

**EUROPEAN COMMISSION**

Directorate-General for Health and Food Safety


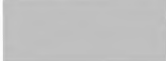

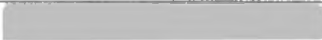







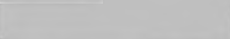



SENSITIVE**RELEASABLE TO: Need to know basis*

FRAMEWORK CONTRACT

for the supply of Veklury (remdesivir) for the treatment of COVID-19 patients requiring supplemental oxygen

NUMBER – SANTE/2020/C3/048

1. The European Union ('the Union'), represented by the European Commission ('the contracting authority'), represented for the purposes of signing this framework contract by Ms Sandra GALLINA, Acting Director-General for Health and Food Safety, and the following contracting authorities:

Contracting authority	Representative for the purposes of signing this framework contract
Kingdom of Belgium (BE)	Frank Vandenbroucke, Deputy Prime Minister and Minister of Social Affairs and Health , Ministry of Social Affairs and Health
Republic of Bulgaria (BG)	Ministry of Health - Prof. Dr. Kostadin Angelov, MD, Minister of Health
Republic of Cyprus (CY)	Ministry of Health -   
Czech Republic (CZ)	Ministry of Health of the Czech Republic - Roman Prymula, Minister of Health
Kingdom of Denmark (DK)	Amgros I/S - 
Republic of Estonia (EE)	Health Board, 
Federal Republic of Germany (DE)	Bundesministerium für Gesundheit -   Federal Ministry of Health
Hellenic Republic (EL)	Institute for Pharmaceutical Research and Technology (IFET S.A) 
Kingdom of Spain (ES)	INGESA (Instituto de Gestion Sanitaria) -     Ministerio de Sanidad 
Republic of Finland (FI)	The Finnish Institute of Health and Welfare,  

French Republic (FR)	Santé publique France - [REDACTED] [REDACTED]@santepubliquefrance.fr
Republic of Croatia (HR)	“Dr. Fran Mihaljevic” University Hospital for Infectious Diseases, [REDACTED]
Republic of Hungary (HU)	National Healthcare Service Center - [REDACTED]
Republic of Ireland (IE)	Health Service Executive, [REDACTED]
Italian Republic (IT)	[REDACTED] COVID-19 Emergency - [REDACTED]
Republic of Latvia (LV)	SIA Riga East University Hospital - [REDACTED]
Republic of Lithuania (LT)	Health Emergency Situations Centre of the Ministry of Health - [REDACTED]
Grand Duchy of Luxembourg (LU)	Ministry of Health - Ms Paulette Lenert, Minister of Health
Republic of Malta (MT)	Ministry of Health. Central Procurement and Supplies Unit, [REDACTED]
Kingdom of the Netherlands (NL)	Ministry of Health, Welfare and Sports, Dr. E. Gerritsen, Secretary General
Republic of Austria (AT)	Federal Ministry Republic of Austria Social Affairs, Health, Care and Consumer Protection [REDACTED]
Republic of Poland (PL)	Ministry of Health of the Republic of Poland — Waldemar Kraska, Secretary of State, Ministry of Health
Portuguese Republic (PT)	Direção-Geral da Saúde - [REDACTED]
Romania (RO)	Ministry of Health, Nelu Tataru Minister of Health
Slovak Republic (SK)	Ministry of Health, Marek Krajčí, Minister of Health
Republic of Slovenia (SI)	University Medical Centre Ljubljana (UMCL), [REDACTED]
Kingdom of Sweden (SE)	National Board of Health and Welfare - [REDACTED]
Republic of Iceland (IS)	The National University Hospital of Iceland - [REDACTED]
Kingdom of Norway (NO)	South-Eastern Norway Regional Health Authority - [REDACTED]
United Kingdom of Great Britain and Northern Ireland (UK)	The Secretary of State for Health and Social Care; [REDACTED] Vaccines & Countermeasures Response, Public Health England; [REDACTED] Public Health England
Montenegro (ME)	Ministry of Health, Mr Kenan Hrapović, Minister of

