Medicines &
Healthcare products
Regulatory Agency

Memorandum of Understanding between (1) Joint Council for Cosmetic Practitioners and (2) Medicines and Healthcare products Regulatory Agency

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Revision history and approval

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Introduction

1. The purpose of this Memorandum of Understanding (**MoU**) is to set out a framework to support the working relationship between the Joint Council for Cosmetic Practitioners (**JCCP**) and the Medicines and Healthcare products Regulatory Agency (MHRA) (the **Agency**).

2. The purpose of this MoU is to define the joint arrangement between the two parties and to indicate a common line of action. It is not intended to, nor shall it be deemed to, create 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, nor otherwise bind or oblige the other party in law.

3. The purpose of this MoU is to have a clear understanding of the operational expectations and governance arrangements required to ensure a mutually beneficial relationship.

4. This MoU is not intended to be legally binding, and no legal obligations or legal rights shall arise between the parties from this MoU. The parties enter into the MoU intending to honour all their obligations. Nothing in this MoU is intended to in any way affect the obligation of each party to comply with their respective legal and regulatory obligations generally, and particularly but not exclusively as outlined in this MoU.

5. As part of the activities undertaken as part of this MoU, other agreements (for example, information sharing agreements, or joint working protocols) may be established. Such agreements will exist separately to this MoU.

Roles and responsibilities

JCCP

6. The Joint Council for Cosmetic Practitioners (JCCP) and the Cosmetic Practice Standards Authority (CPSA) is a recognised self-regulator of the non-surgical aesthetic industry in the UK and the point of access for the public seeking information about this area of practice and where appropriate for raising concerns about practitioners. The JCCP places public protection and patient safety as the focus of its activities.

   JCCP Practitioner Registrants and associated Education and Training Providers will be accredited and endorsed by the JCCP as meeting the highest standards of quality by ensuring that all parties who have been admitted to the JCCP's Registers have met the agreed industry qualifications, benchmarks and abide by the standards of practice and behaviour as determined by the Cosmetic Industry CPSA and the JCCP.

The Medicines and Healthcare products Regulatory Agency

The Agency is an Executive Agency of the Department of Health and Social Care and was established on 1 April 2003. It is the regulator of medicines, medical devices and blood components for transfusion in the UK.

MHRA regulates medical devices under the Medicines and Medical Devices Act 2021 ("**MMD Act**") and the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) ("**MDR 2002**").

Some medical devices are regulated under different legislation in Northern Ireland namely under Regulation (EU) 2017/745 and the Medical Devices (Northern Ireland Protocol) Regulations 2021.

The Agency puts patients first in everything we do, right across the lifecycle of the products we regulate. It rigorously uses science and data to inform its decisions, enable medical innovation and to make sure that medicines and healthcare products available in the UK are safe and effective.

Its responsibilities are to:

- Ensure medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy (effectiveness).
- Secure safe supply chain for medicines, medical devices and blood components.
- Promote international standardisation and harmonisation to assure the effectiveness and safety of biological medicines.
- Educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use.
- Enable innovation and research and development that is beneficial to public health.
- Collaborate with partners in the UK and internationally to support our mission to enable the earliest access to safe medicines and medical devices and to protect public health.

Principles of co-operation

7. JCCP and the Agency acknowledge their respective non-statutory and (in the case of the Agency) statutory, responsibilities and functions and will take account of these when working together.

8. In implementing this MoU, JCCP and the Agency intend that their working relationship will be characterised by the following principles:

    - the need to make decisions that promote high quality healthcare, and which protect and promote patient health, safety and welfare;
    - full openness and transparency between the two organisations as to when cooperation is, and is not, considered necessary or appropriate;
    - respect of each other's independent status;

- the need to use resources and intelligence effectively and efficiently through appropriate coordination and information sharing;
- the need to maintain public confidence in the two organisations & for each to uphold the reputation of the other; and
- a commitment to address any identified overlaps or gaps in the regulatory framework and responsibilities.

Joint Priorities and Areas of Work

Exchange of Information

9. Co-operation between JCCP and the Agency will often require the exchange of information. Exchange of information will be required in, but not limited to, cases where:

    - either JCCP or the Agency identifies concerns about the health and wellbeing, including risks or potential risks to the health and wellbeing, of the public, particularly in relation to the use of medicines or medical, devices in the non-surgical aesthetic industry and those concerns are considered to be relevant, or potentially relevant, to the other organisation's regulatory functions;
    - a resolution to a concern about the health and wellbeing of the public would benefit from a coordinated multi-agency response and provision of information to users and/or the public where necessary; and
    - development of new and/or variation to existing regulations and/or legislation would benefit from an aligned approach.

10. In such cases, all exchanges of information will be lawful and proportionate and shared in confidence with named contacts only in the other organisation at the earliest possible opportunity. Onward dissemination of this shared information within the parties respective organisations is permitted only to the extent necessary to advance public health and wellbeing and where any person receiving the information treats it with strict confidence. Onward dissemination of this shared information to other organisations is not permitted without prior agreement.

11. All arrangements for co-operation and exchange of information set out in this MoU and any joint working protocol that may be developed will take account of and comply with all applicable legislation, including but not limited to the UK General Data Protection Regulation, Data Protection Act 2018, Freedom of Information Act 2000**,** Health and Social Care (Community Health and Standards) Act 2003, section 76 of the Health and Social Care Act 2008, Care Standards Act 2000, the Clinical Trials Directive (Directive 2001/20/EC), and all relevant JCCP and Agency Codes of Practice, frameworks or other policies relating to confidential information including personal information and information issues.

