maximus

Varenicline Patient Group Direction (PGD)

Service Level Agreement

Confidential

[Publish Date]

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Service Level Agreement (SLA) for Varenicline PGD Delivery

On this day the [ ] day of [ ] 2025 (the "Effective Date") this Service Level Agreement ("the Agreement") is made between:

A. Maximus UK Services Limited, with registered address 18c Meridian East, Meridian Business Park, Leicester, England, LE19 1WZ and company incorporation number 09072343 ("Maximus"); and

B. [Insert full legal name of pharmacy] trading as [name of Pharmacy] with registered address [ ] and company registration number [ ] ("Provider").

(Each a Party and together the Parties)

1. Definitions

The following terms shall have the meaning ascribed to them below:

Applicable Laws: means all applicable laws, legislation, regulation, codes of practice, or requirements including any implementing regulations of any relevant government or governmental agency in the United Kingdom including but not limited to the Bribery Act 2010.

Critical Breach: means a breach by the Provider of any of the Regulations, the Critical Warranties set out in this Agreement or any other provision in the Agreement referred to specifically as a Critical Breach.

Critical Compliance Threshold: means full adherence to all applicable requirements set out in the PGD. Partial compliance is not permitted.

Good Industry Practice: means the exercise of reasonable skill, care, prudence, efficiency, foresight and timeliness which would reasonably be expected from a person properly skilled and experienced in providing products and/or services similar to those envisaged or set out in this Agreement.

Informed Consent: means it must be voluntary and informed, and the person consenting must have the capacity to make the decision for the purposes of this definition:

- 'voluntary' shall mean the decision to either consent or not to consent to treatment must be made by the User, and must not be influenced by pressure from Personnel, friends or family.
- 'informed' shall mean the User must be given all of the information about what the treatment involved, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead.
- 'capacity' shall mean the User must be capable of giving consent, which means they understand the information given to them and can use it to make an informed decision.

If an adult User has the capacity to make a voluntary and informed decision to consent to or refuse a particular treatment, their decision must be respected. This is still the case even if refusing treatment would result in their death, or the death of their unborn child. If a User does not have the capacity to make a decision about their treatment and they have not appointed a lasting power of attorney the healthcare professionals treating them can go ahead and give treatment if they believe it's in the User's best interests. Consent may be given verbally or in writing and a User is entitled to withdraw consent at any time. Consent for children and young people up to the age of 16 may be given by someone with parental responsibility.

Intellectual Property: means (a) patents, designs and trademarks (whether registered or unregistered), copyright, database rights and know how; (b) all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (c) applications, extensions and renewals in relation to any such rights.

Marks: means trademarks, service marks, trade names, logotypes or other means of identification of products or services, whether registered or unregistered, and whether domestic or foreign.

Maximus Approved Payee: means the setting up of the Provider on Maximus payment system contingent on the supply of the following documents by the Provider to Maximus before the commencement of Services (subject to verification, acceptance and satisfaction of Maximus) (i) Bank details on headed paper signed by a director listed at Companies House and (ii) a cancelled or void cheque, or (iii) a redacted bank statement (showing only the top portion with bank information), or (iv) a blank bank statement (screenshot of the top portion with bank information only).

Patient Group Direction (PGD): the written instrument established under the Human Medicines Regulations 2012 dated [ ] and executed by [ ], [ ] and [ ] permitting applicable Personnel to supply and/or administer Varenicline to a defined group of patients without the need for a prescription. and applies only within the defined scope of the approved protocol, including clinical criteria, dosage, and practitioner responsibilities.

Personnel: means a healthcare professional who is legally authorised and trained to operate under the PGD, and who acts strictly within its scope to supply and/or administer prescription-only medicines. This excludes the exercise of independent prescribing authority.

Regulations: means the regulations of the General Pharmaceutical Council (GPHC), National Centre for Smoking Cessation and Training (NCSCT), the National Institute for Health and Care Excellence (NICE) guidelines regarding prescribing and smoking cessation advice and the PGD.

User: means an eligible participant under the Prime Contract referred to the Provider by Maximus for smoking cessation advice and treatment.

Working Day: means Monday to Friday between 9am and 5pm, excluding public holidays.

