Pfizer Draft 1.6.2021 POVJERLJIVO

UGOVOR O PROIZVODNJI I OPSKRBI
**PO I MEĐU**

**PFIZER EXPORT B.V.,**

**MINISTARSTVO ZADRAVATVA I SOCIJALNE ZAŠTITE ALBANIJE**

**DRŽAVNI MINISTAR ZA OBNOVU**

**I**

**INSTITUT ZA JAVNO ZDRAVSTVO**

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UGOVOR O PROIZVODNJI I OPSKRBI

OVAJ UGOVOR O PROIZVODNJI I OPSKRBI na snazi je od datuma posljednjeg potpisa u nastavku (“datum stupanja na snagu”) sačinjen je između Pfizer Export B.V., tvrtka osnovana prema zakonima Nizozemske, sa sjedištem na adresi Rivium Westlaan 142, 2909LD Capelle aan den Ijssel, the Netherlands (u daljnjem tekstu “Pfizer”) i Albanskog Ministarstva zdravstva isocijalne zaštite, koje djeluje u svoje ime i u ime Republike Albanije s uredima na adresi at Kavaja St 25, Tirana 1001 (“MOH”), Albanskog državnog ministra za obnovu, koji djeluje u svoje ime i u ime Republike Albanije s uredima na Boulevard “Deshmoret e Kombit”, Tirana 1001 (MOR) i Instituta javnog zdravstva koji djeluje u svoje ime i u ime Republike Albanije s uredima na Rr. Aleksander Moisiu, nr. 80, Tirana, 1001 (“IPH”) (MOH,MORand IPH, pojedinačno i zajedno u daljnjem tekstu “Purchaser”). Kupac i Pfizer mogu se pojedinačno nazvati “Strana ” ili zajedno “Strane”.

S OBZIROM DA, Pfizer Inc. (“Pfizer US”) I BioNTech SE, tvrtka organizirana i postojeća prema zakonima Njemačke (“BioNTech”), surađuju na razvoju cjepiva za rješavanje globalne pandemije COVID-19

S OBZIROM DA DA uz klinički uspjeh, Pfizer US and BioNTech biti će odgovorni za sve zahtjeve procesa odobravanja kliničkih ispitivanja i odobrenja za stavljanje Proizvoda u promet

S OBZIROM DA Kupac želi kupiti Proizvod za korištenje u Albaniji, te podliježe kliničkom uspjehu i regulatornom odobrenju, Pfizer želi proizvesti i isporučiti Kupcu takav Proizvod i

S OBZIROM DA su Strane voljne provesti gore navedeno u skladu s uvjetima i odredbama utvrđenim ovim Ugovorom

SADA, STOGA, uzimajući u obzir ove premise i dogovore navedene u ovoj dokumentaciji, čija je dovoljnost ovime priznata i dogovorena, te time namjeravaju biti pravno vezani, stranke se slažu kako slijedi:

**DEFINICIJE**

1.

Slijedeći izrazi, korišteni u ovom Ugovoru, imat će dolje navedeno značenje:

1. “Prilagođeni raspored isporuke ” ima značenje navedeno u Odjeljku [2.4(c).](#bookmark9" \o "Current Document)
2. “Predujam” ima značenje navedeno u Odjeljku [3.2(a).](#bookmark9" \o "Current Document)
3. “Podružnica(e)” znači, u odnosu na svaku stranku ili, ako je primjenjivo, BioNTech, bilo koju korporaciju, tvrtku, partnerstvo ili drugi entitet ili osobu koja izravno ili neizravno kontrolira ili je pod kontrolom ili je pod zajedničkom kontrolom navedene Strane,,uključujući bez ograničenja Pfizer US ili, ako je primjenjivo, BioNTech. Za potrebe ove definicije, smatra se da postoji "kontrola" (uključujući, s korelativnim značenjem, izraze "kontrolirano od" i "pod zajedničkom kontrolom s“) ako je ispunjen jedan od sljedećih uvjeta: (a) u slučaju korporativnih subjekata, izravno ili neizravno vlasništvo nad najmanje pedeset posto (50%) dionica ili dionica koje imaju pravo glasovati za izbor direktora takvog korporativnog subjekta ili bilo kojeg izravnog ili neizravnog „roditelja“ takvog korporativnog subjekta, i (b) u slučaju nekomercijalnih subjekata, izravno ili neizravno vlasništvo nad najmanje pedeset posto (50%) udjeli u kapitalu koji imaju moć usmjeravanja upravljanja i politike takvih nekomercijalnih subjekata.
4. “Ugovor” znači ovaj Ugovor o proizvodnji i opskrbi i svi njegovi Prilozi koji se s vremena na vrijeme mogu mijenjati, mijenjati i prepravljati, nadopunjavati ili na neki drugi način zamijeniti.
5. “Alokacija” ima značenje navedeno u Odjeljku  [2.5(a).](#bookmark29)
6. “Autorizacija” znači Uvjetno odobrenje ili Odobrenje za stavljanje na tržište
7. “BioNTech” ima značenje navedeno u uvodnoj izjavi.
8. “Radni dan” znači bilo koji dan različit od subote. nedjelje ili praznika u New York, New York ili Tirana, Albania.
9. “Komercijalno razumni napori”, znači napore koje će uložiti Pfizer za postizanje relevantnog cilja, aktivnosti i stupanj napora koje bi slična strana (s obzirom na veličinu, resurse i imovinu) u farmaceutskoj industriji uložila da postigne sličan cilj u svojim komercijalnim interesima pod sličnim okolnostima i uzimajući u obzir relevantne rizike, nesigurnosti, ograničenja i izazove razvoja, proizvodnje, komercijalizacije i distribucije novog proizvoda cjepiva protiv COVID-19, uzimajući u obzir sljedeće čimbenike: stvarna i potencijalna pitanja sigurnosti i učinkovitosti, novinuodgovarajuće opskrbe za , profil proizvoda, vlasnički položaj, aktualno konkurentno okruženje za takav Proizvod, vjerovatno vrijeme ulaska Proizvoda na tržište, regulatorno okruženje i status Proizvoda, usklađenost sa zakonima, prošle performanse Proizvoda i drugih sličnih proizvoda, mogućnost proizvodnje ili postizanja odgovarajzće opskrbe Proizvoda, ili bilo koje komponente ili materijala korištenih u proizvodnji Proizvoda i druge relevantne znanstvene, tehničke, operativne i komercijalne čimbenike, u svakom slučaju mjereno činjenicama i okolnostima u vrijeme do kojih su takvi napori na snazi.:
10. “Uvjetno odobrenje znači uvjetno tržišno odobrenje (“CMA”) ili odobrenje za hitnu uporabu **(„EUA”)** za Proizvod koje je (a) izdala (i) američka Uprava za hranu i lijekove (federalna agencija Sjedinjenih Država Odjel za zdravstvo i ljudske usluge) **("FDA")** (u slučaju EUA -e) ili (ii) Europska komisija (u slučaju CMA -e) i (b) putem odgovarajućeg regulatornog mehanizma od (i) Nacionalne Agencija za lijekove i medicinsku opremu **(“NAM”)** ili (ii) Ministrar zdravstva i socijalne zaštite koji dopušta stavljanje proizvoda na tržište u Albaniji **(“Albansko uvjetno odobrenje”).**
11. “**Povjerljivi podatci”** znače sve povjerljive ili vlasničke informacije, osim Izuzetih informacija, u bilo kojem obliku, izravno ili neizravno otkrivenih Primatelju ili njegovimPredstavnicima od ili u ime Strane koja je objavila podatke u skladu s ovim ugovorom, bez obzira na način na koji se takve informacije otkrivaju, dostavljaju, , saznaju ili promatraju, bilo označene kao "povjerljive" ili, ako su usmene, proglašene povjerljivima kada su otkrivene i pismeno potvrđene u roku od trideset (30) dana od objavljivanja. Povjerljivi podatci uključuju, bez ograničenja, odredbe i uvjete ovog Ugovora. Neuspjeh označavanja povjerljivih podataka koji su u pisanom obliku objavljeni u nastavku kao "povjerljivi" neće uzrokovati da se podaci smatraju nepovjerljivima, a na Strani koja ih je otkrila a je teret da razjasni i dokaže kako je takve informacije trebala znati razumna osoba sa znanjem o toj temi, na temelju prirode informacija i okolnosti njihovog otkrivanja da su to Povjerljive informacije , pod uvjetom da je Strana koja ih je otkrila inače uložila napore u dobroj vjeri da jasno označi povjerljive podatke kao takve

**“Ugovorene doze ”** ima značenje navedeno u Odjeljku  [2.3(](#bookmark25)a).

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**“Trenutna dobra proizvodna praksa ”** ili “cGMP” znači primjenjivu dobru proizvodnu praksu kako je navedeno u Zakonu o saveznim propisima Sjedinjenih Država i/ili dobrim smjernicama EU -a, te svim sljednim zakonima koji povremeno prevladavaju u vrijeme proizvodnje proizvoda

**“Cijena isporuke ”** ima značenje navedeno u Odjeljku  [3.2(](#bookmark8)b).

**“Raspored isporuka”** ima značenje navedeno u Odjeljku  [2.4(](#bookmark26)d).

**“Specifikacije isporuke ”** ima značenje kao u Odjeljku  [2.4(](#bookmark26)d).

**“Strana koja otkriva podatke”** znači Strana ili bilo koje od njezinih povezanih društava koja otkriva ili uzrokuje otkrivanje povjerljivih podataka drugoj Strani ili bilo kojoj od njenih podružnica

**“Datum stupanja na snagu”** ima značenje navedeno u uvodnoj izjavi

**“Izuzete informacije ”** znači informacije koje t: (a) Primatelj ili bilo koji od njegovih predstavnika zakonito posjeduju, što je dokazano nadležnim dokazom, prije nego što je Strana koja ih otkriva otkrila takve podatke prema ovom Ugovoru; ili (b) već su bile općenito dostupnen i u javnoj domeni u vrijeme objavljivanja, ili postaju javne (osim kao posljedica kršenja ovog Ugovora od strane Primatelja ili njegovih predstavnika);

(c) Primatelj ili bilo koji od njegovih predstavnika zakonito dobije od Osobe koja ne krši bilo koju obvezu povjerljivosti (ili drugu zabranu otkrivanja podataka) Strani koja objavljuje podatke u vezi s tim podacima (a Primatelj je u vezi s tim napravio razumnu istragu ); ili (d) primateljeve dokaze na razumno zadovoljstvo Strane za otkrivanje neovisno su razvijeni u ime primatelja ili njegovih predstavnika bez upotrebe, upućivanja, pomoći ili oslanjanja na povjerljive podatke. Radi pojašnjenja prethodnoga, općenito objavljivanje u javnoj domeni neće uzrokovati da se konkretniji (ali povezani) podaci smatraju izuzetim podacima prema jednoj od gore navedenih iznimki; na sličan način, kombinacija nekoliko podataka, koji bi se pojedinačno smatrali izuzetim podacima, neće se smatrati izuzetim informacijama osim ako je sama kombinacija u javnoj domeni, neovisno.

