

**MEMORANDUM OF UNDERSTANDING**  
**between**  
**The Health Products Regulatory Authority**  
**and**  
**Sport Ireland**  
**CONCERNING COOPERATION IN THE REGULATION OF HEALTH PRODUCTS**

## 1. BACKGROUND

- 1.1 **Sport Ireland**, established by the Sport Ireland Act 2015 and the Health Products Regulatory Authority (**HPRA**) established by the Irish Medicines Board Act 1995, as amended (hereinafter referred to as the 'Parties'), wish to establish a framework for cooperation in the regulation of Health Products.
- 1.2 This Memorandum of Understanding (the "**MOU**") is intended to provide a framework to assist the joint working of the Parties to ensure maximum effectiveness and efficiency when carrying out their statutory functions. It outlines the basis of co-operation and collaboration designed to ensure that the relationship is effective and meets each Party's aims and objectives, particularly when there are overlapping interests and responsibilities.

## 2. OBJECTIVES

- 2.1 The objectives of this MOU are:
  - a. to promote an understanding between the Parties of each other's regulatory framework, requirements and processes;
  - b. to facilitate the exchange of information and documentation relating to areas of common interest;
  - c. to facilitate collaborative activities between the Parties; and
  - d. to enhance the ability of the Parties in the provision of their respective roles relating to or in connection with preserving the integrity of sport through the detection, prevention and elimination of doping in sport and the regulation of Health Products.
- 2.2 This MOU represents the understanding reached by the Parties, in particular:
  - a. that each Party has jurisdiction over different areas. This MOU is intended to cover areas of common interest and permit meaningful collaboration between the Parties. This collaboration may include all activities that are related to preserving the integrity of sport through the detection, prevention and elimination of doping in sport and the regulation of Health Products.
  - b. each Party may limit the scope of disclosure of information to the other Party particularly if the disclosure may be prejudicial to the commercial interests of a third party, breach the duty of confidence or privacy, disclose a trade secret, is contrary to the public interest or the interests of the Party concerned, would be in breach of or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by law.

### 3. DEFINITIONS

3.1 In this MOU the following definitions will apply:

**Data Protection Law** means all data protection and privacy legislation, regulations and guidance applicable in respect of a party from time to time including, without limitation as applicable:

- the Data Protection Acts 1988 to 2018 (as amended from time to time);
- Regulation (EU) 2016/679 (as amended from time to time) (the "GDPR"); and
- any applicable guidance or codes of practice issued by the Article 29 Working Party, the European Data Protection Board or the Data Protection Commission from time to time (all as amended, updated or re-enacted from time to time).

**Health Products** means the products and matters regulated by the HPRA.

### 4. AREA OF COOPERATION

4.1 The Parties having reached the above understanding will:

- 4.1.1 establish avenues of communication to facilitate the exchange of information in situations where either Party comes across information which could be considered relevant to the other Party's role;
- 4.1.2 establish avenues of communication with each other to facilitate the exchange of information about their respective fields of regulation and operation of their organisations;
- 4.1.3 where appropriate, share information relating to investigations and the development of active intelligence, including in support of law enforcement activities; and
- 4.1.4 undertake collaborative activities consistent with this MOU.

### 5. CONFIDENTIALITY

*HPRA*

5.1 Nothing in this MOU requires the HPRA to release personal data or confidential information to Sport Ireland, except in accordance with law.

- 5.2 The HPRA will make all reasonable efforts to inform Sport Ireland of any effort made by a judicial, legislative or other authority to obtain personal data or confidential information that has been provided by Sport Ireland to the HPRA.
- 5.3 Unless otherwise required by law, the HPRA will not disclose personal data or information received from Sport Ireland under this MOU, except with the written consent of Sport Ireland. If disclosure is required by law, the HPRA will consult with Sport Ireland in advance of releasing such information and will take all reasonable measures to ensure that the information received from Sport Ireland will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.
- 5.4 Unless otherwise required by law, the HPRA will not use the personal data or information disclosed to it under this MOU for any other purpose than the performance of its regulatory activities.

