Primalac istovremeno pruža usluge ROCHE-u u oblasti strategije, promocije, marketinga ili Roche inicirane medicinske edukacije (RIME), ovim putem se obavezuje da će aktivnosti biti u potpunosti odvojene od onih koje dio ovog Ugovora.</p>	<p>2.3. Should Recipient at the same time provide services to Roche in the areas of strategy, promotion, marketing or Roche-Initiated Medical Education (RIME), hereby undertakes that the activities will be completely separate from those which are part of this Agreement.</p>

<p><b>3. FARMAKOVIGILANCA</b></p> <p>3.1. Ugovorne strane su saglasne da će se primjenjivati odredbe u skladu sa postojećim zakonom i regulativom koja se odnosi na izvještavanje o bezbjednosti lijekova.</p> <p>3.2. Ukoliko tokom primjene lijekova definisanih ovim ugovorom Primalac donacije sazna za postojanje sumnje na neželjeni događaj, neželjenu reakciju ili specijalnu situaciju i ostale tipove bezbjednosnih prijava, odnosno pritužbi na kvalitet proizvoda povezanih sa upotrebom lijeka kompanije Hoffmann-La Roche, potrebno je da to prijavi kompaniji Hoffmann-La Roche Ltd Podgorica.</p> <p>3.3. Neželjeni događaj, neželjena reakcija i ostali tipovi bezbjednosnih prijava su definisani aktuelnim Pravilnikom o načinu prijavljivanja, prikupljanja i praćenja neželjenih reakcija na lijekove. Navedene bezbjednosne prijave se mogu dostaviti kompaniji Hoffmann-La Roche Ltd Podgorica na email adresu montenegro.drugsafety@roche.com</p>	<p><b>3. PHARMACOVIGILANCE</b></p> <p>3.1. The Parties agree to apply the provisions in accordance with existing law and regulation relating to medication safety reporting.</p> <p>3.2. If, during the administration of the medicines defined in this contract, the Donation Recipient becomes aware of a suspected adverse event, adverse reaction or special situation and other types of safety complaints, or complaints about the quality of the products related to the use of the drug of the Hoffmann-La Roche, he should report it to Hoffmann-La Roche Ltd Podgorica.</p> <p>3.3. Adverse events, adverse reactions and other types of security reporting are defined in the current Rulebook on the manner of reporting, collecting and monitoring adverse drug reactions. These security reports can be submitted to Hoffmann-La Roche Ltd Podgorica by email montenegro.drugsafety@roche.com</p>
<p><b>4. TRANSPARENTNOST</b></p> <p>4.1. Primalac shvata obavezu Roche-a da ostane transparentan, te će se u slučaju upita izjasniti da je navedena podrška adekvatna.</p> <p>4.2. U skladu sa mnogim globalnim, regionalnim i lokalnim pravilima i propisima i najboljom praksom u industriji i standardima koje Roche poštuje, Roche prikuplja podatke o svim aranžmanim sličnim ovom, čuva ih u internom registru i zadržava</p>	<p><b>4. TRANSPARENCY</b></p> <p>4.1. Recipient understands that Roche is committed to full transparency and asks that Recipient acknowledges this support as appropriate and if asked.</p> <p>4.2. In line with multitude of global, regional and local rules and regulations and best industry practices and standards which Roche applies, Roche is collecting data of any arrangements similar to this Agreement in an internal register and</p>

