**IMVO-MAH CO-OPERATION AGREEMENT**

1. **Parties**
2. Irish Medicines Verification Organisation, a company limited by guarantee, with its registered office at 7 Clanwilliam Terrace, Dublin 2, D02 CC64, Ireland, and registered in Ireland, registered number 602266, (“**IMVO**”); and
3. [Name of Company], [type of company] (Company Number (*or other applicable national identification code*]), whose registered office is at [registered /official address of Company] (the “**Company**”).

Both IMVO and the Company are hereinafter also individually referred to as a “Party” and collectively as the “Parties”.

WHEREAS

1. IMVO is a non-profit organisation set-up by stakeholders in the medicines supply chain in Ireland pursuant to Article 31 of the Delegated Regulation, to establish and manage the National Medicines Verification System in Ireland.
2. The Company is a Marketing Authorisation Holder (MAH) as defined in Section 2 of this Agreement.
3. The Irish Medicines Verification System (IMVS) as defined in Section 2 is part of the European Medicines Verification System.
4. Pursuant to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the National Medicines Verification System shall be borne by MAHs for Medicinal Products in the relevant market.
5. The purpose of this Agreement is to agree on the implementation and maintenance of the IMVS by IMVO, the financing of the IMVS, the invoicing of the Company by IMVO and the Parties’ related obligations.
6. The Parties agree that amendments to EU legislation relating to falsified medicines, including the Directive and the Delegated Regulation, may lead to extra responsibilities on the Parties, in which case the Parties may need to update or amend this Agreement accordingly. Furthermore, the Parties agree to update or amend this Agreement, if necessary, based on changes to the agreement between IMVO and EMVO or IMVO and its IT Service Provider.
7. **Definitions**

“**Agreement**” means this Cooperation Agreement and its appendices;

“**Confidential Information**” means any and all technical and/or commercial information and other material of a Party relating to, without limitations, its business, business plans, financial details, customers, partners, intellectual property, facilities, products, techniques and/or processes whether in oral, written or electronic form, that is specifically marked or otherwise communicated as being confidential at the time of disclosure or reasonably should be understood as being confidential. IMVO’s Confidential Information includes information provided by EMVO under a non-disclosure agreement with IMVO and other confidential information;

“**Data**” means information uploaded, processed, transferred, generated or stored in the EMVS or the IMVS as set out in the Directive and the Delegated Regulation (in particular its Article 33(2));

“**Data Protection Legislation**” means the Data Protection Acts 1988 and 2018, and the European Union General Data Protection Regulation (Regulation (EU) 2016/679 of 27 April 2016), Directive 2002/58/EC (as amended), European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011 (S.I. No. 336 of 2011) and any other laws and regulations relating to the processing of personal data and privacy which apply to a Party and, if applicable, the guidance and codes of practice issued by the relevant supervisory authority as well as any other rules, procedures, standards and guidelines which apply to either Party under law;

“**Delegated Regulation**” means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use;

“**Directive**” means the Directive on Falsified Medicines 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, as well as, the relevant implementing Irish laws, as applicable;

“**EMVO**” means the European Medicines Verification Organisation, which is the non-profit legal entity established to set up and manage the European Hub in accordance with the Directive and Delegated Regulation;

“**EMVS**” means the European Medicines Verification System, which is set up and managed in accordance with Chapter VII of the Delegated Regulation. The EMVS consists of the European Hub and the National Systems and allows wholesalers and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of Medicinal Products in accordance with the provisions of the Directive and the Delegated Regulation;

“**European Hub**” means the component of the EMVS that serves as a central information and data router for the transmission of Data to and from the National Systems;

“**IMVO**” means the Irish Medicines Verification Organisation, which is responsible for the implementation of the National System for Ireland in accordance with the Directive and the Delegated Regulation;

**“IT Service Provider”** means the provider(s) of IT services with whom IMVO has signed an agreement in relation to the implementation and operation of the IMVS;

**“IT Software Provider”** means a legitimate software service provider / connected system support organisation (be they internal or external to an authorised user of the IMVS) that provides services to pharmacies, wholesalers or to other authorised users of the IMVS;

