

AMENDMENT AND RESTATEMENT AGREEMENT
in relation to a LICENCE AGREEMENT dated 16 April 2018

THIS AMENDMENT AND RESTATEMENT AGREEMENT (the "**Amendment**") is made and entered into as of 11 NOVEMBER 2019 (the "**Amendment Date**") by and between the Medicines Patent Pool Foundation, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, CH-1202 Geneva (the "**Licensor**") and **Adcock Ingram Limited & Adcock Ingram Healthcare (Pty) Limited**, companies incorporated under the laws of Republic of South Africa, and having its registered office at 1 New Road, Midrand, 168, South Africa, Private Bag X69, Bryanston, 2021, South Africa (the "**Licensee**").

RECITALS

WHEREAS, ViiV and the Licensor entered into a licence agreement dated 31 March 2014 (the "**ViiV-MPPF Agreement**") to promote access to the antiretroviral drug dolutegravir for paediatric patients in a number of low- and middle-income countries;

WHEREAS, ViiV and the Licensor entered into an amendment and restatement agreement dated as of 21 March 2019 (the "**ViiV-MPPF Amendment**"), which restated the ViiV-MPPF Agreement (including the Form of Sublicence attached as Schedule 1 to that agreement) as amended by the ViiV-MPPF Amendment (the "**Restated ViiV-MPPF Agreement**");

WHEREAS pursuant to the ViiV-MPPF Agreement, the Licensor and the Licensee entered into an licence agreement dated 16 April 2018 (the "**Sublicence Agreement**").

WHEREAS, the Licensor and the Licensee wish to amend and restate the Sublicence Agreement in order to (i) extend the scope of and (ii) make certain other amendments to the Sublicence Agreement; and

WHEREAS, ViiV is willing to approve the amendment and restatement of the Sublicence Agreement as contemplated by this Amendment and has joined as a party to this Amendment in accordance with clause 24 (*Amendments*) of the Sublicence Agreement.

NOW THEREFORE, based on the foregoing premises and the covenants and obligations set forth below, the parties agree as follows:

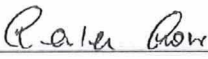
AGREEMENT

1. **Definitions.** All capitalized terms not otherwise defined herein shall have the meaning assigned to them in the Restated ViiV-MPPF Agreement and in the Restated Sublicence Agreement.
2. **Amendment and Restatement.** The Sublicence Agreement is, with effect from the Amendment Date, amended to take the form set out in the Annex to this Amendment, which restates the Sublicence Agreement as amended by this Amendment (the "**Restated Sublicence Agreement**"). For the avoidance of doubt, the Restated Sublicence Agreement shall be deemed a Sublicence under the Restated MPPF-ViiV Agreement.
3. **General.**
 - 3.1 **Amendments.** No provision of this Amendment may be modified or amended except expressly in a writing signed by all parties.


- 3.2 No impact on Letter of Indemnity. The letter of indemnity entered into between the Licensee and ViiV dated 16 April 2018 shall remain in full force and effect notwithstanding the amendment and restatement of the Sublicence Agreement pursuant to this Amendment.
- 3.3 Governing Law and Jurisdiction. The provisions of clause 28 (*Governing Law and Jurisdiction*) of the Restated Sublicence Agreement are hereby incorporated into this Amendment as if set out herein.
- 3.4 Counterparts. This Amendment may be executed in any number of counterparts, and by the parties on separate counterparts, but shall not be effective until each party has executed at least one counterpart. Each counterpart shall constitute an original of this Amendment, but all the counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF the parties have executed this Amendment by their duly authorized officers as of the Amendment Date.


Medicines Patent Pool Foundation

By: 
Name: Charles Gote
Title: Executive Director

Adcock Ingram Limited & Adcock Ingram Healthcare (Pty) Limited

By: 
Name: ASHCET PEARCE
Title: M. D.

ViiV Healthcare Company

By: 
Name: AGNIESZKA GALLAGHER
Title: VICE PRESIDENT and SECRETARY

Annex

Restated Sublicence Agreement

LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this "Agreement") is made as of 16 April 2018 (the "Effective Date"), and is amended and restated on _____ (the "Effective Amendment Date"),

BETWEEN:

- (1) **THE MEDICINES PATENT POOL FOUNDATION**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva (the "Licensor"); and
- (2) **Adcock Ingram Limited & Adcock Ingram Healthcare (Pty) Limited**, companies incorporated under the laws of Republic of South Africa, and having its registered office at 1 New Road, Midrand, 168, South Africa, Private Bag X69, Bryanston, 2021, South Africa (the "Licensee"),

with Licensor and Licensee collectively referred to as the "Parties".

WITNESSETH THAT:


WHEREAS the Licensor has been granted by ViiV (as defined below) the right to sublicense certain patents and patent applications, which relate to the compound known as dolutegravir for paediatric use;

WHEREAS the Licensee desires to obtain a licence from the Licensor to use the aforesaid patents and the Licensor is willing to grant to the Licensee such a licence in accordance with the terms and subject to the conditions of this Agreement;

WHEREAS the intent of this Agreement is to provide access to Patents (and therefore facilitate access to medicines for patients in resource-limited jurisdictions), and not to create any non-patent-related barriers where Patents or Non-Territory Patents (as defined below) do not exist;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1 DEFINITIONS

- 1.1 "Adult Licence" means a licence agreement which may have been entered into between the Licensor and Licensee relating to the manufacture and supply of products containing the Compound for use in antiretroviral therapy for HIV / AIDS in patients of age eighteen (18) years or more and who are not Child Patients.
 - 1.2 "Adverse Event" or "AE" means any untoward medical occurrence in a patient or clinical trial subject administered a Product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a Product. For a marketed Product, this can also include failure to produce expected benefits (i.e. lack of efficacy), and adverse events associated with circumstances of overdose, medication errors, abuse or misuse. In addition to the foregoing, in the context of clinical trials an AE will also mean events associated with and/or possibly attributable to the clinical trial protocol design or clinical trial procedures.
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- 1.3 “**Affiliate**”, in relation to an entity, shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such entity. For the purposes of this definition, “**control**” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of an entity are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.
- 1.4 “**Agreement Quarter**” shall mean any period of three months ending on the last day of March or June or September or December.
- 1.4A “**Approved Affiliate**” shall mean an Affiliate of the Licensee (i) which the Licensee has demonstrated by means of appropriate supporting documents is an Affiliate of the Licensee, and (ii) approved in writing by the Licensor and ViiV to sell the Products of the Licensee in the Territory, such approval not to be unreasonably withheld. The Licensor and ViiV shall respond to any requests for approval within thirty (30) days of receipt by ViiV of the appropriate supporting documents from the Licensor.
- 1.5 “**Approval Date**” shall mean:
- (a) in relation to the Licensed Mono Product, the date on which the Compound first receives the relevant regulatory approval(s), and
- (b) in relation to a Licensed Combination Product, the date on which that Licensed Combination Product first receives the relevant regulatory approval(s),
- in each case from a Relevant Regulatory Authority.
- 1.6 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.
- 1.7 “**Child Patients**” shall mean:
- (a) Paediatric Patients who fall within the scope of the patient recipient specification set out in the relevant Product label approved by (i) the FDA or the World Health Organisation pre-qualification programme and (ii) the Relevant Regulatory Authority; and/or
- (b) in relation to any jurisdiction in the Territory where Product containing 50 mg of the Compound is not available for the treatment of HIV patients of age eighteen (18) years or more, such HIV patients of age eighteen (18) years or more who, when they were Paediatric Patients, were Child Patients for the purposes of part (a) of this definition, and were treated with Product manufactured pursuant to this Agreement at the time they turned eighteen (18) years of age.
- 1.8 “**Compound**” shall mean the chemical compound known generically as dolutegravir, whose more specific chemical name is set out in Appendix A.
- 1.9 “**Confidential Information**” shall mean all information that would reasonably be regarded as, or is designated as, of a confidential or commercially sensitive nature by the party to which the information relates including, without limitation, any matter relating to, or arising in connection with, this Agreement or the business or affairs of any of the Parties, ViiV, and/or any of their Affiliates.