2. Recitals and Purpose

2.1. On [ ] Maximus and [ ] (the "Authority") entered into a contract for Maximus to deliver smoking cessation services to eligible participants in [ ] (the "Prime Contract").
2.2. On [ ] the Authority provided Maximus with an additional budget to help deliver additional smoking cessation services.
2.3. On [ ] the Parties signed the PGD which shall form part of the Regulations with which the Provider shall comply when delivering the Services. The PGD shall be version-controlled and signed by all relevant parties. Any updated version shall supersede prior versions once formally issued by Maximus and receipt of which is acknowledged by the Provider.
2.4. This Agreement and the PGD sets out the terms upon which Maximus intends to contract with the Provider in order to ensure (i) the safe administration of pharmacotherapy within the scope of the PGD to Users in compliance with all Applicable Laws and the Regulations and (ii) accurate data collection and reporting to support service evaluation and quality assurance.
2.5. Any reference to Provider shall include an obligation to ensure that it's Personnel comply with the same.

3. Term and Termination

3.1. This Agreement shall commence on the Effective Date for a period of twelve (12) calendar months (the "Initial Term") whereupon it shall terminate unless Maximus provides the Provider with no less than fourteen (14) days written notice of its intention to renew this Agreement (the "Additional Term"). The Initial Term and any Additional Terms shall together be referred to as the "Term".
3.2. Maximus may terminate this Agreement at any time upon at least thirty (30) days written notice to the Provider.

3.3. Either Party may terminate this Agreement with immediate effect if:

3.3.1. The other Party materially breaches any of its obligations under this Agreement and such breach, capable of being remedied and not being a Critical Breach, is not remedied to the satisfaction of the other Party within ten (10) days after written notice thereof by the other Party.

3.3.2. A resolution is passed, or an order is made for the winding up (or equivalent order in the relevant jurisdiction) of the other Party, otherwise than for the purposes of a bona fide scheme of solvent amalgamation or reconstruction.

3.3.3. Either Party becomes subject to an administration order; a liquidator, receiver or administrative receiver or similar is appointed over any of its property or assets.

3.3.4. Either Party enters into an arrangement or composition with its creditors, ceases or threatens to cease to carry on business, becomes insolvent or ceases to be able to pay its debts as they fall due, or if a Force Majeure Event continues for a period of sixty (60) days.

3.4. Maximus may terminate this Agreement with immediate effect if (i) the Provider is or has been in Critical Breach, (ii) in the reasonable opinion of Maximus is likely to commit a Critical Breach.

3.5. If the Agreement is terminated by Maximus pursuant to (i) Clause 4.2 and/or (ii) Maximus failure to remedy a default under Clause 4.3 then Maximus shall pay the Provider the Fees for the Services delivered up until the effective date of termination.

3.6. Maximus shall be entitled to withhold Fees, whether or not invoiced by the Provider, for termination of this Agreement under Clause(s) 3.3.2 – 3.3.4 and Clause 3.4 and no such Fees shall be considered past due by Maximus.

4. Services

4.1. The Provider acknowledges and understands that Maximus makes no commitment as to the number of monthly or total Users that are referred to the Provider (if at all) during the Term.

4.2. The Parties shall each comply with their respective roles and responsibilities as set out in Schedule 1 (*Service Specification*) attached herewith, in order for the Provider to administer a smoking cessation service to Users and, if deemed applicable in the independent judgement of the Provider and in accordance with Clause 7 (*Critical Warranties),* the administration of Varenicline (the “Service”).

4.3. In the event of a conflict between the terms of this Agreement and the Applicable Laws and/or the Regulations (the “Conflict”), the Applicable Laws and the Regulations shall take priority.

4.4. If the Provider identifies a Conflict, it shall immediately notify the Maximus Appointed Representative in writing and set out the details of the alleged Conflict. The Provider shall immediately suspend delivery of the Service that is deemed to be in Conflict until such time as Maximus notifies the Provider in writing to resume the delivery of Services (the “Suspension Period”).

4.5. During the Suspension Period and provided (i) the Provider immediately notified Maximus of the Conflict and (ii) suspended the performance of the Service the Provider shall not deemed to be in Critical Breach.

4.6. During the Suspension Period the Provider shall not be entitled to claim, and Maximus shall not pay any Fees relating to the delivery of the Service. The Term shall continue to run during the Suspension Period.

4.7. If Maximus decides to resume the suspended Services, the Provider shall comply with any additional conditions and/or requirements including amendments to this Agreement stipulated by Maximus which shall be incorporated into this Agreement through a Change Request procedure.