“**Intellectual Property Rights**” means all patents and patent rights, trademarks and trademark rights, trade names and trade name rights, service marks and service mark rights, service names and service name rights, brand names, copyrights and copyright rights, trade dress, business and product names, logos, slogans, trade secrets, industrial models, utility models, design models, designs, rights in confidential information, software, know-how, rights in the nature of unfair competition rights and rights to sue for passing off, and all pending applications for and registration of patents, trademarks, service marks and copyrights together with all connected and similar or analogous rights in any country or jurisdiction for the full term thereof;

“**IMVS**” means the Irish National Medicines Verification System implemented by IMVO;

“**MAH**” means the Company as well as other holders of a marketing authorisation for a Medicinal Product with effect on the territory of Ireland. MAH also includes parallel importers of Medicinal Products in Ireland;

“**Medicinal Products**” for the purposes of this Agreement shall mean medicinal products which are required by the Delegated Regulation to bear safety features on their packaging;

“**National Medicines Verification System**” or “**National System**” means a national medicines verification system that is connected to the European Hub and allows wholesalers and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

“**Personal Data**” has the meaning given to it in Data Protection Legislation; and

“**Security Breach**” means an event that endangers the security or the functioning of the EMVS (including, where applicable, the IMVS), including but not limited to any security breach leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or unauthorised access to Data or (other) Confidential Information, as well as the unauthorised upload of data or the upload of illegitimate data to the EMVS, including, where applicable, the IMVS;

Any other capitalised terms not defined in this Agreement are given the meaning allocated to them in the Directive and/or the Delegated Regulation.

1. **Obligations of IMVO**

IMVO undertakes to:

1. develop, implement and maintain the IMVS in compliance with the Directive, Delegated Regulation and this Agreement;
2. take appropriate security measures to protect the integrity and safety of the IMVS as well as confidentiality of the Data in the IMVS;
3. cooperate in good faith with the Company in the development, testing, implementation, operation and maintenance of the IMVS;
4. give access to the IMVS only to wholesalers and persons authorised or entitled to supply medicinal products whose identity, role and legitimacy has been verified by IMVO as required by Article 37(b) of the Delegated Regulation, so as to allow their IT Software Provider(s) access to the IMVS when necessary; and
5. process in the IMVS the Data of MAHs that have signed an agreement with IMVO and that have connected and entered into the European Hub, unless otherwise required by the Health Products Regulatory Authority (**“HPRA”**).

IMVO shall publish on its official website, or some other manner deemed appropriate by IMVO, information about changes in the organisation and its legal status (e.g., registered address and address of management, representative etc.), and on the process of the development and implementation of the IMVS.

Upon due request in compliance with applicable law, IMVO may provide Ireland’s national competent authorities with access to the Company’s Data available in the IMVS within the scope specified in Article 39 of the Delegated Regulation, in which case IMVO will inform the Company thereof without undue delay, unless doing so would be prohibited by law.

1. **Obligations of the Company**

The Company undertakes to:

1. perform its obligations set out in the Directive, Delegated Regulation and this Agreement duly and in a timely manner and report to IMVO on the performance of such obligations as is reasonably requested by IMVO;
2. pay fees to IMVO in accordance with Section 5 of this Agreement;
3. inform IMVO in writing of any relevant change in the status of the marketing authorisation(s) for Medicinal Product(s) of which the Company is the holder, where the result of such change would be that the Company’s Data is no longer held in the IMVS.
4. designate a contact person for the purposes of this Agreement and communicate it to IMVO;
5. directly connect and enter the Data to the European Hub;
6. cooperate in good faith with IMVO in the development, testing, implementation, operation and maintenance of the IMVS; and
7. provide IMVO with exhaustive information necessary for the execution of this Agreement, including the payment of fees, including, without limitation, details of its legal status: registered address, company registration number and/or other national identification code, tax number and other data as applicable for the identification of the Company and/or any third party nominated by the Company to pay, on its behalf, fees due on IMVO under this Agreement. A registration form may be provided by IMVO for the purpose of providing the relevant information. The Company shall immediately notify IMVO of any changes in the information that has been supplied to IMVO. For the avoidance of doubt, if a nominated third party fails to pay invoices in respect of any fee due to IMVO, on behalf of the Company, the Company remains liable for the fee.