- 1.10 **“Development Activity”** shall mean any of the following:
- (p) initiating, conducting, sponsoring, supporting or providing Products for use in, any clinical research relating to the Products;
 - (q) engaging with guideline bodies or external experts in relation to development of the Products; and/or
 - (r) developing a Licensed Combination Product in accordance with this Licence Agreement.
- 1.11 **“Effective Date”** shall mean the date of this Licence Agreement.
- 1.12 **“Event of Force Majeure”** has the meaning given in Clause 15.
- 1.13 **“FDA”** means the United States of America’s Food and Drug Administration.
- 1.14 **“Head Licence”** means the Licensor’s agreement with ViiV dated 31 March 2014 (as subsequently amended and restated) under which its right to licence the Patents is derived
- 1.15 **“Improvement”** shall mean any new or improved process any new or improved manufacturing techniques or any further invention which relate to the manufacture or formulation of the Products and/or Compound or incorporate or are based on the Patents.
- 1.16 **“Improvement Patents”** shall mean any patents or patent applications which generically or specifically claim any Improvements which are developed by the Licensee, or to which the Licensee party otherwise has the right to grant licences, now or in the future.
- 1.17 **“Jurisdiction-Specific Packaging”** means the packaging of a Product which is specific to a particular jurisdiction.
- 1.18 **“Licensed Combination Product”** shall mean an oral pharmaceutical composition:
- (a) containing the Compound as an active ingredient in combination with (an)other active ingredient(s) (subject to the limitation set out in Clause 2.8); and
 - (b) where the combination of active ingredients, quantitative composition and pharmaceutical form of the composition
 - i. corresponds to that of a pharmaceutical composition which has been approved for use in Paediatric Patients by the FDA, and/or
 - ii. has been recommended by the World Health Organisation or the United States Department of Health and Human Services for use in Paediatric Patients,but for the avoidance of doubt shall not be limited to a pharmaceutical composition approved or recommended solely for use in Paediatric Patients; and
 - (c) prepared and ready for administration to Child Patients solely for antiretroviral therapy for HIV/AIDS.
- 1.19 **“Licensed Mono Product”** shall mean an oral pharmaceutical composition:
- (a) containing the Compound as its sole active ingredient; and
 - (b) where the quantitative composition and pharmaceutical form of the composition

- i. corresponds to that of a pharmaceutical composition which has been approved for use in Paediatric Patients by the FDA, and/or
 - ii. has been recommended by the World Health Organisation or the United States Department of Health and Human Services for use in Paediatric Patients,
but for the avoidance of doubt shall not be limited to a pharmaceutical composition approved or recommended solely for use in Paediatric Patients;
and
- (c) prepared and ready for administration to Child Patients solely for antiretroviral therapy for HIV/AIDS.

1.20 “Non-Territory Patents” shall mean:

1.20.1 in relation to those jurisdictions falling outside of the Territory but being a jurisdiction listed in Appendix C (low and middle income jurisdictions), those patents owned by ViiV as are set out in Appendix E; and

1.20.2 in relation to those jurisdictions falling outside of the Territory but not being a jurisdiction listed in Appendix C (low and middle income jurisdictions), any patents equivalent to those specified in Clause 1.20.1 owned by ViiV or its Affiliates which have been granted in such jurisdictions.

1.21A “Paediatric Patient” shall mean HIV patients of less than eighteen (18) years of age.

1.21 “Patents” shall mean those patents and patent applications owned by ViiV as are set out in Appendix D.

1.22 “Pregnancy Report” means a report of pregnancy in a patient or trial subject to whom a Product has been administered or a report of a pregnancy where the father is a patient or trial subject to whom a Product has been administered.

1.23 “Private Market” shall mean any entity that is not in the Public Market.

1.24 “Product” shall mean the Licensed Mono Product and/or the Licensed Combination Product.

1.25 “Public Market” shall mean (a) the following organisations to the extent that they are not for profit organisations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside of an applicable country to the extent that they are supporting implementation locally in an applicable country, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) of this Clause.

- 1.26 “**Raw Materials**” shall mean, as the context admits and requires, the active ingredients which are protected by the Patents and which (i) are required to prepare the Products in final consumer package form as envisaged under the licences granted under Clauses 2.1 and 2.2; and (ii) are solely for use in the Products.
- 1.27 “**Relevant Regulatory Authority**” means (i) in relation to a particular jurisdiction in the Territory, the local regulatory authority having jurisdiction over the manufacture and/or commercialisation of the Products in that jurisdiction, or (ii) the World Health Organization (“WHO”) pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).
- 1.27A “**Reporting Guidance**” means the guidance on reporting (as required in Sections 3.5 and 10.2 of this Agreement) on, inter alia, development timelines, regulatory activities, manufacturing and sales of Raw Materials and Products, issued by Licensor to Licensee and as amended from time to time.
- 1.28 “**Sanctions**” shall have the meaning given in the definition of “Sanctions Target”.
- 1.29 “**Sanctions Authorities**” shall have the meaning given in the definition of “Sanctions Target”.
- 1.30 “**Sanctions Target**” shall mean an individual or entity that is, or is owned or controlled by, an individual or entity which is: (i) the target of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of foreign Assets Control (“OFAC”), Her Majesty’s Treasury, the United Nations Security Council, the European Union or other relevant sanctions authority (together, the “Sanctions Authorities”) (collectively “Sanctions”); or (ii) located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions (which, at the date of this License, includes without limitation Cuba, Iran, Dem. Rep. Korea, Sudan and Syrian Arab Republic) or (iii) listed on OFAC’s List of Specially Designated Nationals and Blocked Persons or any equivalent list of parties designated by the European Union, or the United Kingdom.
- 1.31 “**Territory**” shall mean all those countries as are set out in Appendix B, as may be amended from time to time in accordance with Clause 24.
- 1.31A “**Trade Dress Guidance**” shall mean guidance on trade dress, elaborating the requirements in clauses 7 and 9 of this Agreement, issued by the Licensor and ViiV, as amended from time to time.
- 1.32 “**Third Party(ies)**” shall mean any party other than a party to this Agreement.
- 1.33 “**ViiV**” means ViiV Healthcare Company and/or its Affiliates, as the context admits.
- 1.34 References to “this Agreement” shall mean this licence agreement and shall include the Appendices.
- 1.35 References to “Clauses” and “Appendices” are references to clauses and appendices of and to this Agreement and references to sub-clauses or paragraphs are, unless otherwise stated, references to sub-clauses or paragraphs of the Clauses or Appendices in which the reference appears.
- 1.36 Unless the context otherwise requires, the singular shall include the plural and vice

versa and the masculine includes the feminine and neuter genders and vice versa.

- 1.37 The headings and sub-headings used in this Agreement are for convenience only and shall not affect the construction or the interpretation of this Agreement.
- 1.38 References to "Party" or "Parties" shall, unless otherwise stated or unless the context otherwise admits or requires, mean a Party or Parties to this Agreement.

2 GRANT OF SUBLICENCE

- 2.1 Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a licence in respect of the Patents, the Licensor hereby grants to the Licensee a non-exclusive, royalty-free, non-sublicensable, non-transferable licence under the Patents to:
- (a) manufacture, have manufactured, use, sell, supply, import or export in the Territory Raw Materials for use in the manufacture of Products to be supplied in the Territory solely for use in antiretroviral therapy for HIV / AIDS in Child Patients; and
 - (b) manufacture, have manufactured, use, sell, have sold by an Approved Affiliate, supply, import or export Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Child Patients.
- 2.2 Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a licence in respect of the Non-Territory Patents, the Licensor hereby grants to the Licensee a non-exclusive, royalty-free, non-sublicensable, non-transferable licence under the Non-Territory Patents to:
- (a) manufacture, have manufactured, use, sell, have sold by an Approved Affiliate, supply, import or export outside the Territory Products exclusively for use, sale, supply, import or export of such Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Child Patients;
 - (b) manufacture, have manufactured, use, sell, supply, import or export outside the Territory Raw Materials exclusively for supplying into the Territory for use in the manufacture of Products in the Territory to be supplied in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Child Patients; and
 - (c) manufacture, have manufactured, use, sell, supply, import or export outside the Territory Raw Materials for the manufacture of Products outside the Territory exclusively for use, sale, supply, import or export in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Child Patients.
- 2.3 Notwithstanding anything contained in this Agreement, nothing in this Agreement shall be construed to:
- (a) prevent the Licensee from engaging in any activities within any country of the Territory that would not infringe a Patent granted and in force in such country of the Territory, or
 - (b) impose on the Licensee a positive obligation to (i) restrict the sales of Product to any person other than a Child Patient, (ii) have packaging that specifies that products are not authorised for supply to any person other than a Child Patient, pursuant to Clause 7.2 or (iv) provide the statements contemplated by Clause 10.2, in each case

in relation to the supply of Product into a country of the Territory where such supply would not infringe a Patent granted and in force in such country of the Territory.