*Sport Ireland*

- 5.5 Nothing in this MOU requires Sport Ireland to release personal data or confidential information to the HPRA, except in accordance with law.
- 5.6 Sport Ireland will make all reasonable efforts to inform the HPRA of any effort made by a judicial, legislative or other authority to obtain personal data or confidential information that has been provided by the HPRA to Sport Ireland.
- 5.7 Unless otherwise required by law, Sport Ireland will not disclose any personal data or information received from the HPRA under this MOU, except with the written consent of the HPRA. If disclosure is required by law, Sport Ireland will consult with the HPRA in advance of releasing such information and will take all reasonable measures to ensure that the information received from the HPRA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.
- 5.8 Unless otherwise required by law, Sport Ireland will not use any personal data or information disclosed to it under this MOU for any other purpose than for the purposes of its regulatory activities.

**6. FINANCIAL ARRANGEMENTS**

Each Party will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

**7. VARIATION**

- 7.1 The Parties agree to keep the suitability of this MOU under review, and to formally review the MOU every three years from the effective date.

- 7.2 Any provision of this MOU may be amended at any time by the mutual consent in writing of the Parties via the respective signatories.

## 8. STATUS OF MEMORANDUM OF UNDERSTANDING

This MOU reflects the intentions of the Parties and both Parties recognise the importance of maintaining the confidentiality of confidential material and observing Data Protection Law, and will take particular care to do so in respect of any materials shared pursuant to this MOU.

## 9. EFFECTIVE DATE

This MOU will come into effect upon the date on which the MOU has been signed by both its signatories and will continue in effect until terminated in accordance with clause 12.

## 10. AGENCY CONTACT

The liaison officers responsible for the administration of this MOU are:

- For the HPRA, the person holding the position of: **[Director of Compliance of the HPRA]**
- For Sport Ireland, the person holding the position of: **[Director of Anti-Doping and Ethics of Sport Ireland]**

## 11. DATA PROTECTION



11.1 The Parties will comply with their duties as applicable under Data Protection Law and will give each other all reasonable assistance as appropriate or necessary to enable the other to comply with their duties as applicable under Data Protection Law.

11.2 Without prejudice to clause 11.1, where both Parties agree on a case by case basis that it is necessary to process personal data under this MOU in the context of law enforcement and investigative activities, such processing will not take place until the Parties have agreed in writing the terms under which the processing will take place. The Parties will process such personal data in accordance with their duties as applicable under Data Protection Law.

## 12. TERMINATION

12.1 Either Party may, at any time, give written notice of termination to the other Party. This MOU (excepting clause 5) will be terminated 28 days after the date of receipt of the notice of termination.

12.2 The termination of this MOU will not affect the confidentiality undertakings expressed by the Parties to this MOU and any commitments given under or as a consequence of this MOU in respect of any arrangement or action taken during the period before the termination takes effect.

<p>Signed</p> <p>On this <u>16</u> day of September, 2022</p> 	<p>Signed </p> <p>On this <u>16</u> day of <u>September, 2022</u></p>
<p>Lorraine Nolan, Chief Executive of the Health Products Regulatory Authority (HPRA)</p>	<p>Una May, Chief Executive of Sport Ireland</p>

**INFORMATION EXCHANGE AGREEMENT**  
**between**  
**SPORT IRELAND**  
**and**  
**THE HEALTH PRODUCTS REGULATORY AUTHORITY**

**This Agreement** is made on the 16th day **of** September, 2022

**BETWEEN**

1. **Sport Ireland** having its head office at The Courtyard, Sport Ireland National Sports Campus, Snugborough Road Blanchardstown, Dublin 15, Ireland; and
2. The **Health Products Regulatory Authority** having its head office at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 ("**HPRA**").

Each a **Party** and together the **Parties**.