	Health
Republic of North Macedonia (MK)	Ministry of Health Skopje- Dr. Venko Filipche, Minister of Health
Republic of Albania (AL)	Ministry of Health, Ms Ogerta Manastirliu, Minister of Health
Bosnia and Herzegovina (BiH)	Council of Ministers of Bosnia and Herzegovina -Ms Ankica Gudeljević, Minister, Ministry of Civil Affairs
Republic of Serbia (RS)	Institute of Public Health of Serbia "Dr Milan Jovanovic Batut" - [REDACTED]
Kosovo¹	Ministry of Health; [REDACTED]

all the above contracting authorities being represented for the purposes of the signature of this framework contract by Ms Sandra GALLINA, Acting Director-General of the European Commission's Directorate-General for Health and Food Safety,

of the one part and

2. Gilead Sciences Ireland UC

ULC – Private Unlimited Company

Statutory registration number: 259755

IDA Business and Technology Park, Carrigtohill, County Cork, Ireland

VAT registration number IE8259755V

appointed as the leader of the group by the members of the group that submitted the joint tender

3. Gilead Sciences Limited

Limited Liability Private Company

Statutory registration number: 02543818

280 High Holborn, London WC1V 7EE, United Kingdom

VAT registration number: GB792402037

4. Gilead Sciences GesmbH

Limited liability company

Statutory registration number: 278577 y

Wagramer Straße 19, 1220 Vienna, Austria

VAT registration number: ATU62732635

5. Gilead Sciences Belgium BV

besloten vennootschap (bv/srl)

Statutory registration number: BE 0882.565.584

Culliganlaan 2D - 1831 Diegem

VAT number: BE 0882.565.584

6. Gilead Sciences s.r.o

Limited Liability Company

Statutory registration number: 24268551

Na strži 1702/65, Nusle, 140 00 Praha 4, Czech Republic

VAT number: CZ24268551

7. Gilead Sciences Denmark ApS

ApS

Statutory registration number: 30899032

Arne Jacobsens Alle 7, DK - 2300 Copenhagen S, DENMARK

VAT number: DK3089903

8. Gilead Sciences Finland Oy

Oy

Statutory registration number: 2151739-1

Karhumäentie 3, 01530 Vantaa, FINLAND

VAT number: FI21517391

9. Gilead Sciences GmbH

Gesellschaft mit beschraenkter Haftung

Statutory registration number: HRB119375

Fraunhoferstr.17, 82152 Martinsried

VAT number: DE 153 708 711

10. Gilead Sciences Hellas EPE / SPLTD

SINGLE PERSON LIMITED LIABILITY COMPANY

Statutory registration number: 4304401000

2 RIZOUNTOS & THRAKIS 16 7 77 HELLINIKON

VAT number: 099989853

11. Gilead Sciences S.r.l

Contract number: SANTE/2020/C3/048

FWC conditions of December 2018

Societa a responsabilita limitata

Statutory registration number: 11187430159

Via Melchiorre Gioia 26, 20124 Milan, Italy

VAT number: 11187430159

12. Gilead Sciences Netherlands BV

Besloten Vennootschap (private entity)

Statutory registration number: 34249498

Claude Debussylaan 22, 1082 MD Amsterdam

VAT number: 815897996B01

13. Gilead Sciences Norway AS

AS

Statutory registration number: 991 461 841

C.J. Hambros Plass 2 C, 0164 Oslo, NORWAY

VAT number: 991461841

14. Gilead Sciences Poland sp.zo.o

spółka z ograniczoną odpowiedzialnością (ang. limited liability company)

Statutory registration number: 0000350550

Warszawa (02-676), Postępu 17A St.

VAT number: 1070015800

15. Gilead Sciences, Lda

Limited liability company

Statutory registration number: 503604704

Atrium Saldanha, Praça Duque de Saldanha, nº 1, 8º A e B, 1050-094, Lisbon, Portugal