The Company warrants that the Data relating to the Medicinal Products for which it is the MAH, have been entered in the European Hub correctly, fully, accurately and not misleadingly, and that such Data will ensure the proper functioning of the IMVS and EMVS in compliance with the Directive and the Delegated Regulation when used by other MAHs, wholesalers and persons authorised or entitled to supply medicinal products to the public.

1. **Financing of the IMVS**
   1. ***Fees***

The Company shall pay the fees as set out in Appendix 1 of this Agreement.

IMVO has the right to, at any time during the term of this Agreement, amend or vary the fees in any event including (but not limited to) instances where IMVO’s IT Service Provider or EMVO increases its fees or charges additional fees to IMVO or if the fees related to the development, testing, implementation, operation, maintenance or update of the IMVS increase or decrease for any other reasons.

IMVO shall notify the Company of such amendment in fees at least ninety (90) days in advance and provide the reasoning behind the amendment.

* 1. ***Payment terms***

All payments will be made in Euro and all fees expressed herein are exclusive of value added tax (VAT). The Company shall be responsible for the payment of any withholding taxes, similar taxes, duties levies and such payments relating to the fees payable under this Agreement.

Payment term is thirty (30) days net from the date of the invoice. Interest for delayed payments will accrue in accordance with the European Communities (Late Payment in Commercial Transactions) Regulations 2012 (as amended).

In addition to any other rights and remedies available to IMVO, if the Company fails to pay an invoice within sixty (60) days of the invoice due date, IMVO reserves the right to:

1. notify the HPRA of the non-fulfilment of the Company’s obligation under Article 31(5) of the Delegated Regulation, and
2. suspend access to the IMVS in respect of the Company’s Data until all overdue invoices are settled.

If the fees are paid by a third party on behalf of the Company, the Company shall in any case remain solely responsible and liable for the compliance with this Agreement, including the Directive and the Delegated Regulation.

1. **Intellectual Property Rights**

The Intellectual Property Rights:

1. to the IMVS will be held by IMVO (and/or its subcontractors and/or IT Service Provider; and
2. to the EMVS will be held by EMVO (and/or its subcontractors and/or IT service provider).

For the avoidance of doubt, the Company and the users of the IMVS and the EMVS shall not obtain any Intellectual Property Rights to the IMVS or EMVS.

1. **Ownership and access rights to Data**

The Parties agree that ownership of (and access to) the Data shall be determined in accordance with Articles 38 and 39 of the Delegated Regulation. Any person that lawfully generates Data in the IMVS shall be the owner of said Data.

As set out in Section 3 of this Agreement, IMVO may allow access to all Data in the IMVS to Ireland’s national competent authorities.

IMVO will only grant access to the IMVS and the Data contained therein to Ireland’s national competent authorities for the purposes outlined in Article 39 of the Delegated Regulation unless it is otherwise required to do so under the Directive, Delegated Regulation or other applicable legislation.

1. **Processing of personal data**

The Company shall share certain limited Personal Data (‘Shared Data’) with IMVO, for the performance of this Agreement, as follows: Company employee contact points including name, work email address, correspondence address and work phone number solely for the purpose of performing this Agreement and complying with the Directive and the Delegated Regulation.

The Parties agree that they are independent controllers of the Shared Data for the purpose of this Agreement and shall be responsible for complying with their own obligations as controllers of the Shared Data under Data Protection Legislation. The Company hereby agrees to direct a data subject to the IMVO’s Privacy Notice (available at [www.imvo.ie](http://www.imvo.ie)), where that data subject’s personal data forms part of the Shared Data.

The Parties shall indemnify the other in respect of any breaches caused by it of the Shared Data under the Data Protection Legislation.

1. **Security breaches**

If either Party becomes aware of a Security Breach that might affect the other Party, it shall notify the other Party immediately. The notification shall contain:

1. the nature of the Security Breach, including the categories and number of persons affected, and the categories and number of relevant Data records;
2. the consequences of the Security Breach;
3. measures that are or will be undertaken by the Company or IMVO as the case may be to repair the Security Breach and limit its consequences; and
4. the measures that are or will be undertaken by the Company or IMVO as the case may be to prevent such a Security Breach in the future.