**WHEREAS**

- A. **Sport Ireland** was established by the Sport Ireland Act 2015 (the "**2015 Act**") and, as the national anti-doping organisation, acts to protect Ireland's sporting integrity.
- B. **The HPRA** was established by the Irish Medicines Board Act 1995 as amended (the "**IMB Act**") and has regulatory remit for Health Products. The role of the HPRA is to protect and enhance public and animal health by regulating Health Products.
- C. The Parties have entered into a Memorandum of Understanding to establish a framework for cooperation in relation to their respective functions.
- D. Where either Party is in possession of information which may be relevant to the functions of the other party, that Party shall, where appropriate and in accordance with the law and terms of the MOU and this Agreement share that information with the other Party.

**1. Definitions**

"**controller**", "**processor**", "**data subject**", "**personal data**", "**process**", "**processing**" and "**special category of personal data**" shall have the meanings set out in Data Protection Law.

**Data Protection Law** means all data protection and privacy legislation, regulations and guidance applicable in respect of a party from time to time including, without limitation as applicable:

- the Data Protection Acts 1988 to 2018 (as amended from time to time);
- Regulation (EU) 2016/679 (as amended from time to time) (the "**GDPR**"); and
- any applicable guidance or codes of practice issued by the Article 29 Working Party, the European Data Protection Board or the Data Protection Commission from time to time (all as amended, updated or re-enacted from time to time).

**Data Security Breach:** a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the Shared Data.

**Health Products:** means the products and matters regulated by the HPRA.

**Relevant Purpose:** means Sport Ireland's purpose of preserving the integrity of sport through the detection, prevention and elimination of doping in sport, including the application of sanctions in



connection with such doping, on public interest grounds and for the benefit of sportspersons generally.

**Shared Data:** personal data shared between the Parties under this Agreement, as further described in clause 5.

**The Minister:** Refers to the Minister for Transport, Tourism and Sport and any successor minister in charge of any future ministerial department with responsibility for Sport Ireland.

**WADA:** Refers to the World Anti-Doping Agency.

**WADA Prohibited List:** Refers to the WADA International Standard List of prohibited substances and methods as may be amended / updated from time to time.

## 2. Introduction

- 2.1. Sport Ireland and the HPRA have a Memorandum of Understanding concerning cooperation in relation to their respective functions (the “**MOU**”), the purpose of which is the establishment of a framework for co-operation, which encompasses, among other things, the exchange of information between them. It sets out some of the principles underpinning the interaction between the Parties and provides guidance on the exchange of information between them.
- 2.2. Having regard to the purpose of the MOU, this Agreement is an agreement in writing further to Clause 11.2 of the MOU and specifies the terms of data processing relevant to the sharing of personal data between the Parties, including processing of personal data under Part 5 of the Data Protection Act 2018. This MOU also provides further detail on the exchange of information between the Parties.

## 3. Purposes and Objectives

- 3.1. Sport Ireland is concerned with the investigation and prosecution of potential anti-doping rule violations by athletes or athlete support persons (e.g. doctors, coaches, physiotherapists etc.). In striving to make the fight against doping in sport as effective as possible, WADA and anti-doping organisations are moving to a more intelligence-based approach which targets those who supply and administer doping substances (rather than relying mainly on the testing of athletes).
- 3.2. The role of the HPRA is to protect and enhance public and animal health by regulating Health Products.
- 3.3. The sale and supply of certain products, for example anabolic steroids, outside of a pharmacy setting or without a valid prescription is illegal. As the sale and supply of such doping substances may also constitute criminal offences, Sport Ireland must work with the HPRA (among other enforcement agencies), including entering into information sharing initiatives such as this Agreement, to obtain the necessary information to support such an intelligence-based approach and to provide information to assist the HPRA to detect and prevent the illegal sale and supply of products and to bring persons involved to justice through detection and investigation.