- 2.4 Other than as set in Clauses 2.1 and 2.2, no rights are granted to the Licensee under this Agreement to manufacture, sell or supply either Raw Materials or Products inside or outside the Territory. The licence granted under this Agreement is subject to the intellectual property rights of any Third Party anywhere inside or outside the Territory. For avoidance of doubt, it shall not be a breach of this Agreement for licensee to manufacture, use, sell or supply Products or Raw Materials outside the Territory where such activities would not infringe Non-Territory Patents, including, without limitation, where a country outside the Territory has issued a compulsory licence on Non-Territory Patent(s) provided that Licensee is authorised to supply such country under the compulsory licence and such use is within the scope of the compulsory licence.
- 2.4A The Licensee's licence to have manufactured by a Third Party Raw Materials and Products in accordance with Clauses 2.1 and 2.2 shall be limited solely to manufacture on behalf of the Licensee of (i) Raw Materials for supply to the Licensee and (ii) Products for supply to the Licensee and/or an Approved Affiliate. Clauses 2.1 and 2.2 shall not be construed as conferring any right for a Third Party to manufacture Raw Materials and/or Products for supply to any party other than the Licensee and/or an Approved Affiliate (as applicable).
- 2.4B For the avoidance of doubt, this Agreement confers no rights on the Licensee to sublicense its rights hereunder, which is expressly prohibited. The Licensee shall procure that any Third Party manufacturer and/or any Approved Affiliate shall comply with the terms of this Agreement as if it was the Licensee, and the Licensee shall remain fully liable for the acts and omissions of such Third Party manufacturer and/or Approved Affiliate.
- 2.5 The Licensee shall, acting in compliance with all applicable laws and regulations, use its best endeavours to maximise access to the Products in the Territory for administration to Child Patients.
- 2.6 It is expressly acknowledged by the Licensee that this Agreement confers no intellectual property rights whatsoever on the Licensee other than those expressly granted in Clauses 2.1 and 2.2 for the term of this Agreement. Without prejudice to the generality of the foregoing, other than as expressly granted in Clause 2.1 and 2.2, no licence is granted to the Licensee:
- (a) to perform any acts or omissions which infringe any rights (including, but not limited to, patent rights) of the Licensor, ViiV and/or any of their Affiliates and/or their sublicensees inside or outside the Territory;
 - (b) to perform any acts or omissions which infringe any rights of any Third Party (including, without limitation, ViiV and their Affiliates) inside or outside the Territory (including, without limitation any rights relating to any active ingredient, other than the Compound, used in the Licensed Combination Products); and/or
 - (c) in relation to the Patents for the use, manufacture, sale or supply of Products where such Products would be supplied directly or indirectly to any patient other than a Child Patient.
- 2.7 This Agreement is without prejudice to any other rights and/or obligations that Licensee may have pursuant to separate written agreement(s) with ViiV and/or MPPF (signed by

the relevant parties) relating to Patents and/or Non-Territory Patents. Notwithstanding anything contained in this Agreement, activities of Licensee performed in compliance with such other agreement(s) shall not constitute a breach of this Agreement.

- 2.8 Nothing in this Agreement shall be deemed to constitute a licence for the Licensee to manufacture, import, use or supply any active ingredient other than the Compound.
- 2.9 Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or offer for sale a Product in a jurisdiction of the Territory prior to the relevant Approval Date for that Product for that jurisdiction.
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- 2.10 Where this Agreement requires the Licensee to obtain approval from ViiV, the Licensee shall request such approval through the Licensor.

3 DEVELOPMENT AND REGISTRATION

- 3.1 As of the Effective Date and subject always to ViiV's retained rights to the Patents and Non-Territory Patents (and that of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.
- 3.2 Licensee agrees that it will manufacture Raw Materials and Product in a manner consistent with (i) World Health Organization ("WHO") pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority ("SRA"), defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.
- 3.3 The Licensee will obtain from the relevant authorities in the Territory and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Products which are necessary to enable the Products to be sold or supplied in the Territory in accordance with this Agreement. Licensee shall file for regulatory approval before at least one Relevant Regulatory Authority (including, but not limited to the WHO pre-qualification programme) not later than 30 months from the Effective Date in respect to the Compound and not later than 36 months from the Effective Date in respect to at least one of the Products. Licensee shall also, upon Licensor's reasonable request, file for regulatory approval before the Relevant Regulatory Authority for any subsequent Products within a reasonable time.
- 3.4 If the Licensee sells, supplies or otherwise disposes of any Product in the Territory but has not obtained the necessary approvals pursuant to Clauses 3.2 and 3.3, the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.
- 3.5 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report on the status of development of the Product and any regulatory filing regarding the Products in relation to that Agreement Quarter. Such reporting shall be made in accordance with the Reporting Guidance issued by the Licensor and should cover (a) Products in its development pipeline, (b) status of development of each Product in development, (c)

regulatory filing plan for each Product, and (d) a list of countries for which such regulatory approvals or authorizations have been filed and/or obtained for any Product. The Parties agree to confer on a quarterly basis regarding such reports and also review development and filing status of Products. For avoidance of doubt, ViiV and the Licensor agree that information contained in quarterly and other such reports shall be treated as Confidential Information.

- 3.6 The Licensee will manufacture and sell the Products in accordance with all laws and regulations relevant to the manufacture and sale of the Products and in accordance with good industry practice.
- 3.7 Prior to engaging in any Development Activity, Licensee shall:
- 3.7.1 provide Licensor and ViiV with not less than one (1) month written notice of its intention to carry out such Development Activity;
- 3.7.2 meet with the Licensor and/or ViiV at such times and with such frequency as is reasonably requested by them to discuss the proposed activity; and
- 3.7.3 comply with the Licensor's and ViiV's reasonable requests in relation to the design and conduct of such Development Activity.

4 SUPPLY, DISTRIBUTION AND LABELLING

- 4.1 The Licensee shall be solely responsible for providing its own clinical, promotional and commercial infrastructure to support the manufacture and sale of the Products in the Territory. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Products.
- 4.2 The Licensee shall be solely responsible for the distribution in the Territory of all Products to be sold in the Territory under this Agreement.