<p>pravo da objelodani informacije u vezi sa predmetom ovog Ugovora, uključujući, ali ne ograničavajući se na bilo koji dio, kompenzaciju, njegov iznos ili vrijednost, primaloca , svrhu i datum podrške , gde i kada Roche to zahteva ili smatra prikladnim.</p> <p>4.3. Ako i u mjeri u kojoj zakoni i propisi o zaštiti podataka objavljivanje podataka, odgovarajuće predstavništvo Roche-a će zatražiti saglasnost od strane Primaoca putem posebnog obrasca. U takvim slučajevima, Roche neće otkriti podatke o individualnoj osnovi, osim ako je Primalac za to dao svoj pristanak.</p>	<p>reserves its right to disclose information regarding the subject matter of this Agreement including but not limited to any consideration and compensation and its amount or value, the recipient, the purpose and the date.</p> <p>4.3. If the regulations require the consent of the individual data subject for disclosure on an individual basis, the respective Roche local affiliate will seek consent from Recipient via a separate form. In such cases, Roche will not disclose data on an individual basis unless Recipient has provided consent.</p>
<p><b>5. OSTALO</b></p>	<p><b>5. MISCELLANEOUS</b></p>
<p>5.1. Potpisivanjem ovog Ugovora Primalac ne krši obaveze prema trećim licima ili bilo kojim važećim zakonima.</p>	<p>5.1. By signing this Agreement Recipient does not violate obligations toward third parties or any applicable laws.</p>
<p>5.2. Primalac se obavezuje da će postupati u skladu sa svim važećim Zakonima, lokalnim i industrijskim propisima u pogledu donacije. Osim toga Primalac potvrđuje da je ispoštovao proces odobravanja, aplikacije za obezbjeđivanje lijeka u sklopu ovog Ugovora.</p>	<p>5.2. Recipient warrants that it will comply with all applicable laws, government or industry regulations with respect to the donation. Furthermore Recipient confirms that it has followed processes with respect to all matters in relation to the donation including application for, review and provision of product in scope of this Program.</p>
<p>5.3. Primalac ovim putem potvrđuje da nije upoznat sa bilo kakvim konfliktom interesa koji bi ga spriječio da dobije donaciju.</p>	<p>5.3. Recipient ensures that is not aware of any conflict of interest which would prevent it from receiving the donation.</p>
<p>5.4. Primalac nema pravo ovaj Ugovor ili neki njegov dio dodijeli bilo kojoj trećoj strani bez prethodne pismene saglasnosti Roche-a.</p>	<p>5.4. Recipient has no right to assign this Agreement or any part thereof to any third party without the prior written approval of Roche.</p>
<p>5.5. Nijedan zaposleni ili predstavnik bilo koje stranke nema ovlašćenje da obaveže drugu stranu ovog Ugovora</p>	<p>5.5. No employee or representative of either party shall have any authority to bind or obligate the other party to</p>

<p>za bilo koju sumu ili na bilo koji način ili da kreirate ili nametne bilo kakvu odgovornost bez rekao prethodne pismene saglasnosti druge strane.</p>	<p>this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other party without said party's prior written approval.</p>
<p><b>6. REVIZIJA</b></p>	<p><b>6. REVISION</b></p>
<p>6.1. Primalac prihvata da Roche ima puno pravo da izvrši kontrolu o adekvatnosti upotrebe obezbijedene donacije. Primalac će na zahtjev Roche obezbijediti svu potrebnu dokumentaciju i potvrde koje će obezbijediti adekvatan nivo pouzdanosti.</p>	<p>6.1. Recipient acknowledges that Roche has the full right to audit the appropriate use of the provided donation. Recipient will provide, upon request by Roche, all required documentation and justification necessary to allow a reasonable level of assurance to Roche.</p>
<p><b>7. NADLEŽNOST I ZAKONSKE OBAVEZE</b></p>	<p><b>7. APPLICABLE LAW AND JURISDICTION</b></p>
<p>7.1. Ugovorene strane se obavezuju da će postupati u skladu sa odgovarajućim Zakonima i propisima države Crne Gore, kao i u skladu sa svim pravilima i propisima farmaceutske industrije.</p>	<p>7.1. Contractual parties are obliged to act in line with the substantive laws of Montenegro and in line with rules and regulations in pharmaceuticals industry.</p>
<p>7.2. ROCHE zadržava pravo raskida ovog Ugovora u bilo kom momentu uz adekvatno prethodno objašnjenje.</p>	<p>7.2. Roche keeps its right to terminate this Agreement in any moment, with the appropriate explanation.</p>
<p>7.3. Ugovorne strane su se sporazumjele da sve eventualne sporove iz ovog Ugovora rješavaju sporazumno, a ako taj sporazum nije moguć, spor će rješavati nadležni sud u Podgorici. U slučaju spora ili tumačenja, za vjerodostojnu verziju se uzimaju primjerci ugovora koji su sačinjeni na službenom jeziku Crne Gore.</p>	<p>7.3. The parties shall attempt to settle all disputes arising out of or in connection with the present Agreement in an amicable way. In case a controversy cannot be settled amicably the matter shall be decided by the ordinary Courts of Podgorica. In case of dispute, or dilemma, Montenegrin version of this Agreement shall prevail.</p>
<p>7.4. Ovaj Ugovor je sačinjen u 4 (četiri) istovjetna primjerka, od kojih ugovorne strane zadržavaju po 2 (dva).</p>	<p>7.4. This Agreement is made in 4 /four) identical copies, of which every party shall keep 2 (two).</p>

ROCHE  
Hoffmann - La Roche Ltd, Podgorica  
Dio stranog društva, Podgorica



Miloš Ičević,  
Ovlašćeno lice

Datum: 08/02/2014

PRIMALAC  
Klinički centar Crne Gore  
Ljubljanska bb



dr Ljiljana Radulovic  
Direktor

Datum: 10.03.2014.g.