VAT number: 503604704

16. Gilead Sciences Slovakia s.r.o

Limited Liability company

Statutory registration number: 47868520

Laurinská 18, Bratislava - mestská časť Staré Mesto 811 01, Slovak Republic

VAT number: 2024162393

17. Gilead Sciences S.L.U.

SOCIEDAD DE RESPONSABILIDAD LIMITADA UNIPERSONAL

Statutory registration number: M-122.181

Contract number: SANTE/2020/C3/048

FWC conditions of December 2018

PARQUE EMPRESARIAL CRISTALIA, EDIFICIO 7/8, PLANTA 6ª. C/ VÍA DE LOS POBLADOS Nº3. 28033. MADRID

VAT number: B-80754799

18. Gilead Sciences Sweden AB

AB

Statutory registration number: 556726 – 7769

Hemvarnsgatan 9, SE-171 54 Solna, Sweden

VAT number: SE556726776901

19. Gilead Sciences SAS

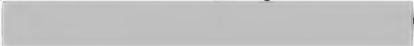
SOCIETE PAR ACTIONS SIMPLIFIEE

Statutory registration number: Nuttier() SIREN 391 360 971

RCS Nanterre- APE 4646Z

65 Quai George Gorse 92100 BOULOGNE BILLANCOURT

VAT number: FR 663 913 609 71

(collectively ‘the contractor’), represented for the purposes of the signature of this framework contract by  Gilead Sciences Ireland UC

on the other part

HAVE AGREED

to the **special conditions**, the **general conditions for framework contracts** for supplies and the following annexes:

Annex I Tender specifications SANTE/2020/C3/048 (reference Ares(2020)4767656)

- Part 1: Administrative specifications
- Part 2: Technical specifications

Annex II Contractor's tender SANTE/2020/C3/048 (reference

Ares(2020)5131420, Ares(2020)5001139, Ares(2020)4894194, Ares(2020)4894246, Ares(2020)4894265, Ares(2020)4894271, Ares(2020)4894164, Ares(2020)4894213, Ares(2020)4894229, Ares(2020)4894301, Ares(2020)4894289, Ares(2020)4894320, Ares(2020)4894346, Ares(2020)4894367, Ares(2020)4894334, Ares(2020)4894386, Ares(2020)4894397, Ares(2020)4894414, Ares(2020)4894427, Ares(2020)4894432, Ares(2020)4894446, Ares(2020)4894456, Ares(2020)4894465, Ares(2020)4894472, Ares(2020)5184634, Ares(2020)5182997, Ares(2020)5132867, Ares(2020)5131849, Ares(2020)5131269, Ares(2020)5131394 Ares(2020)5091386, Ares(2020)5091477, Ares(2020)5076506, Ares(2020)5071637 Ares(2020)5071654, Ares(2020)5028270, Ares(2020)5032681, Ares(2020)5076512, financial form and Power of Attorneys (attached)

Annex III Model for specific contracts

which form an integral part of this framework contract (the 'FWC').

This FWC sets out:

1. the procedure by which the contracting authority may order supplies from the contractor;
2. the provisions that apply to any specific contract which the contracting authority and the contractor may conclude under this FWC; and
3. the obligations of the parties during and after the duration of this FWC.

All documents issued by the contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this FWC. In all circumstances, in the event of contradiction between this FWC and documents issued by the contractor, this FWC prevails, regardless of any provision to the contrary in the contractor's documents.

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I. SPECIAL CONDITIONS

I.1. ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this FWC, the following rules must be applied:

The provisions set out in the special conditions take precedence over those in the other parts of the FWC.

The provisions set out in the general conditions take precedence over those in the specific contract (Annex III).

The provisions set out in the specific contract (Annex III) take precedence over those in the other annexes.

The provisions set out in the tender specifications (Annex I) take precedence over those in the tender (Annex II).

The provisions set out in the FWC take precedence over those in the specific contracts.

I.2. SUBJECT MATTER

The subject matter of the FWC is the supply of up to 3 000 000 vials of Veklury (remdesivir) for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen.



The delivery schedule during any renewal term will be mutually agreed to by the parties.



Veklury supplied under this contract will be labelled in accordance with the applicable EU legislation. The contractor may confirm with Member States whether full or partial exemptions apply to the obligation that the labelling and the package leaflet must be in the official language(s) as per Article 63(3) of Directive 2001/83/EC.

The contractor agrees to use commercially reasonable efforts to deliver, upon request, the full amount of supplies based on the agreed delivery schedule.

The contractor does not guarantee hereunder that it will have sufficient amounts of Veklury to meet demand, and nothing in this contract shall be interpreted as providing such guarantee. The contractor will supply Veklury once per calendar month.

The allocation of vials to the contracting authorities will be determined according to Article I.10.

