Memorandum of Understanding between (1) Joint Council for Cosmetic Practitioners and (2) The Secretary of State for Health and Social Care acting as part of the Crown through the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care (the Agency)

Contents

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Authors	**JCCP:** **The Agency:**
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Formally agreed by	JCCP The Agency:
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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 Joint Council for Cosmetic Practitioners (**JCCP**) and the Secretary of State for Health and Social Care acting as part of the Crown through the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care (the **Agency**).

2. The purpose of this MoU is to define the joint agreement between the two organisations and to indicate a common line of action. It is not intended to, or shall 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 agreement 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) are the recognised self-regulators 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

7. The MHRA is an Executive Agency of the Department of Health and Social Care and was established on 1 April 2003. The Agency has three centres:

- The Clinical Practice Research Datalink (CPRD) - a data research service that aims to improve public health by using anonymised NHS clinical data.
- The National Institute for Biological Standards and Control (NIBSC) - a global leader in the standardisation and control of biological medicines; and
- The Medicines and Healthcare products Regulatory Agency (MHRA) regulatory centre - the UK's regulator of medicines, medical devices and blood components for transfusion. The regulatory centre is responsible for: ensuring their safety, quality and efficacy/performance; supporting innovation and new products being developed safely for the benefit of public health; monitoring the safety of medicines devices and blood; and, ensuring secure supply in globalised industries.

8. The Agency is the UK Competent Authority under relevant EU Directives for medicinal products, medical devices and for blood and blood components. The Agency's objectives are to:

- Safeguard public health through our primary role in ensuring that the products we regulate meet required standards of safety, quality and efficacy.
- Carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public.
- Support research, ensuring through the application of better regulation principles that regulation does not stifle innovation.
- Influence the shape of the future regulatory framework through use of our effective European and international relationships; and
- Run an organisation with a skilled and equipped workforce that is fit for the future.

9. The Agency's objectives are achieved through:

- Authorising medicines before they can be marketed, taking both their safety and efficacy into account.
- Ensuring clinical trials meet robust standards and safeguard the interests of patients.
- Inspecting the quality of medicines as manufactured and distributed.
- Overseeing UK Notified Bodies that audit medical device manufacturers.

- Encouraging the reporting of suspected problems with both medicines and devices and investigating reports, including taking action where necessary; and
- Investigating and prosecuting where necessary, cases of non-compliance.

Principles of co-operation

10. 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.

11. 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

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

- either JCCP or the Agency identifies concerns about 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 to the other organisation's regulatory functions; and
- a resolution to a concern would benefit from a coordinated multi-agency response.

13. In such cases, all exchanges of information will be lawful and proportionate and shared in confidence with the named contact in the other organisation at the earliest possible opportunity.

14. 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 the 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 legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

15. Both JCCP and the Agency are subject to the 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.

Communications

16. 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.

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

18. 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.

19. JCCP and the Agency respect confidentiality of any documents shared in advance of 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.

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 regular contact, either formally or informally.

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 have been identified, 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, 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 in March 2021 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, but may also be reviewed more urgently at any time at the request of either organisation. The principles set out in this MoU is MoU is not time-limited and will continue to have effect unless 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, 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 [INSERT] 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	Signed
Professor David Sines CBE Chair JCCP	Dr June Raine Chief Executive Medicines and Healthcare products Regulatory Agency