In the event of a Security Breach, the Party who has made a notification to the other Party under this Section 9 shall, upon request of the other Party:

1. cooperate with the other Party in investigating the Security Breach;
2. take all reasonable steps to repair the Security Breach and limit its consequences;
3. take all reasonable steps to prevent the recurrence of such Security Breaches in the future; and
4. assist the other Party in measures required by applicable law.
5. **Confidentiality**

For the purposes of this Agreement, the Parties may provide Confidential Information to each other. Each Party receiving Confidential Information from the other Party shall:

1. use the other Party’s Confidential Information only for the purposes of this Agreement or as otherwise provided under the Directive or the Delegated Regulation;
2. keep the other Party’s Confidential Information secret and confidential and not disclose it to any third party, expect as expressly permitted under this Agreement or the Directive or the Delegated Regulation;
3. exercise the same degree of care and protection with respect to the other Party’s Confidential Information as it exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with reasonable care; and
4. take necessary precautions to prevent unauthorised use or disclosure of the other Party’s Confidential Information, and to notify immediately the other Party upon becoming aware of the same and take necessary measures in order to reduce the effects of such unauthorised misuse or disclosure.

Each Party may disclose the other Party’s Confidential Information to its affiliates or subcontractors on a need to know basis for the purpose of this Agreement and under at least as stringent confidentiality obligations as set out in this Section 10.

The confidentiality obligations set out in this Section 10 do not apply to material and information that:

1. is generally available or otherwise public without the receiving Party being in breach of this Agreement; or
2. the receiving Party has received from a third party without breach of confidentiality; or
3. was in the possession of the receiving Party without any confidentiality obligation prior to receiving the information from disclosing Party; or
4. the receiving Party has independently developed without using the information or material received from the disclosing Party.

Upon termination of this Agreement, the receiving Party shall return to the disclosing Party the Confidential Information received from it or, upon the disclosing Party’s request, certify destruction of the same. The receiving Party shall, however, be entitled to retain such material as is required by applicable law.

The obligations under this Section 10 will remain in force after termination of this Agreement.

1. **Force Majeure**

Neither Party shall be liable for delay or damage caused by an impediment beyond the Party’s control and which the Party could not have reasonably taken into account at the time of conclusion of this Agreement and the consequences of which the Party could not reasonably have avoided or overcome. A strike, lockout, boycott and other similar industrial action shall also be considered a force majeure event even when the Party concerned is the target or a party to such an action.

A force majeure event suffered by a subcontractor of a Party shall also be considered a force majeure event in relation to that Party if the work to be performed by a subcontractor cannot be done or acquired from another source without incurring unreasonable costs or significant loss of time.

Each Party shall without delay inform the other Party in writing of a force majeure event and the termination of the force majeure event.

1. **Limitation of liability**

IMVO does not warrant that the IMVS will not contain any errors or defects (whether visible, hidden or likely to occur in the future). IMVO does not warrant that the IMVS will function without faults.

IMVO shall not be liable for the actions of EMVO and of the persons to whom access to the EMVS and, where applicable, the IMVS, has been provided. IMVO shall not be liable for the content, integrity, or completeness of the Data in the IMVS or the EMVS (including where applicable, the IMVS) and for such Data being up to date.

IMVO will not be liable towards the other Party for any indirect or consequential damages. The total aggregate annual liability of IMVO towards the Company under this Agreement will be limited to the amount of payments received by IMVO from the Company in that calendar year under this Agreement.

The limitation of liability will not apply, if the damage has been caused by:

1. wilful misconduct or gross negligence;
2. breach of confidentiality obligations; or
3. breach of Intellectual Property Rights.
4. **Term and termination**

This Agreement enters into force when it has been signed by the duly authorised representatives of both Parties.

Since this Agreement covers the execution of compulsory legal provisions as set out in the Directive and the Delegated Regulation, both Parties acknowledge and agree that this Agreement may be terminated when the Company no longer acts as a MAH in Ireland or when the applicable legislation ceases to apply to either the Company or IMVO. Furthermore, IMVO shall have the right to terminate this Agreement without any liability to the Company, if the agreement between EMVO and IMVO for the use of the European Hub is terminated for any reason.