12. Both JCCP and the Agency are subject to the UK General Data Protection Regulation and Data Protection Act 2018. If one organisation receives a subject access request for information that originated from the other the receiving organisation will discuss the request with the other before responding.

13. The Agency is a public authority within the meaning of the Freedom of Information Act 2000 and may be required under FOIA powers to disclose information originating from JCCP, including confidential information. The Agency will take reasonable steps to discuss any FOIA request with JCCP before any information originating from JCCP is disclosed but the Agency shall be responsible for determining in its absolute discretion whether any of the information is exempt from disclosure.

14. . Neither party will send any data or other information which originated from the other party to any person or organisation outside the United Kingdom without the written permission of the originating party.

Communications

15. JCCP and the Agency will seek to give each other adequate warning of, and sufficient information about, any planned announcements to the public on issues relevant to both organisations, including the sharing of draft proposals and publications. Each party will provide comment upon request.

16. JCCP and the Agency commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.

17. JCCP and the Agency will explore opportunities for joint engagement activity with patients and patient groups as part of a wider ambition to increase their involvement in the regulatory decision-making process.

18. JCCP and the Agency respect confidentiality of any documents shared in advance of their publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

19. JCCP and the Agency respect confidentiality of any documents shared with the purpose of drafting or agreeing a joint statement and will not act in a way that would cause the content of those documents to be made public at any time.

Representation on JCCP Clinical Advisory Group (CAG)

20. A representative of the MHRA will attend as a member of the JCCP CAG.

Governance

21. The effectiveness of the working relationship between JCCP and the Agency will be supported by either routine formal contact and/or routine informal contact.

22. Meetings to discuss intelligence, policy and operational issues of interest to both organisations should take place between relevant colleagues at both organisations when appropriate. Contact details of relevant operational level contacts in each organisation are shown at Annex A, however it is acknowledged that post holders,

or post titles may change and JCCP and the Agency commit to keeping each other promptly informed of any such changes.

23. Any disagreement between JCCP and the Agency will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at Annex A, who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution. Both organisations should aim to resolve disagreements in a reasonable time.

24. This MoU, including Annex A, may only be varied by written agreement of both parties.

25. Except as otherwise provided, the parties shall each bear their own costs and expenses incurred in complying with their obligations under this MoU.

26. Both parties shall remain liable for any losses or liabilities incurred due to their own or their employee's actions and neither party intends that the other party shall be liable for any loss it suffers as a result of this MoU.

Duration and review of this MoU

27. This MoU shall commence on 31st August 2023 and shall continue unless terminated earlier in accordance with paragraph 30 or 31 below.

28. Both organisations have identified a person responsible for the management of this MoU in Annex A. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.

29. This MoU will be reviewed annually by the MoU managers identified in Annex A, but may also be reviewed more urgently at any time at the request of either organisation. The principles set out in this MoU are not time-limited and will continue to have effect until the MoU is reviewed and updated.

30. As previously set out, both JCCP and the Agency acknowledge that each has to participate in this collaboration within a framework of good and responsible governance and any regulatory regime by which each is, respectively, bound. There may also be a need for each to balance competing priorities for available funds, and this balance has to be found taking into account the best interests of the individual organisation. It follows that either party, acting in good faith, may terminate this MoU (and accordingly withdraw from the collaboration set out in this MoU) at any time by giving prior (and not less than two months') written notice to the other party.

31. Where either party breaches any of the arrangements set out in this MoU, the non-breaching party may at any time terminate this MoU with immediate effect by giving written notice to the other.

Signed

Chair
JCCP

Dr Alison Cave
Chief Safety Officer
Medicines and Healthcare products Regulatory Agency

Annex A – Contact Details

Joint Council for Cosmetic Practitioners (JCCP)	**Medicines and Healthcare products Regulatory Agency**
1st Floor, Elstree Way, Borehamwood, WD6 1JH.	10 South Colonnade Canary Wharf London E14 4PU Tel: 020 3080 6000

There will be named contacts between JCCP and the Agency as follows:

Chair/ Chief Safety Officer	
JCCP	MHRA
Professor David Sines CBE PhD	Dr Alison Cave
Executive Chair	Chief Safety Officer
JCCP	MHRA

MoU managers	
Professor David Sines CBE PhD	**Amanda King**
Executive Chair JCCP	Head of National and Commercial Partnerships
david.sines@jccp.org.uk	**amanda.king@mhra.gov.uk**
07787002297	

John Underwood	**Jas Dhaliwal**
Chair of Marketing and Communications Committee	Partnerships Policy Lead
john.underwood@jccp.org.uk	jas.dhaliwal@mhra.gov.uk
07730 955689	

Operational level contacts for particular topics at JCCP and the Agency are as follows:

Patient, Medicine and Medical Device Safety issues	
Andrew Rankin Co-Chair Clinical Advisory Group **a.rankin@jccp.org.uk** 07876023339	**Janine Jolly** *Deputy Director Benefit Risk Evaluation II, Safety and Surveillance* janine.jolly@mhra.gov.uk Tel: 020 3080 6000