4.8. The Provider acknowledges that Maximus may at its discretion choose not to resume the Services if it is unable to resolve the Conflict whereupon Maximus shall notify the Provider of its intention to terminate the Agreement.

5. Fees, Invoicing and Payment Terms

5.1. Prior to the commencement of the Services the Provider shall be required to become a Maximus Approved Payee.

5.2. Invoices shall be submitted by the Provider to Owain.jones@maximusuk.co.uk for the preceding calendar month in which the Services were delivered. Invoices must be submitted in PDF format and must set out on the face of it (i) a valid reference number, (ii) the period to which the invoice relates (iii) the number of Users assessed during the invoice period, (iv) itemised tax breakdown and (v) the cumulative total fees payable for the applicable month in accordance with the fee rate table set out at Schedule 1 (the "Fees").
5.3. All invoices shall be inclusive of all taxes, charges, VAT and expenses (if applicable) incurred by the Provider.
5.4. Invoices not submitted in accordance with Clause 5.2 shall not be paid by Maximus and Maximus shall not be considered in default of this Agreement.
5.5. In consideration for providing the Service, Maximus shall pay the Provider the Fees set out in an applicable invoice within thirty (30) days of receipt of a valid invoice.
5.6. The Parties acknowledge and confirm that the Fees shall be considered fair remuneration for delivering a smoking cessation intervention (including the administration of Varenicline if clinically appropriate), and not as an incentive to administer a specific product.
5.7. The Provider acknowledges that the Fees are not intended to be and shall not be construed as an inducement, promise or provision of any advantage to administer Varenicline.
5.8. Maximus shall be entitled to amend the Fees if the Authority amends the fees payable to Maximus under the Prime Contract. In the event of such amendment the Parties agree to enter into good faith discussions in order to determine the revised Fees.

6. Mutual Representations and Warranties

6.1. Each Party represents and warrants to the other Party that:
6.1.1. It is a duly organized, validly existing and in good standing as a corporation or other entity under Applicable Laws and the Regulations.
6.1.2. It has, and throughout the Term of this Agreement will retain, the full right, power, and authority to enter into this Agreement and perform its obligations hereunder.
6.1.3. The execution of this Agreement by its representative whose signature is set forth at the end of this Agreement has been duly authorized by all necessary corporate or organizational action of such Party.
6.1.4. When executed and delivered by both Parties, this Agreement will constitute the legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms.
6.1.5. It is not (at the time of entering into this Agreement) involved in any litigation, process, contract or investigation that could materially impact its ability or competency to perform its obligations; and
6.1.6. It shall comply with Applicable Laws.

7. Critical Warranties

7.1. The Provider acknowledges and understands that the representations and warranties in this Clause 7 and its adherence and conformance to the same is critical to the safe delivery of the Services and shall together be referred to as the "Critical Warranties". The Provider hereby represents and warrants:
7.1.1. It has obtained and shall obtain all permissions, licenses and consents necessary for it to comply with its obligations in accordance with the Agreement, Applicable Laws and the Regulations.
7.1.2. The Services shall be performed in a professional manner with the degree of skill and care that is required by good and sound professional procedures in any event such standard to be no less than Good Industry Practice.
7.1.3. It shall at all times comply with it's duties as set out under the Regulations and Applicable Law and ensure that those duties have an over-riding interest over any interest in this Agreement.
7.1.4. It shall at all times make independent, evidence-based clinical decisions when determining whether or not to administer Varenicline.
7.1.5. It shall not permit the existence of this Agreement to create any real or perceived pressure to recommend any particular course of treatment or drug and shall at all times

ensure that administration of Varenicline (if deemed appropriate) is in accordance with the Regulations, its professional judgement and in the User's best interest.

7.1.6. At all material times it shall have completed and maintain up-to-date (i) National Centre for Smoking Cessation (NCST) approved training for the provision of smoking cessation services and the administration of Varenicline.

7.1.7. It shall make such necessary disclosures to Users and/or any applicable regulators as is required under Applicable Law and/or the Regulations.

7.1.8. It shall implement and maintain a formal process for onboarding and removing Personnel authorised to operate under the PGD. This process shall include but not necessarily be limited to:

7.1.8.1. Ensuring Personnel haves signed the current approved version of the PGD prior to delivering any aspect of the Service.