1. **“Postrojenja ”** znači Pfizer -ova proizvodna mjesta u Kalamazoou (Michigan) i Puurs, Belgija, te dva proizvodna mjesta BioNTech -a, u Mainzu i Idar Oberstein -u Njemačkoj, ili takvo drugo proizvodno mjesto koje se koristi u vezi s proizvodom koju isporučuje Pfizer u nastavku.
2. “Događaj više sile” ima značenje navedeno u Odjeljku  [12.9.](#bookmark16)
3. “Obrasci” ima značenje navedeno u Odjeljku  [12.13.](#bookmark20)
4. “Vlada ” znači sve razine i pododjele vlasti (tj. Lokalnu, regionalnu, nacionalnu, pokrajinsku, saveznu, upravnu, zakonodavnu ili izvršnu vlast) Albanije..
5. “ICC” ima značenje navedeno u Odjeljku  [12.2.](#bookmark91)
6. “Odštetni zahtjevi ” ima značenje navedeno u Odjeljku 8.2.
7. “Odšteta” ima značenje navedeno u Odjeljku 8.1
8. “Intelektualno vlasništvo” znači sve procese, trgovinske tajne, izume, industrijske modele, dizajn, metodologije, nacrte, otkrića, rezultate, materijale, formule, procedure, tehnike, kliničke podatke, ili tehničke i druge informacije ili podatke, proizvodne, inženjerske ili tehničke nacrte, uključujući vlasnička prava na bilo koje od gore navedenog, i (b) registrirane trgovačke marke, prijave žigova, neregistrirane marke, trgovačka odijela, autorska prava, know-how, patente, prijave patenata i sve privremene odredbe, podjele, nastavke, nastavke djelomično , proširenja, zamjene, obnove, registracije, ponovne validacije, ponovna izdavanja ili dodatke, uključujući potvrde o dodatnoj zaštiti, na ili bilo koji od gore navedenih patenata i patentnih prijava, te sve strane kopije bilo kojeg od gore navedenih patenata i patenatnih prijava
9. Specifikacije označavanja i pakiranja ” ima značenje navedeno u Odjeljku [2.4(](#bookmark26)e).
10. Prikriveni nedostatak ” znači kvar koji uzrokuje da proizvod nije u skladu s primjenjivim specifikacijama koje kupacu mogu pokazati kako nedostatak nije bio prisutan u vrijeme isporuke proizvoda od strane Pfizer -a kupcu i koje Kupac, njegov ovlaštenik ili njegovo osoblje osoblje nisu mogli otkriti kod isporuka marljivim pregledom.
11. “Zakon/i” znači zajedno sve primjenjive nacionalne i lokalne zakone, zajedničke zakone, statute, uredbe, kodekse, pravila, propise, naredbe, dekrete ili druge objave bilo koje vlade, upravnog ili sudskog tijela sa učinkom zakona.
12. “Gubici” ima značenje navedeno u Odjeljku  [8.1.](#bookmark66)
13. “Odobrenje za stavljanje na tržište ” znači odobrenje za stavljanje u promet ili takvo drugo dopuštenje sa sličnim učinkom u odnosu na Proizvod izdano od (a) (i) FDA, ili (ii) Europske Komisije i (b) (i) NAM ili (ii) Ministra zdravstva i socijalne zaštite od vremena do vremena, kojim se odobrava da se Proizvod stavi, u skladu sa zakonom, na tržište tee zemlje ili teritorija.
14. Ne odgovarajući Proizvod” ima značenje navedeno u Odjeljku  [4.4(](#bookmark11)a).
15. Strana ” ili “Strane” ima značenje navedeno u uvodnoj izjavi.
16. **“Osoba”** znači svaka fizička osoba, subjekt, korporacija, generalno partnerstvo, zajedničko društvo, partnerstvo s ograničenom odgovornošću, zajedničko ulaganje ili sličan subjekt ili organizacija, dioničko društvo, vlasništvo, druga poslovna organizacija, udruženje, udruga sindikata ili Vlade
17. “Osoblje” znači sve povezane osobe, podizvođači ili druge Treće strane, te zaposlenici i zastupnici svake od njih , koje koristi Strana u izvršavanju usluga ili obveza ili u vezi s ovim Ugovorom
18. “Pfizer” ima značenje navedeno u uvodnoj izjavi
19. “Pfizer US” ima značenje navedeno u uvodnoj izjavi
20. “Mjesto isporuke” ima značenje navedeno u Odjeljku  [2.8(a).](#bookmark35)
21. “Cijena” ima značenje navedeno u Odjeljku [3.1.](#bookmark7" \o "Current Document)
22. Privilegije i Imuniteti” znači sve privilegije, imunitete ili zakone u Albaniji, uključujući, bez ograničenja, programe nadoknade cjepiva bez greške, programe osiguranja od pandemije, imunitete od tužbe ili odgovornosti, ili bilo kakvu zaštitu, obranu ili ograničenje odgovornosti (bilo zakonski, regulatorno, opće pravno ili na neki drugi način), postojeće ili buduće, koje mogu zasebno zaštititi od straha za obeštećenje.
23. “Proizvod” znači sva cjepiva proizvedena, u cijelosti ili djelomično, ili isporučena, izravno ili neizravno, od ili u ime Pfizera ili BioNTecha ili bilo koje od njihovih podružnica u skladu s ovim Ugovorom, a namijenjena prevenciji ljudske bolesti COVID-19 ili bilo koje druge ljudske bolesti, u svakom slučaju uzrokovane bilo kojim od virusa SARS-CoV-2, i/ili bilo kojim ili svim srodnim sojevima, mutacijama, modifikacijama ili derivatima prethodno navedenog.
24. “Materijali Proizvoda ” znači svi materijali za pakiranje i komponente potrebni za isporuku Proizvoda
25. “Narudžbenica” znači pisani ili elektronički obrazac za narudžbu koji je Kupac dostavio Pfizeru u skladu s odredbama ovog Ugovora kojim se odobrava proizvodnja i isporuka Proizvoda, u bitnoj formi priloženoj kao Prilog G (koji se s vremena na vrijeme Pfizer može ažurirati nakon obavijesti Kupca
26. “Kupac” ima značenje navedeno u uvodnoj izjavi.
27. “Primatelj” znači Strana koja prima povjerljive podatke od druge Strane
28. “Zapisi” označavaju knjige, dokumente i druge podatke o svim pitanjima vezanim uz ispunjenje obaveza prema ovom Ugovoru.
29. “Predstavnici” znači, u odnosu na Primatelja, njegove podružnice i njegove i njihove odgovarajuće direktore, službenike i zaposlenike, zastupnike, izvođače, konzultante, savjetnike i predstavnike koji (a) podliježu obvezi povjerljivosti štiteći Povjerljive podatke pod uvjetima ne manje restriktivnim od onih sadržanih u ovom Ugovoru; i (b) moraju znati Povjerljive podatke u vezi s ovim Ugovorom.
30. “Specifikacije” znači specifikacije materijala za proizvodnju, preradu, pakiranje, označavanje, postupke ispitivanja i testiranja, otpremu, skladištenje i opskrbu proizvoda kako će biti navedene u Prilogu A, nakon datuma stupanja na snagu (i u svakom slučaju prije isporuke u skladu sa dogovorenim Rasporedom isporuka ), pa se kao takve Specifikacije mogu izmijeniti, nadopuniti ili na neki drugi način izmijeniti od strane Pfizer -a i dostaviti Kupcu.
31. “Porezi” ima značenje navedeno u Odjeljku  [3.4.](#bookmark40)
32. “Rok” u odnosu na ovaj Ugovor ima značenje navedeno u Odjeljku 6.1.
33. Benefiti Treće strane” ima značenje navedeno u Odjeljku [[12.6(](#bookmark40" \o "Current Document)](#bookmark95)[a).](#bookmark40" \o "Current Document)
34. **“USD”** znači zakonitu valutu u Sjedinjenim Američkim Državama
35. **“**Cjepivo” uključuje (a) sva cjepiva proizvedena, u cijelosti ili djelomično, ili isporučena, izravno ili neizravno, od strane ili u ime Pfizera ili BioNTecha ili bilo koje od njihovih podružnica u skladu s ovim Ugovorom, a koja su namijenjena prevenciji ljudske bolesti COVID -19 ili bilo koju drugu ljudsku bolest, u svakom slučaju uzrokovanu bilo kojim virusom SARS-CoV-2, i/ili bilo kojim ili svim srodnim sojevima, mutacijama, modifikacijama ili izvedenicama prethodno navedenog, (b) bilo kojim uređajem, tehnologijom ili proizvod koji se koristi u primjeni ili za poboljšanje uporabe ili učinka takvog cjepiva, ili (c) bilo koje komponente ili sastavnog materijala (a) ili (b)
36. **“VAT** znači Porez na dodanu vrijednost

Osim ako kontekst izričito ne zahtijeva drugačije, (a) smatra se da upotreba bilo kojeg spola u ovom tekstu uključuje upućivanje na jedan ili oba spola, a upotreba jednine smatra se da uključuje množinu (i obrnuto), (b ) smatra se da iza riječi "uključi", "uključuje" i "uključujući" slijedi izraz "bez ograničenja", (c) riječ " ćeš, ćete," tumači se kao da ima isto značenje i učinak kao i riječ " će ”, (d) bilo koja definicija ili upućivanje na bilo koji sporazum, instrument ili drugi dokument u ovom dokumentu tumačit će se kao da se odnosi na takav sporazum, instrument ili drugi dokument koji se povremeno mijenja, dopunjava ili na neki drugi način mijenja (podliježe ograničenjima takve izmjene, dopune ili izmjene navedene ovdje), (e) svako upućivanje na bilo koju osobu u ovom tekstu tumači se tako da uključuje sljednike te osobe, (f) riječi "ovdje", „tu“ i "u nastavku", te riječi sličnog značaja, tumačit će se kao da se u cijelosti odnose na ovaj Ugovor, a ne na bilo koju posebnu odredbu ovog Ugovora, (g) sve reference u odjeljcima ili prilozima tumačit će se kao upućivanje na odjeljke ili priloge ovog ugovora, a reference na ovaj Ugovor uključuju sve njegove priloge, (h) riječ "obavijest" znači obavijest u pisanom obliku (bez obzira je li izričito navedena ili ne) i uključuje obavijesti, pristanke, odobrenja i drugu pisanu komunikaciju predviđena ovim Ugovorom, (i) pozivanja na bilo koji poseban zakon, pravilo ili propis, ili članak, odjeljak ili drugi dio, smatrat će se da uključuju u tom vremenu važeće izmjene ili dopune ili bilo koju zamjenu ili sljednički zakon, pravilo ili propis i (j) izraz "ili" tumačit će se u uključivom smislu koji je obično povezan s izrazom "i/ili".

2 **OPSKRBA PROIZVODA**

1. Ugovor o opskrbi.
2. Tijekom Roka, Pfizer će koristiti Komercijalno razumne napore da bi isporučio ili da je isporučio Proizvod Kupcu, a Kupac će kupiti Proizvod, u skladu s odredbama i uvjetima ovog Ugovora.

Kupac priznaje i prihvaća Pfizerove napore da razvije i proizvede proizvode koji su razumne prirode i podložni značajnim nesigurnostima rizika, i (ii) činjenicu da bilo koji drugi lijek ili cjepivo za sprječavanje, liječenje ili izlječenje infekcije COVID-19 uspješno razvijeno ili odobreno prije izdavanja Autorizacije za Proizvod, neće promijeniti trenutno stanje hitnih potreba za sprječavanje širenja infekcije COVID-19 koje predstavlja ozbiljnu prijetnju i štetne učinke na živote i zdravlje javnosti općenito.