3.4. The sharing of information between the Parties will serve to benefit individuals, society and the public interest by:

- 3.4.1. Preserving the integrity of sport through the detection, prevention and elimination of doping in sport;
- 3.4.2. Protecting athletes who compete in full compliance with the anti-doping rules;
- 3.4.3. Protecting the health and other interests of athletes by preventing or eliminating conduct which may be harmful; and
- 3.4.4. Detecting persons who may be committing criminal offences by illegally importing, procuring, selling, supplying or exporting certain substances or other Health Products in or from the State.

3.5. This Agreement does not create any positive obligations on Sport Ireland or the HPRA in terms of specific actions to be undertaken by either Party.

#### **4. Statutory Basis**

4.1. Sport Ireland was established under the 2015 Act. It is the national anti-doping organisation for the State and performs the functions and obligations referred to in (a) the World Anti-Doping Code, (b) the UNESCO Anti-Doping Convention and (c) the Irish Anti-Doping Rules. Sport Ireland's powers and functions which are relevant to this Agreement are set out in Schedule 1 Part A.

4.2. This Agreement is an arrangement for the purpose of Section 43(2) of the 2015 Act.

#### **5. Shared Data**

5.1. The Parties agree to only process Shared Data, for the purposes set out in clause 3 and the Parties shall not process Shared Data in a way that is incompatible with such purposes (the "**Agreed Purposes**"). The Shared Data must not be irrelevant or excessive with regard to the Agreed Purposes.

5.2. Sport Ireland requires information that will assist in the detection, deterrence, enforcement or prevention of anti-doping rule violations. The information should relate to potential anti-doping rule violations and may include names, addresses and details of prohibited substances. In the context of this Agreement, it is envisaged that the following types of information will be shared between the Parties:

- 5.2.1. Information in relation to a person or persons potentially selling, supplying or otherwise obtaining or using substances prohibited by the WADA Prohibited List to athletes, athlete support persons, sporting clubs or sporting bodies.
- 5.2.2. Information in relation to a person or persons potentially selling, supplying or otherwise obtaining or using Health Products in a manner prohibited by WADA to athletes, athlete support persons, sporting clubs or sporting bodies.

5.3. The HPRA requires information that will assist it in carrying out its functions in relation to the detection, investigation and prevention of the unauthorised importation, procurement, sale,

supply or export of Health Products. In the context of this Agreement, it is envisaged that the following type of information will be shared between the Parties:

- 5.3.1. Information in relation to a person or persons involved in the unauthorised importation, procurement, sale, supply or export of Health Products.
- 5.4. Personal data relating to criminal convictions and offences may be shared between the Parties pursuant to Section 55 of the Data Protection Act 2018 (the “2018 Act”) or Part 5 of the 2018 Act as applicable.
- 5.5. Personal data may be shared between the Parties pursuant to Section 38 of the 2018 Act or Section 45 of the 2018 if it constitutes a special category of personal data.