This Agreement shall remain in force unless terminated in writing by either Party for convenience on at least ninety (90) days’ prior written notice to the other Party.

This Agreement may also be terminated with immediate effect by written notice by the non-defaulting Party in the event that the other Party commits a material breach of this Agreement and fails to remedy such breach within thirty (30) days after having been given written notice in respect thereof.

In the event that this Agreement is terminated by either Party, the Company will have no rights whatsoever to a refund of fees already paid to IMVO (neither as a whole nor pro rata). For the avoidance of doubt, the Company shall remain liable for any fees that are due to IMVO and unpaid at the date of termination of the Agreement, save where the Agreement has been terminated by the Company due to a material breach of the Agreement by IMVO.

Sections 7, 8, 10, 11, 12, 13, 17 and 18 will survive the termination of this Agreement.

1. **Amendment and assignment**

Amendments and modifications to this Agreement are valid only if they are made in writing and signed by the duly authorised representatives of both Parties.

The Company may not assign or novate this Agreement, in whole or in part, without IMVO’s prior written consent and any attempted assignment in violation of this provision shall be invalid. IMVO may assign or novate this Agreement to a successor organisation, in whole or in part, without the Company’s consent at any time, it being agreed that IMVO shall inform the Company about such assignment or novation and the reasons thereof at IMVO’s earliest convenience.

1. **Anti-bribery and anti-corruption**

Each Party agrees that it will comply, at all times, with all applicable anti-corruption laws and regulations.

Each Party shall be entitled to terminate the Agreement immediately on written notice to the other Party, if the other Party is in breach of its obligations set out in Section 15.

1. **Entire Agreement**

This Agreement constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes and replaces any prior proposals, negotiations, agreements and other written or oral communications between the Parties relating to the subject matter of this Agreement.

1. **Governing law and dispute resolution**

The construction, validity and performance of this Agreement and all non-contractual obligations arising from or connected with this Agreement shall be governed by, and construed in accordance with, the laws of Ireland and, subject to the remainder of this clause, any dispute arising out of this Agreement shall be subject to the exclusive jurisdiction of the courts of Ireland to which both Parties hereby agree to submit irrevocably for these purposes.

In the event of any dispute arising out of or relating to this Agreement (“the Dispute”), the Parties shall first seek settlement of the Dispute as set out below:

1. The Dispute shall be referred as soon as practicable to [insert details of Company contact person] and to IMVO’s General Manager respectively.
2. If the Dispute has not been resolved within fifteen (15) business days (or such longer period as may be agreed in writing by the Parties) of being referred to the nominated representative, then either Party may refer the Dispute to an independent mediator, the identity of whom shall be agreed in advance by the Parties. If the Parties are unable to agree on a mediator or if the mediator agreed upon is unable/unwilling to act, either Party may within twenty-one (21) days from the date of the proposal to appoint a mediator or within twenty-one (21) days of notice to either Party that the mediator is unable to act, apply to the Centre for Effective Dispute Resolution (CEDR Ireland) to appoint a mediator.
3. Any submissions made to and discussions involving the mediator, of whatever nature, shall be treated in strict confidence and without prejudice to the rights and/or liabilities of the Parties in any legal proceedings and, for the avoidance of doubt, are agreed to be without prejudice and legally privileged. The Parties shall make written submissions to the mediator within ten (10) business days of his/her appointment.
4. The Parties shall share equally the cost of the mediator. The costs of all experts and any other third parties who, at the request of any Party, shall have been instructed in the mediation, shall be for the sole account of and shall be discharged by that Party.

For the avoidance of doubt, the obligations of the Parties under this Agreement shall not cease, or be suspended or delayed, by the reference of a Dispute to mediation. The Company shall comply fully with the requirements of the Agreement at all times.

1. **Appendices**

*Appendix 1 Fees payable to IMVO*

If there is any discrepancy between the main body of this Agreement and the appendix, the main body of this Agreement prevails.

1. **Signatures**

This Agreement has been drawn up and executed in two (2) identical copies (which may also be electronic) of which each Party has received one (1) copy.