(b)

(c)

Bez obzira na napore i procijenjene datume navedene u Rasporedu isporuke, stranke priznaju da je Proizvod završio klinička ispitivanja faze 2b/3 i da, unatoč naporima Pfizera u istraživanju, razvoju i proizvodnji, proizvod možda neće biti uspješan zbog tehničkih, kliničkih, regulatornih, proizvodnih, otpremnih, skladišnih ili drugih izazova ili kvarova

1. U skladu s tim, Pfizer i njegove Podružnice neće biti odgovorni za bilo kakav propust Pfizera ili njegovih povezanih društava da razviju ili dobiju Autorizaciju proizvoda u skladu s procijenjenim datumima opisanim u ovom Ugovoru. Čak i ako je proizvod uspješno razvijen i dobije Autorizaciju, Pfizer neće biti odgovoran za bilo koji propust u isporuci doza u skladu s bilo kojim procijenjenim datumima isporuke koji su ovdje navedeni (osim kako je izričito navedeno u ovom Ugovoru), niti će bilo koji takav propust dati Kupcuc ima pravo otkazati narudžbe za bilo koju količinu Proizvoda.
2. Pfizer će Kupca obavještavati o napretku materijalnog razvoja Proizvoda te će Kupcu dostaviti informacije o tom razvoju na razuman zahtjev Kupca.
3. Kapacitet.

 Pfizer će upotrijebiti komercijalno razumne napore za izgradnju ili stjecanje proizvodnih kapaciteta za proizvodnju i isporuku Proizvoda Kupcu u skladu s odredbama ovog Ugovora

1. Narudžbenice.
2. Nakon primitka Odobrenja navedenog u odjeljku 9.6, Kupac će dostaviti Pfizeru pravno obvezujuću i neopozivu Narudžbenicu (e) za za četiri stotine devedeset devet tisuća petsto devedeset (499.590) doza **(„Ugovorene doze“)** Proizvoda
3. Narudžbenica se dostavlja zajedno s brojem narudžbe kupca, poreznim brojem i adresom računa. Pfizer će u pisanom obliku prihvatiti Narudžbenicu u skladu s uvjetima navedenim u ovom Ugovoru, a potvrđena Narudžbenica bit će obvezujuća za Strane i podložna je odredbama i uvjetima navedenim u ovom Ugovoru.
4. Raspored isporuka.

Pfizer će isporučiti Proizvod uz plaćeni prijevoz Proizvoda i osiguranjes (“CIP”) Incoterms 2020.

(a)

(b)

Strane će se razumno, u pisanom obliku, složiti s mjestom (mjestima) (uključujući broj lokacija) za isporuku pošiljki Proizvoda **("Mjesto (i) odredišta")** čim to bude razumno izvedivo nakon Dana stupanja na snagu; pod uvjetom da: (i) svako mjesto odredišta ispunjava zahtjeve navedene u Prilogu D, (ii) sve dogovorene lokacije odredišta Strane će pismeno dogovoriti najmanje osam (8) tjedana prije isporuke Proizvoda, (iii) mjesto (a) odredišta opslužuje ugovoreni prijevoznik tvrtke Pfizer **(„Agent otpreme“)**, i (iv) svako odredište je ovlašteno mjesto za primanje Proizvoda, čiji će dokazi biti prezentiran Pfizeru na službenom memorandumu Kupca ili u drugom službenom formatu prihvatljivom za Pfizer, a Kupac će dostaviti sve dodatne informacije, kako ih Pfizer zatraži prije isporuke, radi provjere takvog ovlaštenja. U slučaju da se Strane ne dogovore o mjestu odredišta u gore navedenim rokovima, Pfizer ima pravo revidirati Raspored isporuke. Pfizer će imati mogućnost, postupajući razumno, ograničiti broj odredišnih mjesta na koja će se isporučivati pošiljke Proizvoda. Međutim, Strane se slažu da: (a) vlasništvo nad Proizvodom i rizik od gubitka ili oštećenja prelaze na Kupca na mjestu isporuke kako je definirano u odjeljku 2.8 (a) ovog Ugovora, i (b) Kupac snosi punu odgovornost i odgovornost za bilo kakav daljnji transport i distribuciju nakon isporuke na odredište (mjesta) koja nije Točka isporuke Proizvoda, uključujući, ali ne ograničavajući se na osiguravanje usklađenosti s Prilogom D.

1. Svaka od isporuka Proizvoda imati će minimalni volume od 195 bočica.
2. Pfizer može isporučiti Proizvod u zasebnim ratama i uložit će Komercijalno razumne napore kako bi ispunio raspored isporuke utvrđen u Prilogu B **("Raspored isporuka"),** pod uvjetom da se niti jedan Proizvod ne isporučuje dok se ne primi Autorizacija i Kupac uskladi, na zadovoljstvo Pfizera, uvjete navedene u odjeljku 9.5. Sve isporuke moraju biti popraćene dokumentacijom navedenom u Prilogu C (koju Pfizer može povremeno ažurirati nakon obavijesti Kupca) i bit će u skladu i podložne specifikacijama isporuke koje će biti navedene u Prilogu D (koje se popunjavaju nakon Datuma stupanja na snagu, ali u svakom slučaju prije isporuke u skladu s dogovorenim Rasporedom isporuka, a koje Pfizer može povremeno ažurirati nakon obavijesti Kupca) **(„Specifikacije isporuke“)**.
3. Proizvod će biti označen i pakiran u skladu sa specifikacijama pakiranja koje su navedene u Prilogu E (koji se popunjava nakon Datuma stupanja na snagu, ali u svakom slučaju prije isporuke u skladu s dogovorenim Rasporedom isporuka, koji Pfizer može emeno ažurirati Pfizer nakon obavijesti Kupca) **("Specifikacije označavanja i pakiranja").** Radi jasnoće, Kupac je isključivo odgovoran za usklađenost s lokalnim zahtjevima za označavanje, uključujući, bez ograničenja, sve zahtjeve za prijevod na lokalni jezik.
4. Ako je Autorizacija izdana nakon 31. ožujka 2021. godine, ali prije 30. lipnja 2021., tada će se Raspored isporuka revidirati kako bi se dodao vremenski period između 31. ožujka 2021. i datuma autorizacije **(„prilagođeni raspored isporuke“)**. U slučaju da je autorizacija dana prije 31. ožujka 2021., Pfizer nema obvezu ubrzati isporuku Proizvoda.
5. Ako je Autorizacija primljena do 31. ožujka 2021 ali Pfizer nije u mogućnosti isporučiti bilo koje Ugovorene doze iz tehničkih ili drugih razloga iz postrojenja namijenjenih za proizvodnju Ugovorenih doza prema ovom Ugovoru, Pfizer pristaje koristiti Komercijalno razumne napore za dobivanje Proizvoda s drugog mjesta, ovisno o dostupnosti opskrbe.
6. Ako je Autorizacija primljena do 31. ožujka 2021. godine, ali do 30. rujna 2021. godine, Pfizer nije u mogućnosti proizvesti ili isporučiti bilo koju Ugovorenu dozu iz tehničkih ili drugih razloga iz bilo kojeg pogona, Pfizer neće imati obvezu isporuke prema Rasporedu isporuke , Prilagođenom rasporedu isporuke ili Narudžbenici.
7. Nestašica Proizvoda.
8. Ako je Autorizacija dobivena, ali nema dovoljno za isporuku ukupnog broja Ugovorenih doza u Rasporedu isporuke (uključujući i Prilagođeni raspored isporuke), uključujući i bilo koji nedostatak koji je posljedica zahtjeva Pfizer -a za preusmjeravanjem dostupne ponude Proizvoda na drugo tržište, Pfizer će surađivati na pružanju obavijesti (i upravljati svakom komunikacijom povezanom s nedostatkom Proizvoda). Nakon primitka takve obavijesti, Kupac će pravovremeno izvršavati sve upute navedene u obavijesti (a ni u kojem slučaju dulje od 24 sata). U skladu s gore navedenim, uključujući sve zahtjeve Pfizera za preusmjeravanje Proizvoda na drugo tržište, Pfizer će odlučiti o potrebnim prilagodbama broja Ugovorenih doza i Rasporeda isporuke Kupcu na temelju načela koja će Pfizer utvrditi prema tada postojeće okolnosti **("Raspodjela")** koje će biti navedene u takvoj obavijesti. Smatra se da Kupac pristaje na bilo koju reviziju.
9. Kupac se ovime odriče svih prava i pravnih lijekova koje prema zakonu može imati, na pravičnoj osnovi ili na drugi način, a koja proizlaze ili se odnose na: (i) bilo koji propust Pfizera da razvije ili dobije autorizaciju proizvoda u skladu s procijenjenim datumima opisanim u ovom ugovoru ; ili (ii) bilo koji propust Pfizera da isporuči Ugovorene doze u skladu s Rasporedom isporuke. U slučaju nedosljednosti između odredbi ovog Odjeljka 2.5 (Nestašica proizvoda) i odredaba drugih odjeljaka ovog Ugovora, odredbe ovog Odjeljka 2.5 (Nestašice proizvoda) kontrolirat će i zamijeniti odredbe drugih odjeljaka ovog Ugovora u opsegu takve nedosljednosti.

2.6 Kašnjenja isporuka

Ni.pod kojim okolnostima Pfizer neće biti odgovoran ni podložen penalima za kašnjenje bilo koje isporuke.

2.7 Rukovanje Proizvodom

1. Pfizer će uložiti Razumni komercijalni napor kako bi osigurao da je proizvod proizveden u skladu sa specifikacijama materijala i cGMP -om
2. Nakon isporuke Proizvoda Kupcu na odredišnim mjestima i, u mjeri u kojoj je to primjenjivo, za daljnju distribuciju i/ili transport do odredišnog mjesta koje nije mjesto korištenja Proizvoda, Kupac će skladištiti i rukovati Proizvodom na način naveden u Tehničkim specifikacijama, uputama u Prilogu D i uputama koje pruža Pfizer radi osiguranja stabilnosti i integriteta Proizvoda.
3. Kako bi se izbjegle nedoumice, Kupac snosi sve troškove korištenja Proizvoda nakon prijenosa s Pfizera na Odredište, uključujući, ali bez ograničenja, one za skladištenje Proizvoda i distribuciju i administraciju Proizvoda ( ako je primjenjivo) u Albaniji.
4. Kupac je isključivo odgovoran za pravilno skladištenje, rukovanje, distribuciju, transport, administraciju, upotrebu i odlaganje Proizvoda u Albaniji nakon isporuke Proizvoda Kupcu ili njegovom ovlašteniku na odredištu. Ne dovodeći u pitanje općenitost gore navedenog, Kupac će osigurati da: (a) primatelji Proizvoda slijede upute za vraćanje i odlaganje u Prilogu F (koje Pfizer može povremeno ažurirati nakon obavijesti Kupca) prilikom odlaganja otvoreni i nekorišteni Proizvod i njegove komponente za pakiranje; i (b) takav povratak i odlaganje u skladu su s zakonima CONFIDENTIAL 11 EAST\177977274.10 o farmaceutskom otpadu, medicinskom otpadu ili opasnom otpadu, prema potrebi. Privitak F pruža mogućnost Pfizeru da naplati Kupcu troškove takvih komponenti pakiranja, bez ograničavanja bilo kakvih drugih pravnih lijekova koji su na raspolaganju Pfizeru, u slučaju ako Kupac ne ispuni zahtjev za vraćanjem naveden u Prilogu F.
5. Kupac je odgovoran i osigurava da se sva oprema koja se koristi za isporuku Proizvoda, na primjer otpremnik (i) i uređaji (i) za nadzor, skladišti na odgovarajućem čistom i sigurnom mjestu radi zaštite i održavanja funkcionalnosti takve opreme ( u kontroliranim uvjetima, bez izloženosti vremenskim prilikama ili štetočinama itd.). U roku od trideset (30) dana od isporuke Proizvoda na odredište (mjesta), u skladu s odjeljkom 4.4 (b), Kupac će organizirati siguran povrat sve takve opreme, uključujući otpremnik i uređaj za nadzor, u skladu s Pfizerovim uputama.
6. Pfizer može pružiti kupcu Sigurnosno-tehničke listove i druge informacije kako bi mu pomogao u razvoju procesa i postupaka, uključujući obuku, za rukovanje proizvodom i materijalima proizvoda na siguran način i u skladu sa zakonima, uključujući zakone o zdravlju i sigurnosti na radu. Kupac izjavljuje i jamči da ima i jamči da svi primatelji Proizvoda i materijala proizvoda imaju potrebnu stručnost za razvoj i provedbu odgovarajućih postupaka i programa obuke koji omogućuju pravilno rukovanje Proizvodom i materijalima proizvoda na siguran i zakonit načinih