## **6. Data Protection – General Undertakings**

- 6.1. Part 5 of the 2018 Act relates to the processing of personal data for law enforcement purposes and may, in some circumstances, be applicable to the sharing of personal data between Sport Ireland and the HPRA under this Agreement. The sharing of personal data under this Agreement may, in some circumstances, constitute processing of personal data for the purposes of Part 5 of the 2018 Act and further, the processing is carried out for the purposes of prevention, investigation, detection or prosecution of criminal offences, including the execution of criminal penalties and by means that, where the personal data form part of, or are intended to form part of, a relevant filing system, are not automated. Section 71 of the 2018 Act outlines the general principles of data protection, which both Parties to this Agreement agree to adhere to. In particular, it is agreed that to the extent Part 5 of the 2018 Act is applicable, processing of personal data under this Agreement is lawful in accordance with Section 71(2)(a) as the processing is necessary for the performance of functions of Sport Ireland and the HPRA as hereinbefore stated, and no consent will be obtained from data subjects in relation to the processing of personal data under this Agreement.
- 6.2. Each Party shall comply with Data Protection Law in particular the Parties shall:
  - 6.2.1. Share only the necessary amount of Shared Data;
  - 6.2.2. Where necessary, put in place suitable and specific measures to safeguard the fundamental rights and freedoms of data subject. Such measures may include enhanced access controls and security requirements in relation to Shared Data and access to Shared Data should be limited to a small number of officials on a ‘need to know’ basis;
  - 6.2.3. Agree any necessary restrictions on onward sharing of Shared Data with third parties;
  - 6.2.4. Put in place security measures with the aim of ensuring there is no Data Security Breach; and
  - 6.2.5. Ensure that Shared Data is securely destroyed when no longer required.
- 6.3. Each Party shall ensure that it processes the Shared Data in accordance with the principles relating to the processing of personal data set out in Article 5 of the GDPR, that it processes Shared Data on the basis of one or more of the legal grounds in Article 6 of the GDPR (or Section 38 of the 2018 Act) or Article 9 of the GDPR (or Section 45 of the 2018 Act) in the case of special categories of personal data, and in accordance with Article 10 of the GDPR

and Section 55 of the 2018 Act or Part 5 of the 2018 Act as applicable, and to the extent applicable that it shall comply with the transparency requirements in Articles 12-14 of the GDPR.

- 6.4. Each Party is under an obligation to notify the other as soon as is reasonably possible in the event of a Data Security Breach and the Parties agree to co-operate and work together in response to such a Data Security Breach.

## **7. Joint Controller Agreement**

- 7.1. To the extent the Parties jointly determine the purposes and means of the processing of personal data in respect of particular processing operations, in respect of the sharing of personal data under this Agreement, Sport Ireland and the HPRA jointly determine the purposes and means of the processing of personal data and this Agreement is deemed to be a joint controller agreement for the purposes of Section 79 of the 2018 Act.
- 7.2. For the purposes of this Agreement, in so far as the exercise of data subject rights is permitted in relation to the personal data processed under this Agreement, data subjects may exercise their rights under Part 5 of the 2018 Act against either Sport Ireland or the HPRA, or both. No single point of contact is designated for the purposes of Section 79(2)(b) of the 2018 Act.

## **8. Restriction of Data Subject Rights**

- 8.1. To the extent applicable, Sport Ireland and the HPRA agree to a restriction of the exercise of a right of a data subject as specified in Section 94(4) of the 2018 Act. It is agreed that the restriction of the exercise of a right under Section 94(4) of the 2018 Act constitutes a necessary and proportionate measure in a democratic society with due regard for the fundamental rights and legitimate interests of the data subject for the purposes of some of the constitutive elements of Section 94(2) and Section 94(3) of the 2018 Act, in particular:
- 8.1.1. avoiding obstructing official or legal inquiries, investigations or procedures;
  - 8.1.2. avoiding prejudicing the prevention, detection, investigation or prosecution of criminal offences or the execution of criminal penalties;
  - 8.1.3. protecting public security;
  - 8.1.4. protecting the rights and freedoms of other persons;
  - 8.1.5. the prevention, detection or investigation of offences, the apprehension or prosecution of offenders or the effectiveness of lawful methods, systems, plans or procedures employed for the purposes of the matters aforesaid;
  - 8.1.6. the enforcement of, compliance with or administration of any enactment related to a purpose specified in Section 70(1)(a) of the 2018 Act;
  - 8.1.7. ensuring the safety of the public and the safety or security of individuals and property;
  - 8.1.8. ensuring the fairness of criminal proceedings in a court or other tribunal;
  - 8.1.9. ensuring the security of any system of communications, whether internal or external, of Sport Ireland or the HPRA;
  - 8.1.10. protecting the life, safety or well-being of any person;
  - 8.1.11. preventing the facilitation of the commission of an offence; and

- 8.1.12. avoiding the obstruction or impairment of official or legal inquiries, investigations or procedures or the operation of legal privilege.