The offer submitted by the contractor in the tender and the supply of Veklury in compliance with this contract will be conditional upon the ability of Veklury to be exported out of the United States by law, regulation or executive direction or decree. Should Veklury be in such situation, the contractor will not be liable for any delay or failure to comply with its obligations under the tender and this contract.

I.3. ENTRY INTO FORCE AND DURATION OF THE FWC

I.3.1 The FWC enters into force on the date on which the last party signs it.

I.3.2 The *implementation of the FWC* cannot start before its entry into force.

I.3.3 The FWC is concluded for a period of 6 months with effect from the date of its entry into force.

I.3.4 The parties must sign any specific contract before the FWC expires.

The FWC continues to apply to such specific contracts after its expiry. The supplies relating to such specific contracts must be delivered no later than three months after its expiry.

I.3.5 Renewal of the FWC

The FWC is renewed automatically two times for 6 months each, unless one of the parties receives *formal notification* to the contrary at least 1 month before the end of the ongoing duration. Renewal does not change or postpone any existing obligations.

I.4. APPOINTMENT OF THE CONTRACTOR AND IMPLEMENTATION OF THE FWC

I.4.1. Appointment of the contractor

The contracting authority appoints the contractor for a single FWC.

I.4.2. Period of provision of the supplies

The period for the provision of the supplies starts to run from the date indicated in the specific contract.

I.4.3. Implementation of single FWC

This FWC shall be implemented by specific contracts between contracting authorities in participating countries and the contractor. Specific contracts shall be awarded on the basis of the terms laid down in this FWC, refined or, in duly justified circumstances, supplemented to reflect the particular circumstances of the specific contract, in compliance with the terms of the FWC. The net price charged for Veklury without VAT supplied under a specific contract must reflect the price stated in the FWC, without application of additional charges or further discounts. Specific contracts signed by the contracting authority and the contractor shall include a binding commitment on the contracting authority to purchase and the contractor to sell agreed numbers of vials of Veklury.

The contracting authorities order supplies by sending the contractor a specific contract to be signed (following the model available in Annex III) by e-mail. Within 5 days (unless agreed differently by the contracting parties in writing) following the reception of the specific contract by e-mail, the contractor must either:

- send back to the contracting authority the specific contract duly signed and dated in paper format and an advanced scanned copy by e-mail; or
- send an explanation of why it cannot accept the order.

Within 10 calendar days following the reception of the signed specific contract in paper format (unless agreed differently by the contracting parties in writing) the contracting authority shall sign it and return one copy to the contractor or send an explanation of why it cannot sign it.

If the contractor repeatedly refuses to sign the specific contracts or repeatedly fails to send them back on time, the contractor may be considered in breach of its obligations under this FWC as set out in Article II.17.1 (c).

I.4.4. Delivery

The supplies must be delivered at the locations in the participating countries as stated in specific contracts between the relevant contracting authority and the contractor or as otherwise indicated in writing by the contracting authority to the contractor during the performance of the contract (Delivered Duty Paid; Incoterms® 2020).²

The contractor must notify the contracting authority of the exact date of delivery at least 5 days in advance. Deliveries may be made on any working day during normal working hours, at the agreed place of delivery.

² These terms are for sale on the website <http://www.iccwbo.org/incoterms/>

I.5. PRICES

I.5.1. Maximum amount of the FWC and maximum prices

The maximum amount covering all purchases under this FWC including all renewals and a reserve of 10% is EUR 3,415,500,000 (three billion, four hundred and fifteen million five hundred thousand). For clarity, the contractor has no obligation to provide more supplies than 9,000,000 vials over the duration of the FWC including all renewals, unless mutually agreed to.

However, this does not bind the contracting authority to purchase for the maximum amount.

The net price of the supplies is per unit (vial) without VAT EUR 345 (three hundred and forty five). The net price charged for Veklury without VAT supplied under a specific contract must reflect the price stated in the FWC, without application of additional charges or further discounts.

I.5.2. Price revision index

Price revision is not applicable to this FWC.

I.5.3. International reference pricing

To the extent possible, the Parties will ensure that the terms and conditions in this contract will not be used for the purposes of international reference pricing.

I.6. PAYMENT ARRANGEMENTS

I.6.1. Pre-financing

Pre-financing is not applicable to this FWC.