7.1.8.2. Maintain a local register of all Personnel signed onto the PGD, including the date of signature, role, and evidence of competency.

7.1.8.3. Retaining signed copies of the PGD for all authorised Personnel and ensuring these are available for audit or inspection upon request.

7.1.8.4. Promptly removing Personnel from the register where they are no longer authorised, competent, or employed to deliver the Service, and ensuring they cease all activity under the PGD with immediate effect.

7.1.8.5. Ensuring the register is regularly reviewed and kept up to date.

7.2. If the Provider breaches any part of this Clause 7, or Maximus reasonably believes that there is a risk of the Provider breaching any provision of this Clause 7, without prejudice to any other right of Maximus under Applicable Laws, it shall be entitled to terminate this Agreement with immediate effect.

8. Records and Reporting

8.1. The Provider shall submit to PharmOutcomes monthly reports relating to the delivery of the Service, which shall include (but not be limited to) (the "Report(s)"):

8.1.1. The number of Users assessed for the Service.

8.1.2. Number of Users who received Varenicline.

8.1.3. Carbon monoxide monitoring.

8.1.4. Number and details of adverse side effects reported by Users. For the avoidance of doubt the reporting to Maximus of matters arising under this Clause 9.1.4 does not affect or relinquish the Providers reporting obligations in accordance with the Regulations or specifically to Varenicline through the MHRA Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

8.1.5. Any concerns or complaints received in respect of the delivery or receipt of the Service;

8.1.6. Any incident reporting that the Provider deems necessary to report to Maximus.

8.2. The Provider shall ensure that the Reports are sufficiently anonymised and do not disclose any User personal data or User sensitive personal data.

8.3. Failure to submit Reports for two consecutive months during any 6-month period may lead to Maximus terminating this Agreement.

9. Quality Assurance & Audit

9.1. The Provider shall implement and maintain a documented internal audit programme to ensure compliance with the requirements of the (i) PGD, and (ii) the Regulations (the "Audit Requirements")

9.2. The Provider will submit a quarterly summary report setting out details of it's compliance and non-compliance with the Audit Requirements the form of which is set out in Appendix B herewith.

9.3. Each Quarterly Report shall contain an executive summary which sets out (i) the Providers percentage compliance with the Audit Requirements, (ii) a statement as to whether it has met the Critical Compliance Threshold; and (iii) any identified risks or trends and corrective actions taken.

9.4. The Provider and/or the Authority (including any third parties appointed by them) have the right upon reasonable written notice to the Provider to enter upon the Provider's premises and audit the Provider's records and financial records in connection with this Agreement and in doing so to make, retain and remove copies of any such records it deems necessary.

10. Insurance

10.1. The Provider shall at all material times ensure that it has in place all mandatory and necessary insurance as required by it under Applicable Laws and/or the Regulations including but not limited to (i) professional indemnity (ii) employers liability and (iii) public liability insurance with a reputable insurer and with such limits of indemnity that is customary having due regard to the nature and scope of the Service, but which shall at all material times be no less than the indemnity limit required under Applicable Law and/or the Regulations.

10.2. The Provider shall provide confirmation of its insurance to Maximus upon reasonable written request.

11. Appointed Representatives

11.1. Each Party agrees to nominate the individual set out below, with appropriate level of expertise, skill and qualifications in order to manage and/or act as a point of contact between the Parties (the "Appointed Representatives").

11.2. If, in the reasonable opinion of Maximus, the performance or conduct of the Provider's Appointed Representative is deemed unsatisfactory, Maximus may request that the Provider replace it's Appointed Representative.

11.3. The Provider shall appoint a replacement Appointed Representative as soon as possible and the Appointed Representative shall be of at least the equivalent skill and training and qualifications as the outgoing Appointed Representative. Failure to appoint a replacement Appointed Representative shall be construed as a Critical Breach.

- Maximus Appointed Representative: Owain Jones / Owain.jones@maximusuk.co.uk
- Provider Appointed Representative: [Name / Email Address]

12. Data Protection

Regarding the processing of User personal data in respect of the Users the Provider shall only process, use, transfer, or pass on this data:

12.1. In compliance with the then valid data protection regulations as defined in the Data Protection Act 2018.

12.2. Only in accordance with the instructions given by and for the purposes of the User.

12.3. The Provider shall protect personal data against misuse and loss and shall take all technical and organizational measures to achieve this.