5 EXCHANGE OF INFORMATION AND CONFIDENTIALITY

- 5.1 During the term of this Agreement and for five years thereafter, the Parties shall not, use, reveal or disclose to any Third Party, or to any of its Affiliates, save for those of its Affiliates who need to know such information to exercise the Party's rights under this Agreement, any Confidential Information received from the other Party or ViiV and/or any of their Affiliates or otherwise developed by any party in the performance of activities in furtherance of this Agreement, except as may be otherwise provided herein or as may be required for the purposes of securing essential authorisations in respect of the performance of this Agreement from governmental agencies in the Territory, or as may be required to be disclosed under law or regulation in the Territory. This confidentiality obligation shall not apply to such information which:
- (a) the receiving party can prove, by written records and to the reasonable satisfaction of the disclosing party, is or has become a matter of public knowledge other than through any breach by or at the instigation of the receiving party, or any of its Affiliates, of this Agreement;
- (b) is already legitimately in the possession of the receiving party;
- (c) is disclosed to the receiving party by a Third Party (other than the disclosing

party or ViiV and/or its Affiliates) having the right to do so;

- (d) is subsequently and independently developed by employees of the receiving party or its Affiliates who had no knowledge of the Confidential Information disclosed; or
 - (e) in the case of the Licensor, is required to be disclosed to ViiV under the terms of the Licensor's agreement with ViiV.
- 5.2 The Parties shall ensure that no unauthorised use or disclosure is made by others to whom access to such Confidential Information is granted, by binding such persons on like terms to this Agreement which are enforceable by each of the Licensor and ViiV.
- 5.3 All Confidential Information shall remain the property of the disclosing party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a party to this Agreement, based on the insolvency or bankruptcy of such party (or based on any other analogous or similar status of that party under foreign laws), the bankrupt or insolvent party shall promptly notify the court or other tribunal:
- (a) that Confidential Information remains the property of the disclosing party; and
 - (b) of the confidentiality obligations under this Agreement.
- 5.4 In addition, the bankrupt or insolvent party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of such Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.
- 5.5 Prior to submitting for written or oral publication any manuscript, abstract or the like which includes data or other information generated and provided under the terms of, or in relation to, this Agreement or relating to Products, the Licensee shall provide a copy of such Publication to ViiV and shall take into account ViiV's reasonable comments in connection therewith.
- 5.6 Nothing in this Agreement shall be construed as preventing or in any way inhibiting the Licensee from complying with statutory and regulatory requirements relating to, or arising out of, its rights under this Agreement.

6 ADVERSE EXPERIENCE REPORTING

- 6.1 The responsibilities of the Parties for reporting of adverse drug experiences related to the Products to regulatory authorities in the Territory shall be performed in accordance with local laws and regulations. The responsibilities of the Parties for safety related or Product related inquiries shall be performed in accordance with local laws and regulations.
- 6.2 Without prejudice to Clause 6.1:
- 6.2.1 Licensee undertakes that it will maintain until the termination of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled) pharmacovigilance and risk management systems, procedures and documentation needed to perform and comply with its

regulatory obligations and its related obligations under this Agreement.

6.2.2 Licensee undertakes that it will ensure that it will comply with all applicable laws and regulations regarding the Products in the Territory including without limitation those laws and regulations relating to risk management, drug safety and pharmacovigilance.

6.2.3 Licensee will hold and maintain a safety database regarding the Products in the Territory.

6.2.4 Licensee will be responsible for fulfilling all Pharmacovigilance activities as per the local regulations and requirements for the Products in the Territory (this includes but is not limited to collating AE, and Pregnancy Reports, expedited and periodic reporting to regulatory agencies in the Territory, literature review, performing safety evaluation and signal detection on all available AE and Pregnancy data etc).

6.2.5 Licensee shall provide Licensor and ViiV with a report containing information regarding AEs and Pregnancy Reports which are associated with the Products and which have been received by Licensee, from both spontaneous reporting and clinical trial sources. Such report shall be provided annually and otherwise on reasonable request by the Licensor and/or ViiV.

6.2.6 Licensee shall notify the Licensor and ViiV forthwith of the receipt of an enquiry from a regulatory authority in the Territory relating to the Product that concerns any safety issue. If Licensee becomes aware of action that may or will be or has been taken by a regulatory authority for a safety reason connected with the Product, it shall immediately and in any event no later than twenty-four (24) hours after receiving such notice from a regulatory authority notify Licensor and ViiV in writing (including, but not limited to email communications) with available details regarding the same.

6.2.7 On conclusion of any clinical research relating to the Products, Licensee undertakes to submit to Licensor and ViiV copies of the clinical trial reports generated by or on behalf of Licensee relating to such clinical research.

6.2.8 Notwithstanding Clause 20, notices to be provided pursuant to this clause 6 shall, in addition, also be sent to:

VP, Safety & Pharmacovigilance,
ViiV Healthcare
980 Great West Road
Brentford
Middlesex, TW8 9GS.

With a copy to: oxa63163@viihealthcare.com

or such person as shall be nominated by him in writing from time to time.

7 NON-DIVERSION

- 7.1 Save as provided under this Agreement, and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, sell or supply:
- (a) Products or Raw Materials outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
 - (b) Raw Materials to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Raw Materials other than in the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
 - (c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent; and/or
 - (d) Products to any Third Party that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products to be administered to any patient other than Child Patients in the Territory, unless such sale or supply is performed in compliance with separate written agreement(s) that the Licensee may have with Licensor and/or ViiV. .

7.2 The Licensee shall ensure that packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products to be sold or otherwise supplied by the Licensee under this Agreement shall carry clear statements in bold type that:

- (a) the Products have been produced under a licence from the Medicines Patent Pool (and where appropriate, ViiV Healthcare);
- (b) the Products are not for administration to anyone other than Child Patients, provided however that this obligation shall only apply in relation to Products which are in jurisdictions with Jurisdiction-Specific Packaging and, where an Adult Licence is in place, supplied into jurisdictions which are not within the scope of that Adult Licence; and
- (c) any other use is not authorised.

The obligations under this Clause 7.2 are further elaborated in the Trade Dress Guidance.

7.3 The Licensee agrees that the Products sold pursuant to this Agreement will be visually differentiated from Products sold by ViiV in a manner further elaborated under the Trade Dress Guidance. Licensee will submit samples of the Products to ViiV (to such address and marked for the attention of such person as identified in the Trade Dress Guidance) for ViiV and Licensor's approval once trial batches are manufactured, and agrees not to manufacture exhibit batches of Products or to sell Products pursuant to this Agreement until the Licensor and ViiV have approved the colour and shape of the trial batches, such approval will not be unreasonably withheld, delayed or conditioned. Once Licensor and ViiV have approved the colour and shape of the trial batches (i) the Licensor and ViiV agree not to make any additional requests for differentiation (except as provided in Clause 7.4 below), and (ii) the Licensee agrees

only to sell Products that conform to the colour and shape of the trial batches approved by the Licensor and ViiV pursuant to this Clause 8.3.

7.3A For the avoidance of any doubt, any Product, packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products approved by the Licensor and ViiV before the Effective Amendment Date will be considered as already approved, and ViiV and Licensor will not request the Licensee to make any additional changes except as provided in Clause 7.4 below.

~~7.4~~ Without prejudice to Clause 7.3, Licensee agrees to comply with such additional requirements for differentiation of the packaging of Products as ViiV may request and agrees to use its reasonable endeavours to ensure timely registration of the variation with all Relevant Regulatory Authorities as they may require, provided that:

7.4.1 ViiV shall only be entitled to request such additional differentiation once during the Term of this Agreement;

7.4.2 ViiV shall not request such additional differentiation earlier than the third (3rd) anniversary of the Effective Date of this Agreement; and

7.4.3 Licensee may continue to sell the Products of the original packaging:

7.4.3.1. in all countries in the relevant Territory until the total number of countries which have approved the revised packaging when added to the number of countries for which such approval is not required equates to ten (10) countries (unless the Licensee can demonstrate to the reasonable satisfaction of the Licensor and ViiV that the volume requirements in those 10 countries do not equate to one batch of Products (the "Volume Threshold"), in which case Licensee shall not be obliged to sell the newly differentiated Product until such additional approvals as are necessary to meet the Volume Threshold are obtained); and

7.4.3.2. thereafter on a country-by-country basis until such time as the variation for the differentiated packaging is approved for sale in that country.

7.5 The Licensee shall give written notice, prior to any sale of Products, to any Third Party to which it sells Products of the restrictions contained in this Clause 7 and the Licensee shall use its best endeavours, without prejudice to any other provision of this Agreement, to ensure that such Third Parties will undertake to abide by the restrictions contained in this Clause 7 and will assist the Licensor and ViiV in securing compliance with this Clause 7 and the restrictions which it contemplates.

8 INTELLECTUAL PROPERTY

8.1 If at any time during the term of this Agreement the Licensee (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to Licensor and ViiV in full together with all available information concerning the mode of working and using the same. Licensor and ViiV shall treat this information as Confidential Information.