I.6.2. Interim payments

1. The contractor (represented by the leader of the group or by a group member) may claim for each delivery instalment under a specific contract an interim payment corresponding to the quantity of supplies delivered in accordance with Article II.20.6.

The contractor (represented by the leader of the group or by a group member) must send an invoice in paper format or by electronic mail, depending on the requirements of the contracting authority, for the interim payment, to the address specified in the specific contract, accompanied by the following:

- Proof of delivery of the supplies referred to in Article I.2, to the delivery place mentioned in the specific contract,
- Consignment note(s) as set out in point 1.2 of Technical specifications (Annex I, Part 2).
- Certificate(s) of conformity signed by the contracting authority in accordance with Article II.4.10.

Each invoice must contain the following information:

- Name of contracting authority,
- FWC and specific contract number,

- Order reference,
- Product delivered,
- Quantity delivered,
- Delivery reference and date,
- Contractor name and bank account.

2. The contracting authority must approve any submitted documents or supplies and pay within 60 days from receipt of the invoice.

3. The contracting authority may suspend the time limit for payment specified in point (2.) in accordance with Article II.20.7. Once the suspension is lifted, the contracting authority shall give its approval and pay within the remainder of the time-limit indicated in point (2.) unless it rejects partially or fully the submitted documents or supplies.

I.6.3. Payment of the balance

1. The contractor (represented by the leader of the group or by a group member) may claim the payment of the balance in accordance with Article II.20.6.

The contractor (represented by the leader of the group or by a group member) must send an invoice in paper format or by electronic mail, depending on the requirements of the contracting authority, for payment of the balance due under a specific contract, to the address specified in the specific contract and accompanied by the following:

- Proof of delivery of the supplies referred to in Article I.2, to the delivery place mentioned in the specific contract,
- Consignment note(s) as set out in point 1.2 of Technical specifications (Annex I, Part 2).
- Certificate(s) of conformity signed by the contracting authority in accordance with Article II.4.10.

Each invoice must contain the following information:

- Name of contracting authority,
- FWC and specific contract number,
- Order reference,
- Product delivered,
- Quantity delivered,
- Delivery reference and date,
- Contractor name and bank account.

2. The contracting authority must approve any submitted documents or supplies and pay within 60 days from receipt of the invoice.

3. The contracting authority may suspend the time limit for payment specified in point (2.) in accordance with Article II.20.7. Once the suspension is lifted, the contracting authority shall give its approval and pay within the remainder of the time-limit indicated in point (2.) unless it rejects partially or fully the submitted documents or supplies.

I.6.4. Performance guarantee

Performance guarantee is not applicable to this FWC.

I.6.5. Retention money guarantee

Retention money guarantee is not applicable to this FWC.

I.7. BANK ACCOUNT

Payments must be made to the contractor's (represented by the leader of the group or by a group member) bank account. The bank account details shall be indicated in the specific contracts between the relevant contracting authority and the contractor.

I.8. COMMUNICATION DETAILS

For the purpose of this FWC, communications must be sent to the following addresses:

Contracting authority:

European Commission

Directorate-General for Health and Food Safety
 Directorate for Public Health, Country Knowledge and Crisis Management
 Unit Crisis Management and Preparedness in Health
 L-2920 Luxembourg
 Email: SANTE-LUX-JOINT-PROCUREMENT-SECRETARIAT@ec.europa.eu

Country	Contracting authority – contact person for the performance of the contract
BE	International Relations, Place Victor Horta/Victor Hortaplein, 40/10, 1060 Saint-Gilles/Sint-Gillis, Belgique/België, [redacted] g + [redacted] [redacted]@health.fgov.be
BG	[redacted] da.bg and Ministry of Health – [redacted] Drug Policy Directorate, [redacted]@mh.government.bg , [redacted]
CY	[redacted] Purchasing and Supply Directorate, Ministry of Health, 1 Prodromou & 17 Chilonos str, 1448 Nicosia, Cyprus, Tel no: [redacted] [redacted]@moh.gov.cy
CZ	[redacted] Department of International Affairs and the EU, Ministry of Health, [redacted] [redacted]@mzcr.cz
DK	[redacted] [redacted]@amgro.dk , [redacted] [redacted]
EE	[redacted] [redacted]@terviseamet.ee [redacted], Paldiski mnt 81, Tallinn, 10617 Estonia
DE	[redacted] Department Head 1, Federal Ministry of Health, Friedrichstraße 108, 10117 Berlin, [redacted]@bmg.bund.de
EL	Institute for Pharmaceutical Research and Technology (IFET S.A) - [redacted]