12.4. The Provider will inform Maximus without delay if, in the Providers view, work to be performed by the Provider, contravenes data protection regulations.

12.5. In accordance with the Data Protection Act 2018, the Parties shall ensure that the employees, contractors, agents and subcontractors working for them have signed a written declaration of compliance with data secrecy regulations, and that they have received the appropriate instructions.

12.6. These far-reaching duties of data protection shall remain in force after the termination of this Agreement.

13. Intellectual Property

13.1. Unless stated expressly in writing in this Agreement, neither Party will acquire any ownership interest in or licence of the other's Intellectual Property by virtue of this Agreement.

13.2. Upon creation of the Reports all rights, interest and title in the Reports shall transfer to and belong to Maximus and the Provider shall at its cost take all necessary steps to ensure that all rights, title and interest in the Reports is assigned to Maximus.

13.3. Nothing in this Agreement shall confer in any Party to this Agreement any rights, whether by way of ownership, license or right to use, in any of the Marks of the other Party. Neither Party shall use the names or Marks of the other Party in any advertising, publicity, endorsement or otherwise without the other Party's prior written consent.

13.4. The terms of this Clause 13 shall survive the termination, expiration, non-renewal, or rescission of this Agreement.

14. Indemnification and Limitation of Liability

14.1. THE PROVIDER ACKNOWLEDGES AND AGREES THAT MAXIMUS IS NOT A PROVIDER OF THE SERVICE. MAXIMUS HAS NOT CARRIED OUT AN ASSESSMENT OF THE USER TO DETERMINE ITS SUITABILITY FOR ANY SMOKING CESSATION INTERVENTION, THERAPY, PHARMACOTHERAPY OR DRUG. MAXIMUS SPECFICALLY RELIES ON THE EXPERTISE AND PROFESSIONAL JUDGEMENT AND DUTY OF CARE OF THE PROVIDER TO DETERMINE THE USER'S ELIGIBLITY AND SUITABILITY FOR SMOKING CESSATION SERVICES AND APPLICABLE PHARMOCOTHERAPY AND/OR DRUG.

14.2. MAXIMUS SPECIFICALLY EXCLUDES ANY AND ALL LIABILITY WHETHER UNDER BREACH OF CONTRACT, TORT OR STATUTE FOR (I) ANY INJURY, HARM OR OTHER LIABILITY CAUSED TO ANY USER BY THE PERFORMANCE OF THIS AGREEMENT (II) ANY ALLEGATION THAT THIS AGREEMENT OR PART THEREOF CONSITUTES ANY FORM OF INDUCEMENT TO ADMINISTER A SPECIFIC DRUG AND THE PROVIDER SHALL SPECIFICALLY INDEMNIFY, DEFEND AND HOLD HARMLESS MAXIMUS AGAINST ANY CLAIM AGAINST IT ARISING OUT OF THE DELIVERY OF THE SERVICE OR ANY ACT OR OMMISSION OF THE PROVIDER.

14.3. The Provider shall not limit it's liability and at it's expense defend, indemnify and hold harmless Maximus and it's respective successors, officers, directors and employees from and against any and all claims, actions, demands, liabilities, settlements, costs, damages and fees (including reasonably incurred legal costs) arising, in whole or in part, in connection with (i) death or personal injury, (ii) fraud or fraudulent misrepresentation, or (iii) breach of Clause 4 (*Services*) (iv) breach of Clause 7 (*Critical Warranties*) (v) breach of Applicable Law and/or the Regulations.

14.4. The Provider shall specifically indemnify, and at its expense defend and hold harmless Maximus, it's directors, officers and employees from any allegation that the payment of the Fees constitutes any improper inducement, bribe or pressure to prescribe a specific drug and/or has contributed in whole or in part to the Providers breach of Applicable Laws and/or the Regulations.

14.5. Without prejudice to Clauses 14.1 – 14.4 in no event shall either Party be liable for any indirect, incidental, special or consequential damages, loss of anticipated savings, loss of business, economic loss, loss of profit or loss of goodwill.

14.6. The Provider shall not settle any indemnified claim without Maximus's prior written consent or disclose any settlement nor to permit the complaining party to disclose any settlement without first obtaining Maximus's prior written permission (which may be withheld in its sole discretion).