2.8 Vlasništvo Proizvoda, Rizik od gubitka .

1. Vlasništvo Proizvoda i rizik od gubitka ili oštećenja prelaze na Kupca na prvom mjestu ulaska u Albaniju u bilo kojoj zračnoj luci u Albaniji, prije carinjenja **(„Mjesto isporuke“).** Pfizer zadržava pravo promijeniti bilo koju isporuku ili mjesto isporuke dajući Kupcu odgovarajuću obavijest prihvatljivu prema zakonima, uzimajući u\_obzir i mjesto isporuke u jednoj od susjednih država Republike Albanije. Cijene su navedene na temelju CIP mjesta ili odredišta na snazi u vrijeme i na mjestu isporuke. Za potrebe ovog Ugovora, izrazi CIP imat će značenje dato tom terminu u INCOTERMS -u 2020. objavljenom od ICC -a, Pariz, Francuska.
2. Kupac je jedini uvoznik Proizvoda pred relevantnim carinskim tijelima u Albaniji **(„Uvoznik zapisa“)** i odgovoran je za dobivanje, na svoju odgovornost i o svom trošku, svih uvoznih dozvola ili drugog službenog odobrenja te za izvršenje svih carinske formalnosti za uvoz Proizvoda u Albaniju. Kupac je također odgovoran za plaćanje, gdje je to primjenjivo, svih pristojbi, poreza i drugih dažbina, kao i troškova obavljanja carinskih formalnosti koji se plaćaju pri uvozu Proizvoda. S obzirom na prirodu Proizvoda, Kupac se obvezuje podržati Agenta za otpremu kako bi se Proizvod od strane d relevantnih carinskih tijela očistio u roku od **jednog (1) Radnog dana** od dolaska Proizvoda na Mjesto isporuke; svako kašnjenje u takvom postupku carinjenja moglo bi utjecati na ukupni rok trajanja Proizvoda. Podložno prethodnom pisanom odobrenju Pfizera, Kupac može zatražiti i nabaviti sve takve usluge carinjenja od Agenta za otpremu. Kupac potvrđuje da su potrebni dokumenti za carinjenje Proizvoda navedeni u Prilogu H, dio 1 ovog Ugovora..
3. Ne dovodeći u pitanje općenitost gore navedenog, nakon prijenosa na Kupca prava vlasništva i rizika Proizvoda na Mjestu isporuke, kao što je definirano u odjeljku 2.8 (a), Kupac je u potpunosti odgovoran za bilo kakakv otpad Proizvoda te za osiguranje odgovarajućeg odlaganja u skladu s odjeljcima 2.7 (d) i 2.7 (e). Radi potpune jasnoće, iako će Pfizer podržati Kupca u prijevozu Proizvoda od Mjesta isporuke do odredišta putem dostavljača, Pfizer neće biti odgovoran za ni za kakav rizik gubitka ili oštećenja Proizvoda nakon Mjesta isporuke, uključujući bez ograničenja, promjene temperature, krađu ili bilo kakvu vrstu štete na Proizvodu.
4. Ne dovodeći u pitanje Odjeljak 4.4 Kupac priznaje da Pfizer neće, ni pod kojim okolnostima prihvatiti bilo kakav povrat Proizvoda ( ili bilo koje doze) . Posebno, nakon primitka Proizvoda u skladu ovim Odjeljkom  [2.8,](#bookmark34) nikakav povratak Proizvoda se ne može dogoditi, ni pod kakvim okolnostima ( uključujući buduće promjene zaliha, Proizvode s istekom roka trajanja, promjene u raspodjeli Proizvoda isporuci no Product returns may take place under any circumstances (inclusive of future changes in stock, expired Products, changes in Product allocation, delivery, potražnji ili pojavi novih proizvoda.)
5. CIJENA I PLAĆANJE

3.

3.1

3.2

Nabavna cijena

.Kupac će kupiti proizvod od Pfizera po cijeni po dozi navedenoj u Prilogu B, bez Poreza na dodanu vrijednost **("Cijena")** i u skladu s odredbama ovog Ugovora. Cijena uključuje sve interne troškove tvrtke Pfizer povezane s proizvodnjom i isporukom Proizvoda do odredišta u skladu s ovim Ugovorom. Radi jasnoće, cijena ne uključuje troškove opisane u odjeljku 2.8 (b). Cijena će biti čvrsta za vrijeme trajanja Ugovora..

Fakture i plaćanje

1. Uz djelomično razmatranje ugovorenih doza, kupac će platiti avans u iznosu od 2.997.540 USD (izračunato kao 12,00 USD/dozu pomnoženo s 249.795 Ugovorenih doza) u roku od trideset (30) dana od primitka računa od Pfizera izdanog nakon Potvrde o odobrenju kupca navedene u odjeljku 9.6 **(„Predujam“**); pod uvjetom da Pfizer nema obvezu otpreme ili isporuke Proizvoda do primitka Predujma. Svi dospjeli iznosi prema ovom ugovoru bit će pretvoreni u EUR koji će se odrediti na temelju tečaja koji koristi The Wall Street Journal, Eastern U.S. Edition, jedan (1) Radni dan prije datuma Ugovora.
2. Pfizer će fakturirati Kupcu cijenu za preostalih 249.795 Ugovorenih doza najmanje šezdeset (60) dana prije svake isporuke u skladu s odjeljkom 2.4 (Raspored isporuka) **("Cijena isporuke")** koja se plaća u skladu s odredbama Odjeljka 3.3 (a). Svi takvi iznosi dospijevaju prije isporuke volumena predviđenih doza koje će se isporučiti u takvoj isporuci.
3. Fakture će se slati na  ishp@shendetesia.gov.al, Institut za javno zdravstvo, Aleksander Moisiu, br. 80, Tirana, Albanija 1001. Pfizer će uključiti sljedeće podatke na sve fakture: broj narudžbenice i adresu za naplatu; te će također uključiti, prema potrebi, tipski opis, broj partije (ako postoji) i broj isporučenih ugovorenih doza; datum isporuke; stvarni datum otpreme; cijenu; sve primjenjive poreze ili druge naknade predviđene narudžbenicom; i isporuku do odredišta.
4. Methoda plaćanja.
5. Kupac će sve nesporne (u dobroj vjeri) iznose u EUR platiti u roku od trideset platiti u roku od trideset (30) dana od datuma izdavanja fakture. Plaćanje će biti doznačeno elektroničkom doznakom u odmah raspoloživa sredstva banci i račun koji je odredio Pfizer Bilo koja uplata koja dospijeva na datum koji nije Radni dan može se izvršiti sljedeći sljedeći Radni dan Svaki spor Kupca o fakturi biti će dostavljen Pfizeru u pisanom obliku (zajedno s potkrepljujućom dokumentacijom I razumno detaljnim opisom spora) u roku od deset (10) dana od datuma takve fakture. Smatrat će se da je kupac prihvatio sve fakture za koje Pfizer nije primio pravovremenu obavijest o sporovima i platit će sve nesporne iznose iznose dospjele po takvim fakturama u roku utvrđenom u ovom odjeljku 3.3(a). Strane će nastojati brzo i u dobroj vjeri riješiti sve takve sporove.
6. Bilo koji iznos koji Strana mora platiti, a nije plaćen koji Strana mora platiti, a koji nije uplaćen na datum dospjele obaveze donose kamate, u mjeri u kojoj to dopušta zakon, po najvišoj (a) stopi koju Europska središnja banka primjenjuje za svoje glavne operacije refinanciranja u eurima (referentna stopa) plus pet bodova (ili navedena centralizirana referentna stopa banke) u Obrascu narudžbe za cjepivo) i (b) 2%. Referentna stopa je stopa na snazi kako je objavljeno u seriji C Službenog lista Europske unije, prvog dana u mjesecu u kojem završava razdoblje plaćanja. Takve se kamate obračunavaju na temelju godine od tristo šezdeset (360) dana za stvarni broj dana kašnjenja u plaćanju. Osim svih drugih pravnih lijekova dostupnih prema ovom Ugovoru ili prema zakonu, ako Kupac ne plati bilo koji nesporni iznos u roku dospijeća prema ovom Ugovoru, Pfizer može (i) obustaviti isporuku Proizvoda ili (ii) raskinuti ovaj Ugovor
7. Kupac neće i priznaje da prema ovom Ugovoru nema pravo, bilo koju Narudžbenicu, bilo koji drugi ugovor, dokument ili zakon, zadržati, pobiti, nadoknaditi ili zadužiti bilo koji iznos duga (ili dospjećea) Pfizeru, bilo prema ovom Ugovoru ili na neki drugi način, protiv bilo kojeg drugog iznosa koji mu Pfizer ili pridruženo društvo duguje (ili koji mu dospijeva.).
8. Porezi.

Strane razumiju i dogovaraju se da izvršena plaćanja i druge naknade predviđene ovim Ugovorom isključuju bilo koji Porez na dodanu vrijednost ili sličan Porez i sve ostale Poreze koji nastaju kao rezultat proizvodnje i isporuke Proizvoda (uključujući, bez ograničenja, carine, namete i pristojbe te sve lokalne poreze) **("Porezi")**, koji se na to dodaju prema potrebi Tamo gdje su Porezi uredno zaračunati na uplatu ili naknadu predviđenu ovim Ugovorom, Strana koja vrši uplatu ili plaća naknadu platit će iznos Poreza u skladu sa zakonima i propisima zemlje u kojoj se ti Porezi obračunavaju.

U slučaju da bilo koja plaćanja izvršena prema ovom Ugovoru postanu predmet zadržavanja Poreza prema zakonima ili propisima bilo koje nadležnosti, Strana koja vrši takvo plaćanje će odbiti i zadržati iznos takvih Poreza za račun Primatelja uplate u mjeri propisanoj zakonom, a takvi iznosi plativi Primatelju umanjuju se za iznos Odbijeni i zadržani porezi. Svaki takav zadržani Porez za koji se prema zakonu traži da bude plaćen ili zadržan biti trošak koji snosi samo Primatelj plaćanja.

4 **MANUFACTURING STANDARDS AND QUALITY ASSURANCE**

* 1. Manufacturing Standards.

Pfizer shall manufacture and supply the Product in material accordance with the Specifications and cGMP. Such Specifications may be revised through written notification by Pfizer to Purchaserlo conformAxTiLe Authorization or changes to the manufacturing or distributfchT5FtSe Product.

* 1. Legal and Regulatory Filings and Requests.