8.2 Licensee hereby grants to Licensor and ViiV a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement, Improvement Patent and related know-how (and shall promptly execute such document as ViiV may reasonably request accordingly). Licensor shall not sublicense such rights to any Third Party, provided, however, that should Licensor desire to sublicense any such rights, Licensee and Licensor agree to enter in good-faith negotiations regarding such sublicense. ViiV shall be entitled to grant sublicences (without further right to sublicense) under such licence only to its:

8.2.1 Affiliates; or

~~8.2.2 contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising ViiV products.~~

8.3 The Licensee shall have no rights in relation to the conduct of any matter relating to the Patents or Non-Territory Patents, including the filing, prosecution and maintenance thereof.

8.4 If any suit or claim by a Third Party is instituted against the Licensor or the Licensee for patent infringement involving the Products and/or the Raw Materials, the party sued shall promptly notify the Licensor and ViiV in writing. ViiV shall have the right, but not the obligation, to defend or to conduct the defence of such suit or claim at its own expense. The Licensee shall assist ViiV and co-operate in any such litigation at ViiV's request and expense.

8.5 ViiV (and in no circumstances the Licensee) shall be entitled to bring infringement action at its own expense. To the extent ViiV decides not to bring any such infringement action, ViiV shall not be liable to the Licensee in any respect for such decision. The Licensee shall assist ViiV and co-operate in any such litigation at ViiV's request without expense to the Licensee.

9 TRADE MARKS AND NON-PROPRIETARY NAMES

9.1 Subject always to Clauses 9.2 and 9.3, the Licensee, at its expense, shall be responsible for the selection, registration and maintenance of all trade marks which it employs in connection with the Products to be sold by the Licensee in the Territory under this Agreement and shall own and control such trade marks. Nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensor to use such trade marks for any purpose. Further, nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensee to use the trade marks owned by the Licensor, ViiV, and/or any of their Affiliates anywhere in the world for any purpose.

9.2 The Licensee shall not use or seek to register (or, where it is possible to do so, apply to use or register) any trade or service mark, trade dress (where applicable), symbol or device in relation to any Products or any of their packaging (whether external, intermediate or internal) or promotional material which incorporates or is identical or confusingly similar to any trade or service mark, trade dress, symbol or device used by the Licensor, ViiV and/or any of their Affiliates anywhere in the world. If the Licensor and/or ViiV become aware that the Licensee is in breach of this clause 9.2, the Licensee shall immediately stop any such use and withdraw any such trade mark application and/or registration upon request by the Licensor and/or ViiV. This clause shall be without prejudice to any legal rights the Licensee may have in relation to the use of a trade or service mark, trade dress, symbol or device which is identical or confusingly similar to any trade or service mark, trade dress, symbol or device used by the Licensor, ViiV and/or any of their Affiliates anywhere in the world where that use by the Licensee

pre-dates the rights of the Licensor, ViiV and/or any of their Affiliates.

- 9.3 The Licensee shall obtain the prior written approval, such approval not to be unreasonably withheld or conditioned, of the Licensor and ViiV for all trade or service marks, trade dress (where applicable), symbols or devices which the Licensee proposes to use in relation to the Products or any of their packaging (whether external, intermediate or internal) or promotional material before seeking to register any such trade marks, before offering to sell, selling or otherwise disposing of any Products, and before applying for government or relevant regulatory authorisation to do so. The Licensor and ViiV shall respond to any request for approval from the Licensee within 30 days of receipt by ViiV (from the Licensor) of all the relevant documentation necessary to consider the Licensee's request, with an approval or a written statement of why the request is not being approved by ViiV. For the avoidance of doubt, the Trade Dress Guidance does not limit in any way the Licensor and/or ViiV's right to refuse to provide approval under this Clause 9.3, and the basis of ViiV's refusal to provide approval under this Clause 9.3 shall not be limited to breaches of Clause 9.2.
- 9.4 For the avoidance of doubt, any approval provided by the Licensor and/or ViiV under Clause 9.3 is not to be interpreted as acquiescence by the Licensor and/or ViiV that any packaging and/or labelling complies with any local legal or regulatory requirements, which remains the Licensee's responsibility.

10 STATEMENTS AND REMITTANCES

- 10.1 At all times the Licensee shall keep, and shall require its Affiliates and any Third Party manufacturers and Third Parties making sales on its behalf to keep, complete and accurate records for the previous two years (or for the period from the Effective Date to the then current date if such period is less than two years) of all quantities of Raw Materials and Products manufactured and/or sold under the licences granted by this Agreement, together with that information contemplated by Clause 10.2. The Licensor and ViiV shall have the right (and the Licensee shall procure such right), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two calendar years and provided further that such accountant or like person shall report to ViiV only as to:
- (a) the accuracy of the manufacturing and sales statements of the Licensee (and/or its Affiliates and/or its Third Party manufacturers contemplated by this Agreement) in relation to such manufacture and sales;
 - (b) the appropriateness of quantities of Raw Materials and Products imported or manufactured pursuant to this Agreement by reference to what quantities of Raw Materials and Products would reasonably be required to meet demand for actual sales made and sales forecasted by the Licensee;
 - (c) verification that all sales and other supplies of Products and Raw Materials made by the Licensee have been made (i) in the Territory, except for Products and Raw Materials made outside the Territory as expressly provided for in this Agreement and (ii) otherwise in accordance with Clause 7; and
 - (d) verification that all sales and other supplies of Products and Raw Materials made by Third Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.

- 10.2 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report of all Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter. Such accounting shall be made in accordance with the Reporting Guidance issued by the Licensor and show smallest unit, pack size, and value of sales in US Dollars on a Product-by-Product, country-by-country, month-by-month and purchaser-by-purchaser basis and shall be broken down by reference to sales to the Public Market and the Private Market.

11 SANCTIONS

- 11.1 The Parties acknowledge that a number of organisations and countries including the United Nations, the United States, the United Kingdom and the European Union have adopted sanctions legislation relating to the Territory and/or entities and individuals which or who are resident or operate in the Territory and that such sanctions are varied or amended from time to time.
- 11.2 The Licensee represents and warrants to Licensor and ViiV that (a) neither the Licensee nor, to the knowledge of the Licensee, any Affiliate, director, officer, employee of the Licensee, is a Sanctions Target, or (b) that it has obtained a licence or other authorisation from OFAC and/or any other relevant Sanctions Authorities in relation to such an entity which is a Sanctions Target.
- 11.3 The Licensee represents and covenants that, prior to, directly or indirectly,
- (a) making the Patents or any Product available to, or contracting for Product manufacture with, any Sanctions Target; or
 - (b) making the Patents or any Product available to a country or territory that is the target of country-wide or territory-wide Sanctions;
- it will obtain a license or other authorization, either directly or through MPPF, from OFAC and/or any other relevant Sanctions Authorities.
- 11.4 In the event that performance of this Agreement by either Party or the Head Licence would (or might) in the reasonable opinion of the Licensor and/or ViiV breach any Sanctions, any applicable export control regime or other similar applicable laws of any jurisdiction (whether or not such Sanctions, controls or laws were in existence at the date of this Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of this Agreement), the Licensor shall be entitled to suspend the operation of such provisions of the Agreement (including any payment or supply provisions) which require or permit performance by either or both Parties where, in the reasonable opinion of the Licensor and/or ViiV, such performance would result in a breach of any such Sanctions, controls or laws until, in the reasonable discretion of ViiV and Licensor, such time as all necessary approvals or licences have been obtained to enable the Agreement to continue in a lawful and compliant manner and, notwithstanding any provision of this Agreement, the Licensor shall not be obliged to pay any compensation to the other Party or otherwise indemnify the other Party in respect of any losses or costs which that other Party may suffer or incur as a result of such suspension and/or termination.

12 TERM AND TERMINATION

- 12.1 This Agreement shall be deemed to come into effect on the Effective Date and shall continue thereafter subject to the further provisions of this Clause 12.
- 12.2 Unless otherwise terminated, this Agreement shall expire upon the expiration, lapse or invalidation of the last remaining Patent in the Territory.
- 12.3 Save as otherwise provided in this Agreement, if the Licensee breaches any provision of this Agreement and if such breach (i) is material and incapable of correction; or (ii) is capable of correction but is not corrected within 60 days after receiving written notice with respect to such default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default.