	446, e-mail: [REDACTED]@ifet.gr and info@ifet.gr
ES	[REDACTED] Spanish Agency of Medicines and Medical Devices, [REDACTED]@acmps.es
FI	The Finnish Institute of Health and Welfare, [REDACTED] [REDACTED] Finnish Institute for Health and Welfare [REDACTED]@thl.fi; [REDACTED]
FR	Santé publique France - [REDACTED] [REDACTED]@santepubliquefrance.fr
HR	[REDACTED] "Dr. Fran Mihaljević" University Hospital for Infectious Diseases, Zagreb, Croatia, [REDACTED] [REDACTED]@bfm.hr
HU	[REDACTED] National Healthcare Service Center, [REDACTED]@aek.hu
IE	[REDACTED] National Pharmaceutical Procurement Support Team, Acute Hospitals Drugs Management Programme, Health Service Executive, [REDACTED] Dargan Building, Heuston South Quarter, Military Road, Kilmainham, Dublin D08 DT85, [REDACTED]@hse.ie
IT	[REDACTED] [REDACTED] Ministero della salute, Viale Giorgio Ribotta, 5 - 00144 Roma; + [REDACTED] sanita.it
LV	SIA Riga East University Hospital - [REDACTED] [REDACTED]@aslimnica.lv
LT	[REDACTED] Health Emergency Situations Center of the Ministry of Health, email. [REDACTED]@essc.sam.lt, phone, [REDACTED] M. K. Ciurlionio g. 23, LT-44356 Kaunas, Lithuania
LU	[REDACTED] Direction de la santé, Villa Louvigny, Allée Marconi, L-2120 Luxembourg, <u>direction-</u> <u>sante@ms.etat.lu</u>
MT	[REDACTED] Central procurement & Supplies unit, Ministry for Health, [REDACTED]@gov.mt, [REDACTED] San Gwann Industrial Estate, San Gwann SUB002. [REDACTED] [REDACTED] Central procurement & Supplies unit, Ministry for Health, [REDACTED]@gov.mt, [REDACTED] [REDACTED] San Gwann Industrial Estate, San Gwann SUB002. Malta
NL	[REDACTED] Farmaceutical Procurement. [REDACTED]@rivm.nl. [REDACTED] or [REDACTED] [REDACTED]@rivm.nl tel.: [REDACTED]
AT	[REDACTED] Federal Ministry Republic Austria Social

	Affairs, Health, Care and Consumer Protection; [REDACTED] [REDACTED] Radetzkystraße 2, A - 1030 Vienna; [REDACTED] @gesundheitsministerium.gv.at cc: [REDACTED] @sozialministerium.at
PL	[REDACTED] Ministry of Health, [REDACTED] @mz.gov.pl; - [REDACTED]
PT	Direção-Geral da Saúde - [REDACTED] [REDACTED] @dgs.min-saude.pt ; secretariado.direcao@dgs.min-saude.pt Direção-Geral da Saúde - [REDACTED] National Stockpile Team Management for Medicines and Devices – COVID-19 [REDACTED] @dgs.min-saude.pt
RO	[REDACTED] Ministry of Health, [REDACTED] @ms.ro
SK	[REDACTED] Legal Department, Ministry of Health of The Slovak Republic, [REDACTED] Phone: [REDACTED] [REDACTED] @health.gov.sk
SI	[REDACTED] y department, [REDACTED] [REDACTED] @kclj.si. Contact person for communication and delivery: [REDACTED] UMCL Pharmacy department, hospital pharmacist (mobile: [REDACTED] @kclj.si)
SE	[REDACTED] National Board of Health and Welfare, [REDACTED] @socialstyrelsen.se , tel [REDACTED]
IS	[REDACTED] Department, Landspítali, Skaftahlíð 24, 105 Reykjavík, Tel: [REDACTED] @landspitali.is
NO	[REDACTED] South-Eastern Norway Regional Health Authority, Phone: [REDACTED] e-mail: [REDACTED] @helse- sorost-no
UK	[REDACTED] [REDACTED] Public Health England, [REDACTED] @phe.gov.uk [REDACTED]
ME	[REDACTED] [REDACTED] Ministry of health of Montenegro; [REDACTED] @mzd.gov.me; - [REDACTED]
MK	[REDACTED] Ministrv of Health, [REDACTED] [REDACTED] @zdravstvo.gov.mk
AL	[REDACTED] Rruga e Dibrës, Tirana, Albania [REDACTED] @qsut.gov.al
BiH	Council of Ministers of Bosnia and Herzegovina -Ms Ankica Gudeljević, Minister, Ministry of Civil Affairs Trg BiH 1, 71000 Sarajevo, Bosnia and Herzegovina, [REDACTED] [REDACTED] @vijeceministara.gov.ba;