15. Confidentiality

15.1. Confidential Information" means any information that is disclosed by one Party or its Affiliates ("Discloser") to the other Party ("Recipient"), which, at the time it is disclosed, in any form, is identified or designated by the Discloser as "confidential or proprietary" or reasonably should be known by the Recipient to be proprietary or confidential information of the Discloser including but not limited to information, data relating to financial, business, technical or other data and all other confidential information (whether written, oral, visual or in an electronic form or in magnetic or other media) or which it has access to as a result of any discussions or

dealings or which is learned by a Party through observations made during visits to any premises of the other Party.

15.2. The Recipient shall not, either during the term of this Agreement or thereafter, use or disclose the Discloser's Confidential Information without the prior written consent of the Discloser, except:

15.2.1. as specifically permitted in this Agreement; or

15.2.2. for the purpose of performing its obligations or enforcing its rights under this Agreement, provided that such disclosures are made only to those employees, consultants, contractors, professional advisors, or third-party service providers with a direct business need to know and who have agreed in writing to confidentiality provisions that provide the Discloser with at least as much protection as those contained herein ("Representatives").

15.3. Confidential Information will exclude information that:

15.3.1. The Recipient can demonstrate to have had rightfully and lawfully in its possession prior to disclosure to the Recipient by the Discloser.

15.3.2. Is at the material time available to the public through no wrongful act or breach of this Clause 15 by the Recipient.

15.3.3. Has been rightfully received by the Recipient from a third party who has the right to transfer or disclose it to the Recipient without restriction on disclosure.

15.3.4. Has been independently developed by the Recipient without the use of any Confidential Information as evidenced by appropriate documentation; or

15.3.5. Has been approved for release by written authorization executed by an authorized officer of the Discloser.

15.4. Notwithstanding the foregoing, if the Recipient is required to disclose Confidential Information pursuant to a court order or other requirement of Applicable Law the Recipient shall provide the Discloser with prompt written notice of any such requirement sufficient to permit the Discloser to seek and obtain appropriate protective orders prior to such disclosure by the Recipient.

15.5. All Confidential Information remains the property of the Discloser and no license or other rights in the Confidential Information is granted hereby. Upon termination of this Agreement for any reason, or at any time at the request of the Discloser, the Recipient will return to the Discloser all of the Discloser's Confidential Information, in whatever form, which is in its custody or control or the custody and control of any Representative or at the option of the Discloser ensure that it and all Representatives destroy the Confidential Information in such a manner that makes it irredeemable incapable of being reconstituted and provide to the Disclosure a certificate of compliance by an authorized officer.

16. Miscellaneous

16.1. *Assignment.* The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the Parties' respective successors, executors, and administrators. The Provider may not assign the benefits or obligations under this Agreement to any other Party without Maximus's prior written consent. Maximus may assign the benefits or obligations under this Agreement to any other Party.

16.2. *Subcontracting.* The Provider shall not be permitted to subcontract any part of this Agreement without the prior written consent of Maximus. The Provider shall not be relieved of any obligation under this Agreement by virtue of performance of any portion of services by a subcontractor. The Provider shall remain responsible and liable for any and all (a) performance required hereunder, including the proper supervision, coordination, and performance of the obligation subcontracted; and (b) acts and omissions of any subcontractor (including, such subcontractor's employees and agents, to the same extent as if such acts or omissions were by the Provider.

16.3. *Governing Law and Jurisdiction.* This Agreement is governed by and construed in accordance with the laws of the United Kingdom and the Courts of the England and Wales shall have exclusive jurisdiction to hear and rule upon any dispute relating to the present agreement, including its interpretation and effects.

16.4. *Notices.* Any notice required or permitted hereunder shall be in writing and shall be given to the appropriate party at the addresses set out at the top of this Agreement. Such notice shall be deemed given (i) upon personal delivery to the appropriate address (ii) five (5) Working

Days after the date of mailing if sent by certified or registered mail; or (iii) three (3) Working Days after the date of deposit with a commercial courier service offering next business day service with confirmation of delivery.

16.5. *Survival of Terms.* All terms and provisions of this Agreement, including any and all exhibits, addenda and amendments hereto, which by their nature are intended to survive any termination or expiration of this Agreement, shall so survive.

16.6. *Relationship between the Parties.* Nothing in this Agreement will be construed as creating a partnership, franchise, employment, joint venture, or agency relationship or fiduciary duty of any kind between the Parties.