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| --- | --- | --- |
| **For IMVO:** |  | **For the Company:** |
| *Signature:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | *Signature[[1]](#footnote-2):*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *Name:*  **Leonie Clarke** |  | *Name:*  **[Insert name]** |
| *Title:*  **General Manager** |  | *Title:*  **[Insert title]** |
| *Date:* | *Date:* |

# **Appendix 1 – Fees payable to IMVO**

1. **Registration Fee**
   1. A one-off registration fee is payable by the Company to IMVO pursuant to Section 5.1 of this Agreement and the remainder of this Appendix. The amount of the registration fee shall be determined by the IMVO Board of Directors and notified on the IMVO website ([www.imvo.ie](http://www.imvo.ie)).
   2. For the avoidance of doubt, no registration fees paid to IMVO are refundable.
2. The Parties **Annual MAH User Fees**
   1. An annual MAH user fee is payable by the Company to IMVO pursuant to Section 5.1 of this Agreement and the remainder of this Appendix.
   2. The amount of the fee will be notified by IMVO to the Company in writing no later than 30th September during the previous calendar year, where the Company is registered with IMVO as an MAH at that time.
   3. An invoice for the annual MAH user fee will be issued in January each year and will
   4. be due for payment on 9th February.
   5. New MAHs are required to pay an annual MAH user fee with effect from the year in which they first register with IMVO. The amount of the fee shall be the annual fee charged to existing MAHs, reducing on a pro rata basis depending on the quarter in which the MAH applies for registration.
3. **Fee rebates for MAHs with low turnover**
   1. MAHs with low turnover in Ireland (as may be defined solely by the IMVO Board from time to time) may apply for rebates on IMVO’s MAH registration fee and/or MAH annual user fee. The IMVO Board of Directors determines what the level of rebate, if any, may be granted.
   2. To apply for the rebate, the MAH Fee Rebate Application form must be completed and signed by an authorised representative of the Company and returned to IMVO (by email to [mah@imvo.ie](mailto:mah@imvo.ie)) or other means. The form is available on the IMVO website ([www.imvo.ie](http://www.imvo.ie)) or on request from IMVO.
   3. If the application is successful, the fee rebate is granted for one calendar year only. A separate application must be made each year if the Company considers that it continues to be eligible for the rebate and the application will be considered by IMVO independently of previous decision(s).
   4. Decision on fee rebate application:
      1. The application form is reviewed on receipt by IMVO to ensure that all the relevant information has been provided and that it has been signed by a representative of the Company.
      2. The turnover figure provided must be capable of independent verification, including without limitation statutory accounts, external market data (give details of source). In assessing the application, evidence of the turnover figure may be requested from the Company and independent checks may also be undertaken by IMVO, including without limitation checking statutory company accounts lodged with the Companies Registration Office.
      3. The General Manager of IMVO must approve all fee rebate applications. A decision by the General Manager of IMVO to refuse the application may be appealed to the IMVO Board of Directors whose determination shall be final and binding.
      4. If the Company is granted a fee rebate and has previously paid the MAH registration fee and/or annual MAH user fee to IMVO without any rebate, a credit note will be issued for the sum that has been overpaid and the relevant sum will be refunded to the Company’s nominated bank account.
   5. IMVO reserves the right to audit the turnover figures provided by the Company at any time and at the Company’s expense. In the event it is established that the rebate was granted on the basis of incorrect or misleading information, IMVO may withdraw the rebate with immediate effect and invoice the Company for any additional fees that are owing to IMVO as a result.
4. **Transfer of marketing authorisations**
   1. If the Company transfers to another entity, all the marketing authorisations it holds for products placed on the market in Ireland such that it is no longer required to be registered as an MAH with IMVO, and that entity is not already registered as an MAH with IMVO, the Company and the entity to which the marketing authorisations are being transferred must notify IMVO (by email to [mah@imvo.ie](mailto:mah@imvo.ie)). IMVO will review the specific circumstances of the transfer and advise what fees are payable and the documentation to be completed.
   2. If the entity to which the authorisations are transferred is already registered with IMVO, no additional fees are payable.

1. The person signing this Agreement must be an authorised signatory of the Company with authority to sign agreements on behalf of the Company. [↑](#footnote-ref-2)