	Kabinet.ministra@mcp.gov.ba , [REDACTED]@mcp.gov.ba
RS	Institute of Public Health of Serbia "Dr Milan Jovanovic Batut". [REDACTED] @batut.org.rs
XK	Ministry of Health; [REDACTED] [REDACTED]

Contractor (or leader in the case of a joint tender):

[REDACTED] Gilead Sciences Ireland UC
IDA Business and Technology Park, Carrigtohill, Cork, Ireland
Email: [REDACTED]@gilead.com

By derogation from this Article, different contact details for the contracting authority or the contractor may be provided in specific contracts.

I.9. PROCESSING OF PERSONAL DATA

I.9.1 Processing of personal data by the contracting authority

For the purpose of Article II.9.1,

- (a) the data controller is the Head of Crisis Management and Preparedness in Health Unit of the European Commission's Directorate-General for Health and Food Safety;
- (b) the data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en.

I.9.2 Processing of personal data by the contractor

For the purpose of Article II.9.2,

- (a) the subject matter and purpose of the processing of personal data such as identification data (name and surname) and contact details (e-mail address, business telephone number, postal address) by the contractor are solely and to the extent strictly necessary for the purposes of the implementation, management and monitoring of the contract including sending invoices for payment and communication purposes.
- (b) The localisation of and access to the personal data processed by the contractor shall comply with the following:
 - i. the personal data shall be primarily managed within the territory of the European Union and the European Economic Area;
 - ii. access to data may be given on a need to know basis only to authorised persons;
 - iii. the contractor may not change the location of data processing without the prior written authorisation of the contracting authority;
 - iv. to the extent that the personal data is hosted and/or accessible in any country outside the European Union and the European Economic Area then such transfer of personal data under the FWC to third countries or international

organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU)2018/1725³.

I.10. ALLOCATION, IMPORTATION, DISTRIBUTION AND QUALITY

I.10.1. If the sum of the vials requested by the contracting authorities exceeds the availability from the side of the contractor, the number of vials in each delivery shall be allocated to the contracting authorities based on clinical need (the allocation criteria described in Annex I (tender specifications part 2, point 2.1)). The European Commission will apply these allocation criteria and communicate the number of vials per contracting authority to the contractor.

I.10.2. Veklury supplied in accordance with Article I.2 will be imported into the EU by the contractor. Such supplies will be delivered by the contractor or its designated service provider to the locations indicated in writing by the contracting authority in accordance with Article I.4.4.

I.10.3. In accordance with the contractor's manufacturing and wholesaler dealer authorisation the receiving entity indicated by the contracting authority to the contractor in writing in accordance with Article I.4.4 must hold a valid wholesaler dealer authorisation allowing receipt of the supplies.

I.10.4. The Quality Requirements attached as part of Annex II (contractor's tender) are essential to the supply of Veklury under this contract. The contractor will inform the contracting authority of any adaptation it requests to the Quality Requirements that may be necessary in the context of agreed supply chain arrangements.

I.11. SCIENTIFIC INFORMATION TO HEALTHCARE PROFESSIONALS AND PHARMACOVIGILANCE

I.11.1. When Veklury becomes available in the participating countries under this FWC the contractor may need to communicate with Health Care Professionals regarding scientific information about safe and effective use of the medicinal product. Contracting authorities shall take this into account in the application of their national rules, notably in those cases where national pricing and reimbursement procedures have not been yet concluded. In any case communication with Health Care Professionals shall comply with Directive 2001/83/EC and include in particular essential information compatible with the summary of product characteristics and the supply classification of the medicinal product.

³ Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39, 21.11.2018, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

I.11.2. Each contracting party remains responsible for performing the appropriate pharmacovigilance activities including recording and reporting of suspected adverse reactions in accordance with the applicable legislation. The contracting authority or its competent authorities shall cooperate with and support the contractor in investigating suspected adverse reactions in order to meet the contractor's safety reporting requirements in accordance with the applicable legislation.

I.12. INVOICES AND VALUE ADDED TAX

This Article complements Article II.18.1 (Invoices and value added tax).

The Commission is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union.

The contracting authority, if not an EU institution, shall be subject to taxes and duties, including VAT, pursuant to their respective national law.

For the Commission and for the contracting authority that is not an EU institution, if according to its national law it is exempt from taxes and duties including VAT, the contractor must complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for implementation of the FWC are exempt from taxes and duties, including VAT.

I.13. TERMINATION BY EITHER PARTY

Either party may terminate the FWC and/or the FWC and specific contracts by sending *formal notification* to the other party with 3 months written notice.

If the FWC or a specific contract is terminated:

- (a) neither party is entitled to compensation;
- (b) the contractor is entitled to payment only for the supplies delivered before termination takes effect.

The second, third and fourth paragraphs of Article II.17.4 apply.

I.14. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

Provisions applicable for the FWC between the contractor and the Commission

I.14.1 The FWC and any specific contract is governed by Union law, complemented, where necessary, by the law of Belgium.

I.14.2 The courts of Brussels (Belgium) have exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the FWC and specific contract.

Provisions applicable for the FWC between the contractor and each contracting authority of each participating country

- I.14.3.** Without prejudice of the direct applicability of EU regulations and decisions, the FWC and the specific contract is governed by the law of the country where the relevant contracting authority is established, complemented, where necessary, by the Union law.
- I.14.4.** The courts of the capital city of the country where the contracting authority is established have exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the FWC and specific contract.

I.15. JOINT PROCUREMENT FWC

- I.15.1** This FWC signed by the Commission in the name and on behalf of all the other contracting authorities constitutes a bilateral legal commitment between each contracting authority and the contractor. Each contracting authority is responsible for the implementation of its FWC through the signature of specific contracts with the contractor; and each contracting authority is responsible for the particular specific contracts it awards.
- I.15.2** If the contractor has a complaint about the conclusion, performance or termination of a specific contract, the contractor remains bound by its obligations under the FWC and other specific contracts.
- I.15.3** The contracting authority may offer (a part of) its reserved quantity specified in Annex I that it does not wish to use to one or more contracting authorities under the FWC. The acquiring contracting authority may order these supplies in line with Article I.4.3.

Following the award of a specific contract, a contracting authority may offer (a part of) the ordered quantity still remaining with the contractor to one or more contracting authorities under the FWC. Any terms for redirection of remaining quantities with the contractor, shall be agreed between the contractor, the offering contracting authority and the acquiring contracting authority.

Any terms for resale of delivered quantities by the contracting authority and donation of acquired quantities by the contracting authority shall be agreed between the offering and the acquiring party.

I.16. ROLES AND RESPONSIBILITIES FOR THE JOINT TENDER

Article II.2 is replaced by the following:

‘In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group. The leader of the group represents the group members for the implementation of the FWC. Nevertheless, with the agreement of the contracting authority and the leader of the group, each member of the group may directly sign specific contracts and invoice the contracting authority.

For the purpose of signing specific contracts, including invoicing, where the general conditions refer to ‘the contractor (or leader in the case of a joint tender)’, this is to be read as

‘the contractor (in case of a joint tender, represented by the leader of the group or by a group member)’.

Contract number: SANTE/2020/C3/048

FWC conditions of December 2018

SIGNATURES


For the contractor,
Gilead Sciences Ireland UC



For the Commission; and in the name and
on behalf of all the other contracting
authorities,

Sandra GALLINA
Acting Director-General,

Signature: 
Cork, Ireland

Signature: 
Brussels, 7/10/2020

Done at [place], [date] October 7, 2020 | 9:51:23 AM PDT
Done at [place], [date]

In duplicate in English.