16.7. Entire Agreement and Variation. This Agreement, together with all attached Schedules, constitutes the full and complete understanding and agreement of the Parties and supersedes all prior understandings and agreements relating to such subject matter. Any waiver, modification or amendment of any provision of this Agreement shall be effective only if in writing and signed by the Parties.

SCHEDULE 1 - Service Specification

1. Eligibility Criteria

1.1. Users assessed by the Provider must be adults aged over the age of 18 seeking smoking cessations support.
1.2. Users must meet the clinical inclusion criteria specified within the approved PGD for varenicline.
1.3. Provider must assess Users for contraindications and risk factors before and during any assessment and consideration for smoking cessation therapies including the administration of Varenicline.

2. Pharmacy Responsibilities

2.1. In addition to the responsibilities set out in the Agreement the Provider shall also:
- **2.1.1.** Organise and conduct a structured smoking cessation consultation with the User during which the Provider will use it's professional expertise to independently determine the User's eligibility and suitability for smoking cessation therapy and determining whether Varenicline may be a suitable pharmacotherapy.
- **2.1.2.** Offer follow-up support and adherence monitoring as per NHS smoking cessation guidelines.
- **2.1.3.** Provide lifestyle advice to support quitting efforts alongside pharmacotherapy.
- **2.1.4.** Ensure clear documentation of all interventions, prescriptions, and patient progress.
- **2.1.5.** Ensure A representative attend a medicines management committee (as and when required/requested) in accordance with the terms and frequency as set out in the terms of reference.
- **2.1.6.** Ensure all Provider staff involved in delivery of the Service are trained to the required standards, including:
  - **2.1.6.1.** Completion of relevant NCSCT training modules (see Appendix A).
  - **2.1.6.2.** Completion of CPD updates in line with NICE guidance and NHS smoking cessation frameworks.
  - **2.1.6.3.** Maintain compliance with GPhC regulations and professional standards.
  - **2.1.6.4.** Ensure all consultations and PGD provisions are documented accurately in the pharmacy system.
  - **2.1.6.5.** Submit regular data reports to support service monitoring and quality assurance (see Appendix B).
  - **2.1.6.6.** Immediately escalate critical incidents to Maximus.

2.2. All clinical activity, including the supply and/or administration of varenicline, must be carried out strictly in accordance with the scope, conditions, and limitations of the PGD.
2.3. Ensure safeguarding responsibilities are understood and met in line with local authority requirements, Applicable Laws and the Regulations including escalation of safeguarding concerns arising during consultations.
2.4. The Provider shall be required to complete an Initial Consultation of each User referred to it by Maximus in accordance with the below requirements to determine the User suitability for a smoking cessation intervention (the "Initial Consultation") All aspects of the Initial Consultation as set out in this paragraph 2.4 will need to be completed in order for the Provider to qualify for the Initial Consultation Fee:
- **2.4.1.** Confirm the Service User is 18 years or older.
- **2.4.2.** Assess motivation to quit smoking.
- **2.4.3.** Take a full medical history, including:
  - **2.4.3.1.** Current medications and comorbidities.
  - **2.4.3.2.** Mental health history;
  - **2.4.3.3.** Renal function;
  - **2.4.3.4.** Cardiovascular risk
- **2.4.4.** Identify any contraindications or cautions (e.g. pregnancy, psychiatric illness, hypersensitivity to Varenicline) based on PGD criteria 1.
- **2.4.5.** The Provider must obtain the written and signed Informed Consent of the User to proceed with a smoking cessation intervention and the recommendation and use of an applicable pharmacotherapy (if applicable).

2.4.6. Confirm the User agrees to engage with ongoing behavioural support as part of the stop smoking programme.

2.4.7. The Provider shall in conjunction with the User create a treatment plan which shall include:

2.4.7.1. A smoking cessation date.

2.4.7.2. Information on how Varenicline (if administered in accordance with this ~~Agreecent~~Agreement) will be supplied (e.g. starter pack).

2.4.7.3. Discuss potential side effects and what to do if they occur.

2.4.8. As part of the Initial Consultation the Provider shall ensure that it records all findings and decisions and notifies the User's GP (where consent is given) using a standard template or secure communication.