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1. Pfizer shall (a) comply with all regulatory or government licenses and permits, and
2. comply with all cGMP with respect to its manufacturing and packaging processes, the Facilities or otherwise, to permit the performance of its obligations hereunder. Notwithstanding the foregoing, Pfizer shall use Commercially Reasonable Efforts to obtain the Authorization provided that the Purchaser shall /aive, to the extent applicable, all the requirements set out in Attachment H Part 2 of this Agreement in respect of the issue of the Authorization.
3. Pfizer shall ensure that all Product is properly labelled and packaged in accordance with the applicable Authorization, Specifications and material cGMP standards. For clarity, Purchaser shall be solely liable for compliance with local labelling requirements, including without limitation, any local language translation requirements.
4. Prior to delivery, Pfizer shall comply with all conditions (in the relevant timescales) set out in the Authorization; provided, however, that Purchaser shall grant, or obtain on Pfizer’s behalf, all exemptions, exceptions, and waivers of country specific requirements for the Product granted or permitted by the Government authority (including but not limited to serialization, applicable laboratory or quality testing and/or marketing information form submission and approval), which requirements,absent an exemption, exception or waiver, would prevent Pfizer from supplying and releasing the Product in Albania upon receipt of the Authorization.
5. In the event that a third party is the applicant or holder of the Authorization, any obligation on Pfizer under this Agreement shall be taken as a requirement on Pfizer to use Commercially Reasonable Efforts to procure the compliance of such third party Authorization applicant or holder with such obligations to the extent necessary to ensure the relevant obligation is fully met.
6. Due to the current pandemic situation and the fact that any anticipated Authorization will be initially under an emergency use authorization, and the Parties agreement that Pfizer will only supply the Purchaser directly, the Purchaser agrees to the below conditions and, as a condition precedent to supply of the Product, will issue, or make any other Government authority to issue, any necessary approvals to ensure enforceability of the same:

During the Term, Pfizer will not be required by the Purchaser or any other Government authority to appoint a local agent, distributor, or any responsible Person, including without limitation, for purposes of selling or supplying the Product or applying for the Albanian Conditional Approval, unless Pfizer decides otherwise at a later stage to appoint a local agent or distributor. For the avoidance of doubt, Purchaser also agrees that (i) Pfizer or any of its Affiliates will be the entity applying and submitting any regulatory files required for issuance of Albanian Conditional Approval, and (ii) Albanian Conditional Approval will be issued under Pfizer’s or any of its Affiliates name.

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During the Term, Pfizer will not be required by the Purchaser or any other Government authority to submit a price reference certificate for purposes of applying for Albanian Conditional Approval or otherwise.

Quality Tests and Checks.

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Pfizer shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in­process, bulk finished product and stability (chemical or microbial) tests or checks required to assure the quality of the Product and tests or checks required by the Specifications and cGMP.

Rejection of Product: Disposal of Rejected Shipments.

(a) Purchaser may reject any Product that does not materially conform to Specifications

or cGMP (“Non-Complying Product”) by providing written notice of rejection to Pfizer and the delivery carrier and setting out detailed reasons for such rejection: (i) immediately (and in no event more than 24 hours) upon delivery at the Point of Delivery; (ii) immediately and in any event within 24 hours of delivery at the Place(s) of Destination of such Non-Complying Product to Purchaser; or (iii)

immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect. In the event notice is not provided within 24 hours from delivery, the Product shall have been deemed accepted. Pfizer shall respond to any rejection and notice of Non-Complying Product from Purchaser in a timely manner. For clarity, Purchaser shall not be entitled to reject any Product based on service complaints unless a Product does not materially conform to Specifications or cGMP.

1. Pfizer shall conduct an analysis of the causes of any such quality-related complaint, and shall report to Purchaser on any corrective action taken. If Pfizer’s inspection and testing reveals, to Pfizer’s reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer, Pfizer shall use Commercially Reasonable Efforts to replace such Non­Complying Product as soon as practicable at no additional charge to Purchaser. In such circumstances, Pfizer will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, Purchaser shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers’ specifications. Notwithstanding any other provision of this Agreement, this Section [jL4fb.)](#bookmark45) contams^Thlrchaser’s sole and. exclusive remedy for Non-Complying Product. The provisions of this Section [4.4](#bookmark11) (Rejection of Product; Disposal of Rejected Shipments) shall survive termination or expiration of this Agreement.

4.5 Maintenance and Retention of Records.

1. Each Party shall maintain detailed Records with respect to its activities unc Agreement as required by Laws.

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(b) Purchaser will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If Purchaser does not have a quality system for the activities defined, Pfizer may share details of a proposed quality system for Purchaser’s compliance.

4.6 Diversion Issues.

All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in Albania in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of Albania, and to protect and preserve the integrity and efficacy of the Product. Purchaser shall promptly notify Pfizer by email[[1]](#footnote-1) within 48 hours (with follow up in writing in line with the notice provisions of this Agreement) if at any time Purchaser believes that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise

subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information. Purchaser shall cooperate with Pfizer or its designee, upon Pfizer’s request, to cooperate in connection with such Product diversion.

Recalls.

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Purchaser shall be responsible for all costs of any recall or market withdrawal of the Product in Albania, including, without limitation, reasonable costs incurred by or on behalf of Pfizer and its Affiliates or BioNTech and its Affiliates, except to the extent that such recall or market withdrawal results from willful misconduct (being a wrongful act, willingly and knowingly committed without legal or factual justification, with the intent to cause the harmful effects) on the part of, Pfizer or any of its Affiliates or any of their respective Personnel, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by Purchaser to third parties in implementing such recall or market withdrawal; and (b) replacing, at Pfizer’s expense, the Product which has to be re

**CNTATIONS & WARRANTIES**

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1. No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party’s obligations hereunder (i) do not conflict with or violate any Laws existing as of the Effective Date, or upon date of Approval, and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party existing as of the Effective Date, or upon date of Approval; and
2. Valid Execution. Such Party is duly authorized to execute and deliver this Agreement, and the Person executing this Agreement on behalf of such Party is duly authorized to execute and bind such Party to the terms set forth herein.
3. Warranties of Pfizer.

Pfizer warrants to Purchaser that:

1. At the time of delivery, the Product (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when Pfizer delivered the Product):
2. complies in a material manner with the relevant Specifications; and
3. has been manufactured in material accordance with current Good Manufacturing Practices.

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1. Subj ect to Pfizer’s disclaimer of non-infringement of Intellectual Property rights of a third party (at Section 5.4(a) and (b) below), it has good title to the Product delivered to Purchaser pursuant to this Agreement and shall pass such title to Purchaser free and clear of any security interests,4rens7mrother encumbrances.
2. The execution, delivery and performance of this Agreement by Pfizer will not violate any agreement or instrument to which Pfizer is a party.
3. Anti-Bribery/Anti-Corruption and Global Trade Controls.
4. The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from another Party or its agents to induce a Party to enter this Agreement or perform any part of this Agreement.
5. Pfizer has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party, candidate for political office, or any other Person, in order to gain an improper business advantage.
6. The Parties will comply with applicable economic sanctions, import, and export control laws, regulations, and orders in the performance of this Agreement.
7. Activities performed under this Agreement will not involve Restricted Parties (defined as the list of sanctioned parties maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; and similar lists of restricted parties maintained by relevant governmental entities).
8. Notwithstanding any other provision of this Agreement, Pfizer shall not be required to take or refrain from taking any action prohibited or penalized under the laws of the United States or any applicable non-United States jurisdiction, including, without limitation, the antiboycott laws administered by the U.S. Commerce and Treasury Departments.
9. No Other Warranty.

Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Laws. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise and to the maximum extent permitted by Law, Pfizer expressly disclaims any representations or warranties with respect to the Product, including, but not limited to, any representation, warranties or undertaking as to (a) non-infringement of Intellectual Property rights of any third party, (b) that there is no requirement to obtain a license of third party Intellectual Property rights to enable the use or receipt of the Product, (c) merchantability, or (d) fitness for a particular purpose.

1. Potvrda Kupca.

 Kupac potvrđuje da se cjepivo i materijali povezani s cjepivom, te njegove komponente i sastavni materijali ubrzano razvijaju zbog hitnih okolnosti pandemije COVID-19 i da će se nastaviti s proučavanjem nakon pružanja cjepiva kupcu prema ovom sporazumu. Kupac nadalje priznaje da dugoročni učinci i djelotvornost cjepiva trenutno nisu poznati te da mogu postojati štetni učinci cjepiva koji trenutno nisu poznati. Nadalje, u mjeri u kojoj je to primjenjivo, Kupac prihvaća da se Proizvod ne smije serijalizirati.

1. **TERM; TERMINATION**.
	1. Term of Agreement.

This Agreement shall commence on the Effective Date and shall continue until delivery of the Contracted Doses of the Product under the accepted Purchase Order, unless extended or terminated pursuant to this Section [6](#bookmark54) (Term; Termination), or the mutual written agreement of the Parties, or pursuant to Section 9.6 (“Term”).

* 1. Prestanak zbog uzroka.
1. Pfizer r može raskinuti ovaj Ugovor odmah nakon pismenog obavještenja Kupca u slučaju značajnog kršenja od strane Kupca bilo koje odredbe ovog Ugovora, koje kršenje ostaje neispravljeno trideset (30) dana nakon pisanog obavještenja Kupca o takvom materijalnom kršenju.
2. Kupac može raskinuti ovaj Ugovor odmah nakon pisanog obavještenja Pfizeru u slučaju značajnog kršenja bilo kojeg odredbe ovog Ugovora od strane Pfizer -a, koje kršenje ostaje neispravljeno trideset (30) dana nakon pisanog obavještenja Pfizer -a o takvom materijalnom kršenju.
3. Bez obzira na gore navedeno, ako se takvo značajno kršenje, po svojoj prirodi, ne može ukloniti, stranka koja ga je prekinula može otkazati Ugovor odmah nakon pisanog obavještenja drugim strankama. U slučaju da Pfizer raskine ovaj Ugovor prema ovom odjeljku 6.2, Kupac će platiti u roku od trideset (30) dana od datuma obavijesti o raskidu ovog Ugovora punu cijenu za sve ugovorene doze umanjene za iznose već plaćene Pfizeru od tog trenutka-datum.
	1. Mutual Termination Rights.
4. In the event: (i) the Product does not obtain Authorization by the EC by June 30, 2021, (ii) Pfizer has supplied to Purchaser no doses of Product by December 31, 2021, subject to the extensions set forth in Section [2.4](#bookmark26) (Delivery Schedule), or (iii) Pfizer is unable to supply all of the Contracted Doses by December 31, 2022, then a Party may terminate this Agreement upon written notice to the other Parties. Purchaser may invoice Pfizer for a refund of fifty percent (50%) of the Advance Payment for the initial 249,795 Contracted Doses not delivered (as determined ratably for the doses not delivered) except for cases where the cause of the termination is mainly or solely attributable to Purchaser. In the event this Agreement is terminated pursuant to this Section 6.3(a), the return of fifty percent (50%) Advance Payment shall be Purchaser’s sole and exclusive remedy for the failure to deliver any Contracted Doses.
5. If the Authorization is received on or before June 30, 2021 but there is insufficient supply to deliver the full number of Contracted Doses by December 31, 2022, fifty percent (50%) of the Advance Payment for the initial 249,795 Contracted Doses not delivered (as determined ratably for the doses not delivered) will be refunded to Purchaser except for cases where such event is mainly or solely attributable to Purchaser. In such case and this Agreement is terminated, the return of Advance

Payment for amounts not delivered shall be Purchaser’s sole and exclusive remedy for the Contracted Doses, or portion thereof, that were not delivered to Purchaser. For absolute clarity, there shall be no refund for the Contracted Doses delivered.