12.4 If:

12.4.1 Licensor becomes aware of an actual or threatened claim that Licensee's use of the Patents in the Territory infringes the intellectual property rights of a Third Party; or

12.4.2 Licensor receives notice from ViiV that ViiV's right to grant licences of the Patents is challenged,

Licensor shall (and ViiV shall be entitled to) notify the Licensee in writing, detailing the nature of such claim or challenge. Licensee shall, within ten (10) Business Days of receipt of such notice, and without prejudice to any of the Licensee's other obligations or liabilities under this Agreement or the Licensor's rights (including without limitation under Clause 12.5), elect to:

- (i) suspend the terms of this Licence in respect of the relevant Patent until such issue is resolved; or
- (ii) confirm in writing that it will indemnify Licensor and ViiV against any Losses (as defined in Clause 14.5) incurred by Licensor and/or ViiV in connection with Licensee's continued use of such Patent pursuant to this Licence.

If Licensee does not so notify Licensor within ten (10) Business Days of Licensor's initial notice, the licence shall be deemed suspended pending resolution of the issue.

12.5 If:

- (a) the Licensee breaches any of the provisions of Clause 7;
- (b) it is determined that the Licensee's use of the Patents in the Territory or Non-Territory Patents outside of the Territory infringes the intellectual property rights of a Third Party;
- (c) ViiV's right to grant licences of the Patents or Non-Territory Patents expires or is terminated;
- (d) ViiV or Licensor receives a third party claim or demand for royalty payments relating to sales of the Products or Raw Materials by the Licensee, unless the Licensee agrees to satisfy the claim should such a claim or demand become payable;

- (e) the legal or beneficial ownership or control of the Licensee and/or any of its Affiliates changes in such a manner as ViiV shall in its sole discretion consider significant;
- (f) Licensee repeatedly fails to comply with or to timely provide Licensor with any report such as those contained in Clause 10.2 of this Agreement;

the Licensor may terminate this Agreement, either in whole or in relation to a particular Patent with immediate effect by notice in writing to the Licensee.

- 12.6 The provisions of Clauses 12.5(a), 12.5(b) and 12.5(d) are without prejudice to the Licensor's or ViiV's rights to claim all damage and loss suffered by the Licensor, ViiV and/or any of their Affiliates arising out of, or in relation to, the event giving rise to termination. In respect of such damage or loss under 12.5(a), (b) and/or 12.5(d) the Licensee hereby agrees to indemnify the Licensor and ViiV subject to (i) the Licensor and ViiV (each of which shall be entitled to conduct the defence of such claims against them) taking reasonable account of the Licensee's input in the conduct of the claim to which such loss or damage relates, and (ii) the provisions of 28.3.
- 12.7 Any Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Party if, at any time, the other Party shall compound or make arrangements with its creditors or be adjudicated bankrupt or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) otherwise than as part of a bona fide amalgamation or reconstruction without insolvency or suffer any insolvency event or analogous process under foreign laws.
- 12.8 Any change in the legal or beneficial ownership or control of the Licensee shall be immediately notified in writing to the Licensor and ViiV by the Licensee. For the purposes of this Clause 12.8, "control" shall mean the ability of a person, entity or corporation to ensure, whether through ownership of shares or otherwise, that the affairs of a party are conducted in accordance with the wishes of such person, entity or corporation.
- 12.9 If Licensee fails to file for regulatory approval before at least one Relevant Regulatory Authority (including, but not limited to the WHO pre-qualification programme) within 30 months from the Effective Date in respect to the Compound and within 36 months in respect to at least one of the Products, or fails to respond to Licensor's reasonable request for any subsequent Products, Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.
- 12.10 If, in the reasonable opinion of the Licensor, the Licensee fails to promote access to the Products in the Territory in accordance with this Agreement, the Licensor shall give notice to the Licensee requiring it cure such failure. If in the opinion of the Licensor, the Licensee fails to report reasonable progress within 180 days after receiving written notice with respect to the default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. Without limitation to the generality of this Clause 12.10 in exercising its reasonable opinion, the Licensor shall take into account the period within which the relevant authorities provide the necessary approvals as referred to in Clauses 3.2 and 3.3, normal development lead time for the Products, and progress reported by Licensee in its quarterly reports provided under Clause 3.5.
- 12.11 Unless notice to the contrary is given by ViiV, this Agreement shall terminate immediately in the event that the Head Licence is terminated or expires. This

Sublicense Agreement shall be converted into a licence between ViiV and the Sublicensee, provided that Sublicensee is not in breach of this Agreement and that ViiV has notified both the Licensor and Licensee of such conversion.

- 12.12 Licensee may terminate this Agreement at any time by providing 30 days written notice to Licensor.

13 RIGHTS AND DUTIES UPON TERMINATION OR EXPIRY

- 13.1 Upon termination or expiry of this Agreement, in accordance with Clauses 12.7, 12.8, 12.9, 12.11 and/or 12.12 the Licensee shall immediately notify the Licensor and ViiV of the amount of Product the Licensee then has available to it and, provided that such amount is, in the opinion of ViiV, reasonable in all the circumstances, the Licensee shall be permitted to sell that amount of Product in the Territory. This provision shall only apply to the extent that such termination would deprive Licensee of legal rights with respect to Product and Raw Materials.
- 13.2 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressed or intended to survive the termination or expiration of this Agreement in particular, but without limitation, Clauses 5, 10, 14.5, 14.6 and 14.7 and the relevant provisions of this Clause 13. In addition, any other provisions required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for the full observation and performance of this Agreement by the Parties.
- 13.3 Termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity and shall be without prejudice to any rights that any person may have pursuant to this Agreement for antecedent breaches.

14 WARRANTIES AND INDEMNITIES

- 14.1 Each of the Parties warrants that, to the best of its knowledge and belief:
- (a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and
 - (b) this Agreement constitutes legal, valid and binding obligations of that party in accordance with its terms.
- 14.2 Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix D or Appendix E accurately reflects the status of ViiV's patents and patent applications relating to the Compound and/or Products, (b) any of the Patents or Non-Territory Patents are valid or enforceable or (c) their exercise does not infringe any patent rights of any Third Parties.
- 14.3 The Licensee acknowledges that, in entering into this Agreement, the Licensee has independently evaluated any information supplied by the Licensor and ViiV (including, but not limited to, such information related to the Products), as well as the viability of this Agreement, before making its decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.
- 14.4 The Licensee acknowledges that the Licensor and ViiV do not in any way endorse the use of any Products sold or manufactured by the Licensee containing the Compound or

other active ingredient (including without limitation that used in the Licensed Combination Product), whether as single compounds or in combination with each other, or whether in combination with other compounds.

- 14.5 The Licensee hereby agrees to indemnify the Licensor, ViiV, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "Indemnified Person") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgements, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("Losses"), that arise in connection with (i) the Licensee's breach of this Agreement; or (ii) the Licensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured by or on behalf of Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or wilful misconduct by ViiV, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. ViiV shall, or shall procure that the Indemnified Person shall, provide Licensee with prompt written notice of such claims. Subject to Clauses 8.4 and 12.6, the Indemnified Person and Licensee will agree on the appropriate party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.
- 14.6 Clause 14.5 may be enforced, by each Indemnified Person against the Licensee under the Contracts (Rights of Third Parties) Act 1999.
- 14.7 Immediately upon the first administration of a Product to a human in accordance with this Agreement, and for a period of ten years after the expiration or earlier termination of this Agreement, the Licensee shall obtain and/or maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the pharmaceutical industry of the countries in which the Raw Materials and Products are manufactured, distributed and sold (as relevant), subject always to a minimum limit equivalent to U.S.\$10,000,000 per occurrence (or claim) and in the aggregate annually. Such product liability insurance shall insure against all liability, including product liability, personal liability, physical injury or property damage. The Licensee shall provide written proof of the existence of such insurance to the Licensor and ViiV upon request from either therefor and shall monitor such policy on a monthly basis to ensure that any cover is revised to take account of any currency fluctuations.