## 9. Sharing of Information

9.1. Where information comes to the attention of either Party in the course of its activities that it would consider to be of concern to the other Party, that Party shall, before sharing such information, consider whether the Purposes and Objectives as outlined in Clause 3 of this Agreement could be achieved without sharing personal data or by anonymising personal data.

9.2. Each Party will co-operate as far as possible to ensure that the relevant information is shared in a timely manner with the other Party. However, while every endeavour will be made to facilitate such sharing of information, it is understood by both Parties that there may be occasions on which there may be legal or other impediments which prevent either Party from informing the other.

9.3. The Parties agree that:

- 9.3.1. the receiving party, in respect of personal data transferred to it under the 2018 Act:
  - 9.3.1.1. shall, save as permitted by Section 41 of the 2018 Act, be used only for the purpose for which it is collected; and
  - 9.3.1.2. will be retained by it for no longer than is necessary and, when no longer required, will be destroyed in an appropriate, secure manner;
- 9.3.2. to the extent Part 5 of the 2018 Act is applicable, it will comply with all obligations under Part 5 of the 2018 Act including confidentiality, security, storage, deletion, use and protection against misuse of data transferred;
- 9.3.3. it is responsible for any loss of data transferred to them under the provisions of the 2018 Act and, in the event of such loss, it shall comply with the relevant obligations under the 2018 Act in relation to such data loss.

## 10. Communication

10.1. The Parties shall endeavour to collaborate on external communications where appropriate.

## 11. Status of this Agreement and Governing Law

11.1. Save in respect of the Joint Controller Agreement established between the Parties, nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute either Party as the agent of the other Party, nor authorise either of the Parties to make or enter into any commitments for or on behalf of the other Party.

11.2. This Agreement shall take effect upon the signature of both Parties and shall continue until such time as it is terminated or superseded by a revised document.

11.3. This Agreement may be terminated upon written notification by one Party to the other with 28 days' notice in writing.

11.4. The provisions in this Agreement will be reviewed after three years from the date it was signed by the Parties, and any amendments shall be made by written agreement of both Parties. The provisions in this Agreement can be reviewed at any time at the request of either Party. Both Parties are committed to resolving any issues arising under this Agreement by normal administrative means.

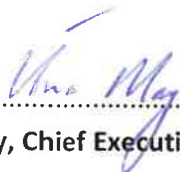
## SCHEDULE 1 – POWERS AND FUNCTIONS

### Part A - Sport Ireland's Powers and Functions

1. Sport Ireland makes and enforces the Irish Anti-Doping Rules to which athletes and athlete support persons are subject.
2. For the purpose of preserving the integrity of sport through the detection, prevention and elimination of doping in sport, including the application of sanctions in connection with such doping, on public interest grounds and for the benefit of sportspersons generally (the "**Relevant Purpose**"), Sport Ireland implements such measures as it considers appropriate for the delivery of a comprehensive, co-ordinated and effective response to doping in sport.
3. The principal functions of Sport Ireland include the following:
  - 3.1. to take such action as it considers appropriate, including testing, to combat doping in sport;
  - 3.2. to make and enforce the Irish Anti-Doping Rules,
  - 3.3. in its capacity as the national anti-doping organisation in the State, to direct the collection of samples, to manage the testing and test results of samples and attend hearings, as required,
  - 3.4. to facilitate, through the promulgation of guidelines and codes of practice, standards of good conduct, fair play and the elimination of doping in sport; and
  - 3.5. to plan, implement, evaluate and monitor education and information programmes for good conduct, fair play and the elimination of doping in sport;

IN WITNESS whereof this Agreement has been duly executed on the date shown at the beginning of this Agreement.

Signed by a duly authorised representative of Sport Ireland



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**Una May, Chief Executive, Sport Ireland**

Signed by a duly authorised representative of the Health Products Regulatory Authority



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**Lorraine Nolan, Chief Executive, Health Products Regulatory Authority**