* 1. Termination in Event of Insolvency.

In the event that Pfizer: (a) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; or (b) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; or (c) is dissolved or transfers a substantial portion of its assets to a third party (excluding any of Pfizer’s Affiliates); or (d) has a receiver appointed for the benefit of its creditors, or has a receiver appointed on account of insolvency; then Pfizer shall immediately notify Purchaser of such event and Purchaser shall be entitled to terminate this Agreement.

* 1. Effect of Termination.
1. Upon expiry or termination of this Agreement for any reason:
2. Purchaser shall pay any sums owed to Pfizer pursuant to this Agreement within thirty (30) days of the date of invoice for the same; and
3. each Party shall use Commercially Reasonable Efforts to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this Agreement, and (2) any costs, fees, expenses or losses that may be incurred by a Party, or for which a Party may be responsible, under this Agreement, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.
4. The termination or expiration of this Agreement shall not affect the survival and continuing validity of Sections [2.1(](#bookmark23)b)-(d), [2.5(b),](#bookmark30) [2.6,](#bookmark4) [2.7(](#bookmark5)b)-(e), [2.8,](#bookmark34) [3.1,](#bookmark7) [3.3,](#bookmark38) [3.4,](#bookmark40) [4.4,](#bookmark11) [4.5,](#bookmark46) [4.6,](#bookmark47) [4.7,](#bookmark12) [5.4,](#bookmark52) [5.5,](#bookmark53) [6.2](#bookmark57) (last sentence), [6.5,](#bookmark61) [9.2,](#bookmark76) [9.3,](#bookmark77) [9.4,](#bookmark78) [9.5,](#bookmark79) [9.6,](#bookmark80) and Articles [1,](#bookmark0) [7,](#bookmark62) [8,](#bookmark64) [10,](#bookmark81) [11](#bookmark87) and [12](#bookmark15) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.
5. Expiry or termination of this Agreement for any reason shall be without prejudice to a Party’s other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; provided that (i) Pfizer shall have no liability for any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement and (ii) even if the Product is successfully developed and Pfizer obtains Authorization, Pfizer shall have no liability for any failure to deliver Contracted Doses in accordance with any estimated delivery dates set forth herein.
6. **INTELLECTUAL PROPERTY**.

Pfizer US will be the sole owner of all Intellectual Property it generates during the development, manufacture, and supply of the Product or otherwise related to the Product.

No Party will gain any rights of ownership to or use of any property or Intellectual Property owned by the other Parties (whether by virtue of this Agreement, by implication or otherwise).

1. **INDEMNIFICATION**.
	1. Indemnification by Purchaser. Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing (“Indemnitees”), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys’ fees and other expenses of an investigation or litigation), whether sounding in contract, tort, intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise (collectively, “Losses”) arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine.

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* 1. Assumption of Defense by Purchaser. The Indemnitee(s) shall notify Purchaser of Losses for which it is seeking indemnification pursuant hereto (“Indemnified Claims”). Upon such notification, Purchaser shall promptly assume conduct and control of the defense of such Indemnified Claims on behalf of the Indemnitee with counsel acceptable to Indemnitee(s), whether or not the Indemnified Claim is rightfully brought; provided, however, that Purchaser shall provide advance notice in writing of any proposed compromise or settlement of any Indemnified Claim and in no event may Purchaser compromise or settle any Indemnified Claim without Indemnitee(s)’ s prior written consent, such consent not to be unreasonably withheld. Indemnitee(s) shall reasonably cooperate with Purchaser in the defense of the Indemnified Claims.
	2. Participation Rights. Each Indemnitee shall have the right to retain its own counsel and to participate in Purchaser’s defense of any Indemnified Claim, at its own cost and expense except as set forth below. A failure by the Indemnitee(s) to give notice or timely notice or to offer to tender the defense of the action or suit pursuant to this Section [8.3](#bookmark69) (Participation Rights) shall not limit the obligation of Purchaser under this Section [8](#bookmark64) (Indemnification), except and only to the extent Purchaser is actually prejudiced thereby.
	3. Assumption of Defense. Notwithstanding the foregoing and without prejudice to Section [12.6,](#bookmark95) Pfizer, directly or through any of its Affiliates or through BioNTech, may elect to assume control of the defense of an Indemnified Claim (a) within thirty (30) days of Indemnitee’s notice to Purchaser of the Indemnified Claim or (b) at any time if, in Pfizer’s sole discretion: (i) Purchaser fails to timely assume the defense of or reasonably defend

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such Indemnified Claim(s) in good faith to the satisfaction of Pfizer (or Pfizer’s Affiliates and BioNTech); or (ii) Pfizer believes (or any of Pfizer’s Affiliates or BioNTech believe) in good faith that a bona fide conflict exists between Indemnitee(s) and Purchaser with respect to an Indemnified Claim hereunder. Upon written notice of such election, Pfizer shall have the right to assume control of such defense (directly or through either one of its Affiliates or BioNTech), and Purchaser shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys’ fees and other expenses incurred by Indemnitee(s), in connection with the Indemnified Claim. In all events, Purchaser shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Indemnified Claim.

* 1. Privileges and Immunities. Purchaser acknowledges that its indemnification obligations under this Agreement are (a) expressly in addition to, and not limited by, any Privileges and Immunities, and (b) do not waive or relinquish Indemnitees’ rights to any Privileges and Immunities.
	2. Costs. Costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnitee(s) in connection with any Indemnified Claim shall be reimbursed on a quarterly basis by Purchaser, without prejudice to Purchaser’s right to refund in the event that Purchaser is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnitee(s).
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* 1. Insurance.

During the Term, Pfizer or its Affiliates shall self-insure or procure and maintain such types and amounts of general liability insurance to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general liability insurance shall be without prejudice to Purchaser’s indemnification obligation as set out in this Agreement.

* 1. Limits on Liability.

(a) Subject to the exclusions set forth in Section [9.3,](#bookmark77) in no circumstances shall (i) a Party be liable to the other Parties or its Affiliates, whether arising in tort (including, without limitation, negligence), contract or otherwise, for any indirect, special, consequential, incidental or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise arising out of or relating to this Agreement, the transactions contemplated therein or any breach thereof (whether or not reasonably foreseeable and even if the first Party had been advised of the possibility of another Party incurring such loss or type of loss), and (ii) in the case of Pfizer and its Affiliates, in no event shall Pfizer be liable to Purchaser for any direct damages except to the extent such direct damages were a result of a material breach of a representation or warranty by Pfizer under this Agreement that directly and

were brought directly against Pfizer.

(b) The aggregate liability of Pfizer and its Affiliates (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) arising out of, under or in connection with this Agreement shall not exceed a sum equivalent to one hundred percent (100%) of the total Price actually received by Pfizer under this Agreement for the Contracted Doses.

solely caused the damage. In no instance shall Pfizer and its Affiliates be liable to Purchaser (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) for any liabilities of Purchaser to any third party, including, without limitation, through contribution, indemnity, or for any claim for which Purchaser would have to indemnify Pfizer if that claim

* 1. Excluded Liability.

Nothing in this Agreement excludes or limits the liability of a Party for:

(iv) in the case of Purchaser, failure to pay the Price for the Product or any other sums properly owing to Pfizer under this Agreement.

* 1. Waiver of Sovereign Immunity. Purchaser, on behalf of itself and the Republic of Albania, expressly and irrevocably waives any right of immunity which either it or its assets may have or acquire in the future (whether characterized as sovereign immunity or any other type of immunity) in respect of any arbitration pursuant to Section 12.2 (Arbitration) or any other legal procedure initiated to confirm or enforce any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 (Arbitration), whether in Albania or any other foreign jurisdiction, including but not limited to immunity against service of process, immunity of jurisdiction, or immunity against any judgment rendered by a court or tribunal, immunity against order to enforce the judgment, and immunity against precautionary seizure of any of its assets. Purchaser expressly and irrevocably submits to the jurisdiction of the courts of New York, or any other court of competent jurisdiction, for the purposes of enforcing any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 and represents and warrants that the person signing this Agreement on its behalf has actual authority to submit to such jurisdiction. Purchaser also expressly and irrevocably waives the application of any Law in any jurisdiction that may otherwise limit or cap its obligation to pay damages arising from or in connection with any Indemnified Claims and represents and warrants that this Agreement and any Indemnified Claims arising hereunder are not subject to the Albanian Public Procurement Laws. Purchaser represents and warrants that the person signing this Agreement on its behalf has actual authority to waive such immunity and bind

Purchaser and the Republic of Albania to the limitations of liability and liability waivers set forth herein.

* 1. Conditions Precedent to Supply.

Purchaser represents that it has and will continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its use. Purchaser hereby covenants and acknowledges and agrees that a condition precedent for the supply of the Product hereunder requires that Purchaser shall implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser’s obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement. For clarity, the sufficiency of such statutory or regulatory requirements or funding appropriation shall be in Pfizer’s sole discretion. Purchaser acknowledges that Pfizer’s supply of Product hereunder is in reliance (without any duty of investigation or confirmation by or on behalf of Pfizer or its Affiliates), inter alia, on Purchaser’s representations and covenants under this Section 9.5, Purchaser implementing and maintaining in effect the requirements and funding appropriation described in this Section 9.5 and the other representations and warranties made by Purchaser under this Agreement.

* 1. Condition Precedent. Purchaser further covenants and acknowledges and agrees that a condition precedent to the effectiveness of this Agreement requires that the Normative Act, and the entry into this Agreement thereunder, be ratified by a law of the Albanian parliament in accordance with Albanian law within ten (10) days of the Effective Date (the “Approval”). Purchaser shall notify Pfizer immediately upon issuance of such Approval and provide a copy of such Approval to Pfizer. A true and correct copy of such Approval shall be attached hereto as Attachment J. Purchaser acknowledges that such Approval is a material term of this Agreement and that Pfizer is entering into this Agreement in reliance thereon. In the event that such Approval is not obtained within the time period prescribed above, this Agreement shall automatically terminate. In such event, Pfizer shall have no liability to Purchaser, and Pfizer shall have no obligation to amend, restate, modify or enter into a new agreement with Purchaser for supply of the Product. For clarity, the provisions of Section 6.5 shall apply upon termination of this Agreement pursuant to this Section 9.6.
1. **CONFIDENTIAL INFORMATION**
	1. Non-Use and Non-Disclosure.

Each Recipient shall, and shall cause its Representatives which have access to the Disclosing Party’s Confidential Information to, maintain in strict confidence, and shall not disclose to any third party, all Confidential Information observed by or disclosed to it by or on behalf of the Disclosing Party pursuant to this Agreement. In particular, the

Purchaser shall protect any Confidential Information pursuant to this Agreement on the bases of applicable provisions of public procurement and/or information right Laws in Albania for the protection of confidential information, trade secrets, industrial property rights. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and proprietary nature of the Disclosing Party’s Confidential Information with at least the same degree of care as it holds its own confidential or proprietary information of like kind, which shall be no less than a reasonable degree of care. The Recipient and its Representatives may use, copy, and make extracts of the Disclosing Party’s Confidential Information only in connection with fulfilling its obligations under this Agreement and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the Recipient or any of its Representatives, or for the benefit of any other Person. In the event that Recipient becomes aware of any breach of the obligations contained in this Section [10](#bookmark81) (Confidential Information) by it or its Representatives, Recipient shall promptly notify the Disclosing Party in writing of such breach and all facts known to Recipient regarding same. In addition, if Recipient is required to disclose the Disclosing Party’s Confidential Information in connection with any court order, statute or Government directive or requirement under any Law, Recipient shall give the Disclosing Party notice of such request, as soon as practicable, before such Confidential Information is disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protecthi£J3rderx(r^tHm:remed^Recipient shall promptly cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party’s cost) in such efforts. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, Recipient shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. Neither this Agreement nor the performance by a Party hereunder shall transfer to the Recipient any proprietary right, title, interest or claim in or to any of the Disclosing Party’s Confidential Information (including, but not limited to, any Intellectual Property rights subsisting therein) or be construed as granting a license in its Confidential Information. Notwithstanding the foregoing, in all cases, (a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Product, without the prior written consent of Pfizer, and (b) Pfizer may disclose (i) Confidential Information to its Affiliates and BioNTech without prior written consent of Purchaser, and (ii) upon foreign government request, financial information relating to this Agreement, including cost per dose.