15 FORCE MAJEURE

If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an "Event of Force Majeure"), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If the Event of Force Majeure continues for a period of more than six months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party.

16 RIGHT OF SET OFF

- 16.1 All amounts due by the Licensee under this Agreement shall be paid in full in US Dollars or such other currency as may be agreed in full without any set-off or counterclaim and free and clear of all taxes, deductions, withholdings and other charges of whatever nature other than as required by law and the Licensee shall not be entitled to assert any set off or counterclaim in order to justify withholding payment of any such amount in whole or in part.
- 16.2 The Licensor and ViiV shall be entitled at any time, without notice to the Licensee, to set off any liability of the Licensor or ViiV to the Licensee (for example, in connection with the purchase of stock in hand and/or Raw Materials pursuant to Clause 13), against any liability of the Licensee to the Licensor or ViiV and may for such purpose convert or exchange any currency. Any exercise by the Licensor or ViiV of their rights under this Clause 16.2 shall be without prejudice to any other rights or remedies available to the Licensor or ViiV under this Agreement.

17 THIRD PARTY RIGHTS

- 17.1 Except for ViiV and ViiV's Affiliates or as otherwise expressly provided under this Agreement, a person who is not a party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.
- 17.2 ViiV and/or any of its Affiliates have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of this Agreement. The Licensee expressly agrees that ViiV or any of their Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a Party to this Agreement in place of the Licensor.
- 17.3 The rights of the Licensor under this Agreement shall be applicable to ViiV to the same extent as for the Licensor and the Licensor shall exercise such rights on behalf of ViiV if so requested by ViiV.

18 SEVERABILITY

- 18.1 In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining portions hereof shall remain in full force and effect.
- 18.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.
- 18.3 In the event that the terms and conditions of this Agreement are materially altered as a result of Clauses 18.1 or 18.2, the Parties and ViiV will seek to renegotiate the terms and conditions of this Agreement to resolve any inequities. If the Parties cannot reach an agreement, they agree to submit their dispute to mediation in accordance with Clause 28.3 of this Agreement. In the event that the dispute remains unresolved, either Party may terminate this Agreement by providing a written termination notice to the other Party.

19 ENTIRE AGREEMENT

- 19.1 This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings between the Parties relating to the transactions contemplated by this Agreement.
- 19.2 Subject to Clause 19.3, each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other party before the date of this Agreement. Each Party waives all rights and remedies which, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 19.3 Nothing in this Clause 19 limits or excludes any liability for fraud.

20 NOTICES

- 20.1 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement:
- (a) shall be in writing;
 - (b) shall be in the English language; and
 - (c) shall be:
 - (i) delivered personally;
 - (ii) sent by commercial courier;
 - (iii) sent by pre-paid post; or
 - (iv) sent by airmail, requiring signature on delivery.
- 20.2 The addresses for delivery of a notice or other communication are as follows:
- (a) to the Licensor at:

Rue de Varembe 7
CH-1202 Geneva
Switzerland,
e-mail: office@medicinespatentpool.org,

marked for the attention of General Counsel,
 - (b) to the Licensee at:

Adcock Ingram Limited, 1 New Road, Midrand, 1685,
South Africa

marked for the attention of the Company Secretary
 - (c) to ViiV at:

ViiV Healthcare,
980 Great West Road,
Brentford,
Middlesex TW8 9GS,
UK,

marked for the attention of Assistant General Counsel – External Affairs.

- 20.3 If a notice or other communication has been properly sent or delivered in accordance with this Clause 20, it will be deemed to have been received as follows:
- (a) if delivered personally, at the time of delivery;
 - (b) if sent by commercial courier, on the date and at the time of signature of the courier's delivery receipt;
 - (c) if sent by pre-paid post, 9.00 a.m. on the second Business Day after posting; or
 - (e) if sent by airmail, 9.00 a.m. on the fifth Business Day after posting.
- 20.4 The provisions of this Clause 20 shall not apply to the service of any proceedings or other documents in any legal action.
- 20.5 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement shall not be validly given if sent by e-mail.

21 ASSIGNMENT AND SUB-CONTRACTING

- 21.1 Neither this Agreement nor any interest arising out of or under this Agreement shall be assignable by the Licensor or the Licensee.
- 21.2 Save as expressly set out in Clauses 2.1, 2.2 or 2.4, and subject to those Clauses, neither the Licensor nor the Licensee shall be entitled to subcontract any of its rights or obligations under this Agreement.

22 NO COMPENSATION

To the extent that such exclusion is permitted by applicable law, no compensation, whether for loss of profit or any other reason whatsoever, shall be payable by any party arising from any lawful amendment or lawful termination or expiry of this Agreement.

23 COSTS

Each Party shall pay the costs and expenses incurred by it in connection with the entering into of this Agreement.

24 AMENDMENTS

The Parties agree that any amendment of this Agreement shall not be effective unless set out in writing, expressed to amend this Agreement and signed by authorised representatives of: (a) each of the Parties; and (b) ViiV. Notwithstanding the aforesaid, the Licensor (pursuant to approval from ViiV) shall have the right to amend Appendix D and Appendix E of this Agreement at any time without the Licensee's consent in order to include additional patents in those appendices.

25 WAIVER

The rights of each party under this Agreement: (a) may be exercised as often as necessary; (b) are cumulative and not exclusive of rights or remedies provided by law; and (c) may be waived

only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.

26 NO PARTNERSHIP OR AGENCY

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties (or between either Party and ViiV), nor constitute either Party as the agent of the other Party (or either Party as the agent of ViiV or ViiV as the agent of either Party).

27 EXECUTION IN COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

28 GOVERNING LAW AND JURISDICTION

- 28.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by English law.
- 28.2 Subject to Clause 28.3, the English courts shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the Parties submit to the exclusive jurisdiction of the English courts.
- 28.3 The Parties agree that in the event of a dispute they shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after 60 days from the date when it was first discussed (in any manner) between the Parties, either party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.
- 28.4 The Parties waive any objection to the English courts on the grounds that they are an inconvenient or inappropriate forum to settle any such dispute.
- 28.5 Without prejudice to the foregoing in relation to the Licensee, nothing in this Clause 28 shall prevent or restrict ViiV from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside England, to which election the Licensor and the Licensee hereby agree.

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

APPENDIX A

SPECIFIC CHEMICAL NAME OF THE COMPOUND

dolutegravir: (4*R*,9*aS*)-5-hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9*a*,10-hexahydro-2*H*-1-oxa-4*a*,8*a*-diazanthracene-7-carboxylic acid 2,4-difluorobenzylamide

APPENDIX B

LIST OF COUNTRIES FORMING THE TERRITORY

1. Afghanistan	30. E.Timor	60. Libya	91. Samoa
2. Algeria	31. Ecuador	61. Madagascar	92. São Tomé and Príncipe
3. Angola	32. Egypt	62. Malawi	93. Sénégal
4. Argentina	33. El Salvador	63. Malaysia	94. Seychelles
5. Armenia	34. Equatorial Guinea	64. Maldives	95. Sierra Leone
6. Azerbaijan	35. Eritrea	65. Mali	96. Solomon Islands
7. Bangladesh	36. Ethiopia	66. Marshall Islands	97. Somalia
8. Belize	37. Fiji	67. Mauritania	98. South Africa
9. Benin	38. Gabon	68. Mauritius	99. South Sudan
10. Bhutan	39. Gambia	69. Micronesia	100. Sri Lanka
11. Bolivia	40. Georgia	70. Moldova, Rep. of	101. Sudan
12. Botswana	41. Ghana	71. Mongolia	102. Swaziland
13. Burkina Faso	42. Guatemala	72. Morocco	103. Syrian Arab Republic
14. Burundi	43. Guinea	73. Mozambique	104. Tajikistan
15. Cambodia	44. Guinea-Bissau	74. Myanmar	105. Tanzania, U. Rep. of
16. Cameroon	45. Guyana	75. Namibia	106. Thailand
17. Cape Verde	46. Haiti	76. Nauru	107. Togo
18. Central African Republic	47. Honduras	77. Nepal	108. Tonga
19. Chad	48. India	78. Nicaragua	109. Tunisia
20. Chile	49. Indonesia	79. Niger	110. Turkmenistan
21. Colombia	50. Iran	80. Nigeria	111. Tuvalu
22. Comoros	51. Iraq	81. Pakistan	112. Uganda
23. Congo, Dem. Rep. Of The	52. Jamaica	82. Palau	113. Ukraine
24. Congo, Rep	53. Kenya	83. Papua New Guinea	114. Uzbekistan
25. Costa Rica	54. Kiribati	84. Panama	115. Vanuatu
26. Côte d'Ivoire	55. Kosovo	85. Paraguay	116. Venezuela
27. Cuba	56. Lao, People's Dem. Rep.	86. Peru	117. Vietnam
28. Djibouti	57. Lebanon	87. Philippines	118. West Bank and Gaza
29. Dominican Republic	58. Lesotho	88. Republic Kyrgyz	119. Yemen
	59. Liberia	89. Democratic People's Republic of Korea	120. Zambia
		90. Rwanda	121. Zimbabwe