2.5. If upon the conclusion of the Initial Consultation the Provider assesses the User to be clinically suitable for Varenicline and the Provider is satisfied having due regard to all the it's \obligations set out in the Agreement that there are no contraindications then the Provider may administer Varenicline.

2.6. In accordance with the User's treatment plan the Provider shall invite the User to ~~a~~ one or more (subject to a maximum of five) follow up consultations during which the Provider shall conduct the assessment set out in paragraph 2.7 (the "Subsequent Consultation(s)"). The Provider must satisfy all the criteria set out in paragraph 2.7 to be eligible for the Subsequent Consultation Fee.

2.7. Assess the User's adherence to Varenicline.

2.7.1. Discuss and, record and if applicable report any side effects or adverse reactions.

2.7.2. Evaluate smoking status, often using carbon monoxide (CO) monitoring to confirm abstinence.

2.7.3. Provide ongoing behavioural support and encouragement.

2.7.4. Address any barriers or challenges the User is facing in their quit attempt.

2.7.5. Reinforce coping strategies and relapse prevention techniques.

2.7.6. Monitor for any emerging contraindications or concerns (e.g. mental health symptoms).

2.7.7. Adjust the treatment plan if necessary (e.g. dose changes, referral to GP).

2.7.8. If appropriate, supply the next stage of Varenicline treatment under the PGD.

2.7.9. Ensure the User understands how to take the medication and what to expect.

2.7.10. Record the consultation details, including CO readings and medication supplied.

2.7.11. Update the User's GP if required and consent has been given.

2.7.12. Undertake a final consultation between weeks 10–12 from the date of the Initial Consultation and:

2.7.12.1. Discuss long-term strategies for staying smoke-free.

2.7.12.2. Provide final support and signpost to further services if needed

3. Maximus Responsibilities

3.1. Provide the Provider with a written copy of the PGD.

3.2. Provide governance oversight for the PGD service.

3.3. Ensure the PGD remains legally authorised and up to date.

3.4. Facilitate training and competency assessment opportunities for its own staff.

3.5. Follow guidance on eligibility criteria and referral pathways.

3.6. Facilitate the medicines management committee.

3.7. Conduct audit and evaluation of Provider performance.

3.8. Ensure timely payment of Fees.

4. Fee Rate Table

Category	Fees (£) inc. applicable VAT / taxes and expenses
Attendance at onboarding webinar and within 30 days of Maximus written acceptance of Provider.	175.00
Initial Consultation Fee per User consultation.	01/07/2025 – 01/07/2026: 33.00 01/ 07/2026 – 01/07/2027: 35.00 01/07/2027 – 01/07/2028: 37.00
Subsequent Consultation Fee per User consultation.	01/07/2025 – 01/07/2026: 10.00 01/ 07/2026 – 01/07/2027: 12.00 01/07/2027 – 01/07/2028: 14.00

Providers shall only be permitted to claim for one Initial Consultation per User and up to a maximum of five Subsequent Consultations per User. one Subsequent consultation for per User.

Appendix A

Appendix A: Required NCSCT Training Modules for Pharmacists

1. NCSCT Stop Smoking Practitioner Certification

Description: This comprehensive module provides foundational knowledge and skills necessary for effective smoking cessation support.

Access Link: NCSCT Practitioner Training

2. Specialist Module: Smoking Cessation and Mental Health

Description: Focuses on tailored cessation strategies for individuals with mental health conditions.

Access Link: Smoking and Mental Health Module

3. Specialist Module: Smoking Cessation in Pregnancy

Description: Addresses the unique considerations and approaches for supporting pregnant individuals in quitting smoking.

Access Link: Smoking in Pregnancy Module

4. Vaping: A Guide for Healthcare Professionals

Description: Offers evidence-based guidance on the use of e-cigarettes as a smoking cessation tool.

Access Link: Vaping Module

5. Very Brief Advice (VBA) on Smoking

Description: Teaches the delivery of concise advice to smokers, designed to be implemented in under 30 seconds.

Access Link: VBA Module

6. NCSCT Standard Treatment Programme (STP)

Description: A structured guide outlining the key steps and information to support smoking cessation consultations.

Access Link: Standard Treatment Programme

All pharmacists involved in delivering the PGD must complete the training modules listed in Appendix A prior to service commencement. Certificates of completion should be maintained and made available upon request for audit purposes.

Appendix B

PGD Data Reporting Draft 1