* 1. Recipient Precautions.

In order to comply with the obligations contained in this Section [10](#bookmark81) (Confidential Information), Recipient shall take at least the following precautions: (a) Recipient shall exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) Recipient shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information to fulfill itsobligations under this Agreement; provided, however, before any disclosure of Confidential Information, Recipient shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, Recipient shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Recipient shall be responsible for all actions of its Representatives, including, without limitation, any breach of the terms hereof, regardless of whether or not such Representatives remain employed or in contractual privity with the Recipient.

* 1. Return of Confidential Information.

Upon the written request of the Disclosing Party, Recipient shall promptly return or, at the Recipient’s option, delete or destroy all Confidential Information of the Disclosing Party (including, without limitation, all copies in whatever medium provided to, or made by, such recipient); provided, however, that, subject to the terms of this Agreement, (i) Recipient shall be entitled to retain one archival copy of such Confidential Information for purposes of determining its obligations under this Agreement; and (ii) Recipient shall not be required to destroy any computer files stored securely by the Recipients or its Affiliates that are created during automatic system back up, or retained for legal purposes by the legal division of the Recipient and its Affiliates, provided that such retained Confidential Information shall remain subject to the terms of this Agreement. Notwithstanding Recipient’s return or destruction of Confidential Information, Recipient shall continue to be bound by its obligation of confidentiality and non-use under this Agreement.

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* 1. Survival.

The provisions of this Section [10](#bookmark81) (Confidential Information) shall survive the termination or expiration of the this Agreement for a period of ten (10) years, except with respect to any information that constitutes a trade secret (as defined under Law), in which case the Recipient of such information will continue to be bound by its obligations under this Section [10](#bookmark81) (Confidential Information) for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10)-year period specified above.

1. **NOTICES**

Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (a) when delivered in person, (b) on the next Business Day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (c) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) Business Day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

If to Purchaser:

Institute of Public Health Aleksander Moisiu, nr. 80

Tirana, Albania 1001 Email: ishp@shendetesia.gov.al

If to MOH:

[**Insert Purchaser notice information**]

If to MOR

Insert Purchaser notice information If to Pfizer:

PFIZER EXPORT B .V.

Rivium Westlaan 142, 2909LD Capelle aan den Ijssel,

The Netherlands

Attn: Andrew Richmond

Email: Andrew.Richmond@Pfizer.com

With a copy (which shall not constitute notice) to:

Pfizer SRB d.o.o.

Tresnjinog cveta 1/VI 11070 Novi Beograd Serbia

Attn: Mila Zmic

Email: Mila.Zrnic@Pfizer.com

With a copy (which shall not constitute notice) to:

Pfizer Inc.

235 East 42nd Street New York, NY 10017 Attention: General Counsel ^egal Notice@Pfizer.com

A Party may, by notice to the other Parties, change the addresses and names given above.

**MISCELLANEOUS**

12.

12.1 Negotiations of Dispute.

Prior to commencing any arbitration with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice to the other Parties of the existence of such dispute. The Parties shall for a period of thirty (30) days following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute. If, by the end of such thirty (30) day period, unless such period is extended by mutual written agreement of the Parties, the Parties have been unable to resolve such dispute, a Party may initiate arbitration in accordance with the procedures set forth in Section [12.2](#bookmark91) (Arbitration). The procedures specified in this Section [12.1](#bookmark90) (Negotiations of Dispute) are a precondition to the initiation of arbitration by a Party, in connection with disputes between the Parties arising from or related to this Agreement or a Purchase Order; provided, however, that a Party may seek a preliminary injunction or other preliminary judicial relief, without attempting to resolve such dispute as provided in this Section [12.1](#bookmark90) (Negotiations of Dispute), if in its judgment such action is necessary to avoid irreparable harm. The Parties expressly and irrevocably submit to the jurisdiction of the courts of New York, New York, U.S.A., for any such injunctive relief. Further, the requirement to attempt to resolve a dispute in accordance with this Section [12.1](#bookmark90) (Negotiations of Dispute) does not affect a Party’s right to terminate this Agreement as

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provided in Section [6](#bookmark54) hereof, and a Party shall not be required to follow these procedures prior to terminating the Agreement. The failure of a Party to participate in good faith discussions and negotiations in an attempt to resolve such dispute shall not delay the date by which another Party may initiate arbitration under this Section [12.1](#bookmark90) (Negotiations of Dispute).

1. Arbitration.

Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof, or relating to arbitrability or the scope and application of this Section [12.2](#bookmark91) (Arbitration), shall be finally resolved by arbitration. The arbitration shall be conducted by three arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce (“ICC”). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator, in consultation with the Parties, within thirty (30) days after the confirmation of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the ICC shall appoint the arbitrator(s). The seat of the arbitration shall be New York, New York, U.S.A. and it shall be conducted in the English language. . The Parties undertake to maintain confidentiality as to the existence of the arbitration proceedings and as to all submissions, correspondence and evidence relating to the arbitration proceedings. This provision shall survive the termination of the arbitral proceedings. The costs of the arbitration, including, without limitation, the Parties’ reasonable legal fees, shall be borne by the unsuccessful Party or Parties. However, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on tl^PailmSr^ftdYhF^arti^s undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.

1. Purchasers Obligations.

MOH, MOR and IPH are defined collectively herein as Purchaser; provided, however, that any references herein to “Purchaser”, or similar references, shall be construed as a reference to each MOH, MOR and IPH. MOH, MOR and IPH shall be jointly and severally liable for all of the obligations of Purchaser under this Agreement. Each of MOH, MOR and IPH, individually, hereby acknowledge and agree that all of the representations, warranties, covenants, obligations, conditions, agreements and other terms contained in this Agreement shall be applicable to and shall be binding upon and measured and enforceable individually against each of MOH,MOR and IPH.

1. Publicity.

A Party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other Parties in publicity releases, advertising or any other publication, without the other Parties’ prior written consent in each instance.

1. Governing Law.

All disputes shall be governed by the Laws of the State of New York, USA, without regard to conflict of Law principles other than Section 5-1401 of the New York General Obligations Law, except that any dispute regarding the arbitrability or the scope and application of this Section shall be governed by the Federal Arbitration Act of the United States.

1. Third Party Rights.
2. Purchaser agrees the applicable rights granted or provided to Pfizer under this Agreement are also granted or provided to Pfizer’s Affiliates or to BioNTech to the extent that those rights relate to such Affiliates or BioNTech, including but not limited to the indemnification in Section 8(a) (each a “Third Party Beneficiary” and together the “Third Party Beneficiaries”). Each Third Party Beneficiary shall be entitled to enforce the terms of this Agreement; provided that, to the extent permissible by Law and where reasonably practicable, any claims, demands or actions from any Third Party Beneficiary shall be brought by Pfizer itself on behalf of the relevant Third Party Beneficiary.
3. Any Losses suffered by a Third Party Beneficiary will not be treated as being indirect solely because it has been suffered by a Third Party Beneficiary and not by

fizer directly.

1. Relationship of the Parties.

**I**

The relationship hereby established between Purchaser and Pfizer is solely that of independent contractors. No Party has authority to act or make any agreements or representations on behalf of the other Parties. This Agreement is not intended to create, and shall not be construed as creating, between Pfizer and Purchaser, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

1. Assignment; Binding Effect.

Neither Purchaser nor Pfizer shall assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement without the prior written consent of the other Parties, which may be withheld at such Party’s discretion, provided that Pfizer, without Purchaser’s consent, may assign, delegate or subcontract any of its duties and obligations under this Agreement to an Affiliate of Pfizer, BioNTech or an Affiliate of BioNTech. Any such attempted assignment of rights or delegation or subcontracting of duties without the required prior written consent of the other Parties shall be void and ineffective. Any such assignment, delegation or subcontracting consented to by a Party in writing shall not relieve the other Parties of their responsibilities and liabilities hereunder and such assigning Party shall remain liable to other Parties for the conduct and performance of each permitted assignee, delegate and subcontractor hereunder. This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto andtheir respective successors and permitted assigns. The Parties agree that this Agreement is not intended by a Party to give any benefits, rights, privileges, actions or remedies to any Person or entity, partnership, firm or corporation as a Third Party Beneficiary or otherwise under any theory of Law.

Force Majeure.

12.9

12.10

12.11

12.12

12.13

Each Party shall not be liable for any failure to perform or any delays in performance, and each Party shall not be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including, without limitation, such causes as acts of God, natural disasters, flood, severe storm, earthquake, civil disturbance, lockout, riot, embargo, acts of Government (other than Purchaser), war (whether or not declared), acts of terrorism, the impact on a Party of an outbreak of any disease or an epidemic or pandemic or other similar causes (“Force Majeure Event”). Failure or inability to pay shall not be a basis for a Force Majeure Event under this Agreement. In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Parties and shall use Commercially Reasonable Efforts to avoid or minimize the delay.

Severability.

If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Agreement shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace any unenforceable provision of this Agreement with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.

Non-Waiver: Remedies.



A waiver by any Party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this Agreement shall be cumulative and in addition to any other remedies provided at Law or in equity.

Further Documents.

Each Party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this Agreement.

Forms.

The Parties recognize that, during the Term, a Purchase Order acknowledgment form or similar routine document (collectively, “Forms”) may be used to implement or administer provisions of this Agreement. The Parties agree that the terms of this Agreement shall prevail in the event of any conflict between terms of this Agreement and the terms of such

Forms, and any additional or different terms contained in such Forms shall not apply to this Agreement.

1. Headings.

Headings of Sections or other parts of this Agreement are included herein for convenience of reference only and shall not constitute a part of this Agreement or change the meaning of this Agreement.

1. Counterparts.

This Agreement may be executed in three or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, and shall become effective when signed by all of the Parties hereto and delivered to the other Parties in accordance with the means set forth in Section [11](#bookmark87) (Notices) or by reliable electronic means (with receipt electronically confirmed).

1. Electronic Delivery and Storage.

Delivery of a signed Agreement by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed Agreement. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights or obligations of the Parties to this Agreement.

1. Entire Agreement; Amendments.

This Agreement, together with any attachments and amendments (and as such attachments may be amended, amended and restated or replaced from time to time), which are hereby incorporated by reference, constitute the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto. Except as otherwise set out herein; no modification or alteration of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto.

1. Rule of Construction.

The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

1. English Language.

This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into

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any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

1. Legal Costs.

Each Party will bear its own legal costs in preparing and concluding this Agreement.



IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

PFIZER EXPORT B.V.