APPENDIX C

LOW AND MIDDLE INCOME JURISDICTIONS

LIC

Afghanistan
Benin
Burkina Faso
Burundi
Cambodia
Central African Republic
Chad
Comoros
Congo, Dem. Rep
Eritrea
Ethiopia

Gambia, The
Guinea
Guinea-Bissau
Haiti
Korea, Dem Rep.
Liberia
Madagascar
Malawi
Mali
Mozambique

Nepal
Niger
Rwanda
Sierra Leone
Somalia
South Sudan
Tanzania
Togo
Uganda
Zimbabwe

LMIC

Armenia
Bangladesh
Bhutan
Bolivia
Cameroon
Cape Verde
Congo, Rep.
Côte d'Ivoire

India
Kenya
Kiribati
Kosovo
Kyrgyz Republic
Lao PDR
Lesotho
Mauritania

Samoa
São Tomé and Príncipe
Senegal
Solomon Islands
Sri Lanka
Sudan
Swaziland
Syrian Arab Republic

Djibouti
Egypt, Arab Rep.
El Salvador
Georgia
Ghana
Guatemala
Guyana
Honduras
Indonesia

UMIC

Angola
Albania
Algeria
American Samoa
Azerbaijan
Belarus
Belize
Bosnia and Herzegovina
Botswana
Brazil
Bulgaria
China
Colombia
Costa Rica

Micronesia, Fed. Sts.
Moldova
Mongolia
Morocco
Myanmar
Nicaragua
Nigeria
Pakistan
Papua New Guinea
Philippines

Fiji
Gabon
Grenada
Iran, Islamic Rep.
Iraq
Jamaica
Jordan
Kazakhstan
Lebanon
Libya
Macedonia, FYR
Malaysia
Maldives
Marshall Islands

Tajikistan
Timor-Leste
Tunisia
Ukraine
Uzbekistan
Vanuatu
Vietnam
West Bank and Gaza
Yemen, Rep.
Zambia

Namibia
Palau
Panama
Paraguay
Peru
Romania
Serbia
South Africa
St. Lucia
St. Vincent and the Grenadines
Suriname
Thailand
Tonga

Cuba
Dominica
Dominican Republic
Ecuador

Mauritius
Mexico
Montenegro

Turkey
Turkmenistan
Tuvalu

APPENDIX D

THE PATENTS

Appendix D

A.R.I.P.O.: Botswana, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

Country	Application Number	Application Date	Patent Number
Algeria	70738	28-Apr-2006	5531
	120523	24-Jan-2011	
A.R.I.P.O.	AP/P/2012/006445	24-Jan-2011	AP3551
Armenia	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Azerbaijan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Chile	2012-2080	24-Jan-2011	
Colombia	07-115501	28-Apr-2006	1886
	12-125.933	24-Jan-2011	6085
Costa Rica	2012-423	24-Jan-2011	
Dominican Republic	P2012-0205	24-Jan-2011	
Ecuador	SP-12-12106	24-Jan-2011	
Egypt	1167/2007	28-Apr-2006	
	1288/2012	24-Jan-2011	
India	3865/KOLNP/2007	28-Apr-2006	
	196/KOLNP/2011	23-Jul-2009	
	1971/KOLNP/2011	9-Dec-2009	
	1942/KOLNP/2011	8-Dec-2009	
	1811/KOLNP/2012	24-Jan-2011	
Indonesia	W-00200703559	28-Apr-2006	ID0025669

Country	Application Number	Application Date	Patent Number
	P-00201403774	25-Jun-2014	
	W-00201102355	8-Dec-2009	
	W-00201203037	24-Jan-2011	
Kyrgyzstan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Libya	PCT/US2011/022219	24-Jan-2011	
Malaysia	PI20071883	31-Oct-2007	MY-149571-A
	PI2012003346	24-Jan-2011	
Moldova	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Mongolia	4889	24-Jan-2011	3887
Morocco	PV/30388	28-Apr-2006	29460
	35145	24-Jan-2011	34002
Nigeria	2007/12/473/LOS/IP	28-Apr-2006	
	NG/C/2012/444	24-Jan-2011	NG/C/2012/444
Peru	001082-2012/DIN	24-Jan-2011	
Philippines	1-2007-502373	28-Apr-2006	1-2007-502373
	1-2012-501537	24-Jan-2011	
South Africa	2007/08970	28-Apr-2006	2007/08970
	2012/05586	24-Jan-2011	2012/05586
Tajikistan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Thailand	1201003753	24-Jan-2011	
Tunisia	TN2012/0376	24-Jan-2011	

Country	Application Number	Application Date	Patent Number
Turkmenistan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Ukraine	200711345	28-Apr-2006	96568
	A201209253	24-Jan-2011	105556
Vietnam	1-2007-02531	28-Apr-2006	12249
	1-2012-02514	24-Jan-2011	

APPENDIX E

NON-TERRITORY PATENTS REGISTERED IN COUNTRIES WHICH DO NOT FALL WITHIN APPENDIX C

Appendix E

Country	Application Number	Application Date	Patent Number
Albania	AL/P/2015/000276	24-Jan-2011	5403
Belarus	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Bosnia and Herzegovina	11737484.3	24-Jan-2011	EP2531027
Brazil	PI0610030-9	28-Apr-2006	
	PI0923217-6	8-Dec-2009	
	BR1120120186701	24-Jan-2011	
Bulgaria	6758843.4	28-Apr-2006	1874117
	11737484.3	24-Jan-2011	EP2531027
China P.R.	2.00680022891.4	28-Apr-2006	ZL200680022891.4
	2.00980135216.6	23-Jul-2009	ZL200980135216.6
	201310734307.X	23-Jul-2009	ZL201310734307.X
	2.01510553862.2	2-Sep-2015	
	200980149670.7	9-Dec-2009	ZL200980149670.7
	201510071074.9	9-Dec-2009	
	200980149697.6	8-Dec-2009	ZL200980149697.6
	201180015114.8	24-Jan-2011	ZL201180015114.8
Hungary	06758843.4	28-Apr-2006	1874117
Kazakhstan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Macedonia	MK/P/2015/352	24-Jan-2011	EP2531027
Mexico	MX/a/2007/013351	28-Apr-2006	302718
	MX/a/2011/006241	8-Dec-2009	321030
	MX/a/2013/008013	9-Jul-2013	

Country	Application Number	Application Date	Patent Number
	MX/a/2012/008774	24-Jan-2011	325889
Montenegro	P-2015/106	24-Jan-2011	EP2531027
Romania	6758843.4	28-Apr-2006	1874117
	11737484.3	24-Jan-2011	EP2531027
Serbia	P-462/15	24-Jan-2011	54123
Turkey	2013/11091	28-Apr-2006	2013/11091
	2015/09487	24-Jan-2011	TR201509487T4

SIGNATORIES

For and on behalf of THE MEDICINES PATENT POOL FOUNDATION

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Position: Executive Director
Date:



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Position: MD, PRESCRIPTION
Date: 25/06/19