**ALBANIA MINISTRY OF HEALTH AND SOCIAL PROTECTION**

By:

Name:

Title:

Date:

By:

Name:

Title:

Date:

AGREED AND ACKNOWLEDGED by MINISTEROF STATE FOR RECONSTRUCTION

By:—

Name:

Title:

[To be inserted following the Effective Date (and in any event before supply in line with the agreed Delivery Schedule)]



|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SupplyPeriod | January 2021 | February2021 | Q3 -Q4 2021 |  | Total |
| Doses | 10,530 | 30,420 | 458,640 |  | 499,590 |
| Price per dose | USD 12 | USD 12 | USD 12 |  |  |



Attachment C- Delivery Documentation **Documentation and Delivery Notes**

**Thermal Shipper Documentation**

It is currently envisaged that the following will be provided with each shipment of the Products:

1. Emergency Use Authorization (EUA) Fact Sheets/Leaflets - Five (5) fact sheets folded 3x2" in a plastic bag
2. Pfizer Brochure - One (1) per thermal shipper container containing product storage and handling information including:
* Dry Ice Handling Insert
* Safety Data Sheet (SDS) for Dry Ice
* Return instructions for GPS loggers and thermal shipping system
* A stand-alone SDS for Dry Ice
* Blank label - purpose of the blank label: for carriers to mark out the dry ice label to indicate that the thermal shipper containers are empty (not containing dry ice)
1. Return Shipping Label - One (1)
2. Outbound Shipping Label - One (1), standard label on thermal shipper
3. Contents Label - One (1) label on inside flap, picking label details how many carton trays are in thermal shipper

**Proof of Delivery Documentation**

Currently, Pfizer intends to use the carrier delivery signal as proof of <

Proof of dehvery docunifint-thatxairhFaccessed online based on track and trace number. See UPS example\* below:



\*The above proof of delivery image is an example only.

Product Delivery, Storage & Handling Specifications

Shipments will arrive in a long-distance thermal shipping container as provided by Pfizer in accordance with the Labelling and Packaging Specifications set forth in Attachment E (“Thermal Shipper”). At this time, the minimum package in any shipment shall be one (1) tray with 195 vials or 1170 doses of Product.

Purchaser ensures that at the expected time of arrival at the Place(s) of Destination, a dedicated person will be available to receive the Product, sign acceptance for delivery, and, immediately, no later than 24 hours of delivery, switch off the temperature logger located in the Thermal Shipper, and:

1. transfer the Product to:
2. a -75 °C (+/- 15 °C) ultra-low temperature (“ULT”) freezer; or
3. a 2-8 °C refrigerator; or
4. maintain the Product with sufficient supply of dry ice in accordance with the protocols for re-icing set forth below with such initial re-icing to occur no later than hours from signature of acceptance of delivery.

Purchase

ges the following stability timelines as of the Effective Date:

The Product has a shelf-life of up to 6 months when stored at a constant -75 °C (+/- 15 °C)

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The Thermal Shipper can be used as temporary storage for up to 30 days, as long as dry ice is replenished upon receipt and at least every five (5) days per Pfizer’s guidelines.

The Product has an effective life of up to 5 days when stored at refrigerator temperatures 2-8°C

OnceAhejhiHiuGt4s-tl^^ and reconstituted it can be retained for up to 6 hours at

standard ambient room temperatures (19-25°C)

Any further shipment or distribution of the Product by Purchaser from the Place(s) of Destination shall be through a certified shipping service, or use of its own logistics system, that will ensure next day delivery from the Place(s) of Destination to point of use of the Product; and Purchaser shall be liable for ensuring continual compliance with the cold chain requirements for any further distribution following delivery to a Place of Destination that is not a point of use of the Product. In all cases, Purchaser shall ensure that all Product is transported in (a) the Thermal Shipper with re-icing performed in accordance with the Protocols for re-icing set forth below, or (b) an alternate shipper purchaser by Purchaser, in each case in a manner to maintain the temperature requirements set forth herein. All costs associated with receiving, handling, storing and further delivery of the Product shall be the responsibility of Purchaser, and Purchaser shall ensure that all locations where any Product is delivered by, or on behalf of Purchaser, shall comply with the requirements set forth in this Attachment D and shall meet the standards set forth herein.

Protocols for Unpacking Product and Re-icing: See Exhibits 1 and 2 of Attachment D Requirements of Delivery Location:

1. EUA, Pre-approval, Post-approval vaccination points with -75 oC (+/- 15 oC) ULT freezer
2. EUA, Pre-approval, Post-approval vaccination points with sufficient access and supply of dry-ice
3. EUA, Pre-approval, Post-approval vaccination points with 2-8oC refrigerator





**Attachment D - Delivery Specification**

***Exhibit 1 — Unpacking and Re-icing: Thermal Shipper A***

Attachment D - Delivery Specification

Exhibit 2 - Unpacking and Re-icing: Thermal Shipper B

**Vaccine Preparation & Administration Instructions** Removing the Vials to Thaw

* From storage, remove 1 vial for every 6 recipients according to planned vaccinations schedule.
* Vials may be stored in the refrigerator for 5 days (120 hours).

Diluting the Vaccine

* Obtain 0.9% Sodium Chloride Injection, for use as a diluent. Do not use any alternate diluents.
* Dilute the thawed vial by adding 1.8 mL of 0.9% Sodium Chloride Injection into the vial.
* Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.

**Preparing the Dose**

Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.

For each additionajjIaseT-ase-^TlCTCitenle syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

Vaccine **Administration**

Diluted vials must be used within 6 hours from the time of dilution and stored between 2-25 °C (35-77°F).

A single 30 mcg/0.3 mL dose is followed by a second dose 21 days later.

Attachment E - Labelling and Packaging Specifications **Product Labelling Specifications**

Product labels for primary, secondary and tertiary packaging will be shared closer to country regulatory filings.

It is currently envisaged that the following will be part of the initial product artwork: Primary Packaging (Vial):

Linear barcode: Scans as the Global Trade Item Number (GTIN) that includes the human- readable National Drug Code (NDC) number.

**Secondary Packaging (Carton Tray):**

* Linear barcode: Scans as the GTIN number that includes the human-readable NDC number.
* QR code: When scanned, this code links to a landing page where a copy of the Fact Sheets for the Healthcare Provider, patient/recipient, and Emergency Use Authorization Product Insert (i.e. e- leaflet) will be available.
* 2D GS1 DataMatrix: Scan of the 2D code will include the GTIN number, lot and expiry information.

**Product Packaging Specifications Primary Packaging**

* 2 mL type 1 glass preservative free multi-dose vial (MDV)
* MDV has 0.45 mL frozen liquid drug product
* 6 doses per vial

**Secondary Packaging “Single Tray”**

* Single tray holds 195 vials
* 1170 doses per tray
* Tray (white box) dimensions: 229 X 229

x 40 mm

Tertiary **Container: Thermal Shipper (Softbox)**

* Minimum 1 tray (1170 doses) or up to 5 trays (max 5850) stacked in a payload area of the

shipper

* Payload carton submerged in 23 Kg of dry ice pellets (9 mm - 16 mm pellets)
* Thermal shipper dimensions:

o Internal Dimensions: 245mm X 245mm X 241mm o External Dimensions: 400mm X 400mm X 560mm

A. Return

“Logistics Delivery Equipment” refers to the long-distance thermal shipping container (“Thermal Shipper”) used for shipping and the temperature data logger/monitoring device attached to such Thermal Shipper.

Once dry ice is no longer needed, open the Logistics Delivery Equipment and leave it at room temperature in a well-ventilated area. The dry ice will readily sublime from a solid to a gas. DO NOT leave dry ice unattended.

Store the empty Logistics Delivery Equipment until return in an appropriate clean and secure location to protect and maintain the functionality of the equipment (e.g., do not store outside under uncontrolled conditions, exposed to weather, exposed to pests, etc.).

Return of the Logistics Delivery Equipment to be undertaken within 30 days following delivery of the Product at the Place(s) of Destination. Instructions and logistics for return will be provided on the interior of the Thermal Shipper and will also be available on Pfizer’s website. In the event that either: (a) the Logistics Delivery Equipment (or any part thereof), is not (i) delivered to the return carrier within 30 days following delivery of the Product or (ii) received by Pfizer within five (5) days following the date of Purchaser’s return shipmentof^uch-iegistrcs'^ehvery Equipment; or (b) the Logistics Delivery Equipment (or any part thereof), is damaged in any way (determined in Pfizer’s sole discretion), Pfizer shall be entitled to charge Purchaser $450 (exclusive of VAT) per Thermal Shipper and temperature data logger/monitoring device; which Purchaser shall pay within 30 days of the date of any invoice for such amount(s). Purchaser acknowledges that such amount represents a reasonable pre-estimate of replacement cost such Logistics Delivery Equipment as a result of Purchaser’s default, act or omission.

B. **Disposal**

refers to the vials that contain the Product.

Destruction of the Primary Container Units that have been opened or are unused must take place at a facility appropriately licensed to handle and destroy pharmaceutical waste, medical waste, and/or hazardous waste, and destruction must be by means of grinding or incineration.

“Secondary Cartons” refers to the immediate boxes that contain the vials of Product.

Secondary Cartons must be defaced and destroyed in accordance with local clinical dosing facility waste management services, and Secondary Cartons may not be disposed of in routine household waste collection or recycling centers.

[To be inserted following the Effective Date (and in any event before supply in line with the agreed Delivery Schedule)]



Attachment H- Customs Clearance Documentation and waivers PART 1

SAMPLE

1. Shipping Document/Airway Bill “AWB”
2. Commercial Invoice
3. Packing List
4. Copy of the Certificate of Origin
5. Copy of the Certificate of Analysis “COA”
6. Copy of Export Declaration.

During the Term of the Agreement:

• Any other documents not included in the above-mentioned list of documents, including but not limited to import permits, will be waived by the Purchaser or any other Government authority.

legalization and/or certification of the above-mentioned list of /aived by the Purchaser or any other Government authority.

Any notarization, document

Any required analysis to release any of the shipments upon arrival at the Point of Delivery will be waived by the Purchaser or any other Government authority.

Any other documents not included in the global Pfizer dossier for Pfizer BioNTech Covid 19 Vaccine registration, will be waived by the Purchaser or any other Government authority.

Any notarization, legalization and/or certification of the documents required for issuing the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. GMPs, CPP, etc).

Any required analysis to issue the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. registration samples and reference standards).





**Attachment J - Approval and Ratification of Agreement by Law of Parliament of Normative Act**

1. Note to Draft: To include quality/diversion notice contact information.

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Mutual Representations and Warranties. Pfizer and Purchaser each represents and warrants to each other the following:

(a) Organization and Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, including, in the case of Purchaser, that all necessary authorizations and approvals havebeenj3btained byTrurchaser to authorize entering into this Agreement and its performance of all of its obligations contained herein, that Purchaser is entering into this Agreement pursuant to the Normative Act of the Albanian Council of Ministers no. 38 dated December 31, 2020 “On the approval of agreement for the manufacturing and supply by and between Pfizer Export B.V. and the Ministry of Health and Social Protection, Minister of State for Reconstruction and the Institute of Public Health, and the authorization of procedure for the anticovid-19 vaccination of the population”, a true and correct copy of which is attached hereto as Appendix H (the “Normative Act”), that this Agreement is exempt from the application of all Albanian Public Procurement Laws and each of the terms and conditions of this Agreement are fully enforceable, that the budgetary allocation set forth in Article 4 of the Normative Act in no respect limits Purchaser’s funding or other obligations under this Agreement, including the indemnification obligations set forth in Article 8, that Purchaser has the authority to bind the Republic of Albania and that Purchaser has exercised that authority to bind the Republic of Albania as to each of the provisions and terms and conditions set forth in this Agreement; [↑](#footnote-ref-1)