Non-confidential response by Macfarlan Smith Limited (now Veranova) to CMA consultation on the Opium Derivatives Undertakings 1989

1. Introduction

Macfarlan Smith Limited, which trades as part of the Veranova group ("**MSL**"), welcomes the Competition and Markets Authority's decision to undertake a review of the Opium Derivatives Undertakings 1989.

With its origins in a business dating from 1815, MSL is a UK manufacturer of opiate-based active pharmaceutical ingredients (APIs) that are sold globally, primarily to finished dose manufacturers.

While MSL remains a proud manufacturer of APIs at our historic Edinburgh site, its commercial reality in 2026 is unrecognisable from the position held in 1989. Following our divestment from Johnson Matthey in 2022 and subsequent acquisition by Altaris Capital Partners, MSL now operates as an independent competitor in a globalised supply chain.

While two undertakings were initially imposed on MSL following the 1989 report on the opium derivatives market by the Monopolies and Mergers Commission, only one remains in effect. That undertaking requires MSL to "ensure that a maximum price list [of certain opium derivatives]… shall be published and made generally available on a continuing basis". We refer to that surviving undertaking in this response to the consultation as the "**Undertaking**".

We submit that the Undertaking is no longer necessary or appropriate, given the profound changes in market and regulatory conditions that have occurred over the nearly 40 years since the Undertaking was imposed. We summarise the relevant principal changes in circumstances below.

2. Market developments and changes in the regulatory landscape

The primary justification for the 1989 MMC findings was the existence of an absolute barrier to entry. UK customers wishing to buy opiate-based pharmaceutical products had few viable alternatives to MSL. The MMC report explicitly noted that MSL's position was sustained because "it has been Home Office policy for many years not to issue import licences".[1] The report went on to say that MSL "faces little competition in the United Kingdom and there is little prospect of new entry".[2] In 1989, the Home Office, the

[1] Paragraph 1.2 of Part 1 (Summary) of the 1989 MMC report.

[2] Paragraph 1.3 of Part 1 (Summary) of the 1989 MMC report.

Government department responsible for the operation of the controlled drugs licensing system in the UK, did not permit any importation unless UK manufacturing capacity was unable to meet legitimate medical or scientific demand.[3]

The Undertaking was a product of a different era and regulatory approach—a "closed" national market where Government policy effectively prohibited cross-border trade, insulating domestic suppliers from external competitive forces. The regulatory and commercial landscape of today bears little if any resemblance to that of 1989. Following the overturning of the import ban[4] and a fundamental change in the importation policy, major global entities now actively compete for business in the UK, putting an end to the approach circa 1989. Crucially, this competition often comes in the form of finished dose imports which bypass the UK API market entirely, rendering a domestic API price cap ineffective.

3. Age and impact

Maintaining a maximum price list in a customer-driven global market serves no protective purpose. It imposes an administrative burden on MSL and results in a compliance cost that our competitors do not bear.

While we make the maximum price list publicly available in accordance with the Undertaking, we do not believe that it has any significance to our customers. A published maximum price list does not reflect the reality of how prices are negotiated today. The Undertaking was intended to address MSL's market dominance and the pricing discrimination between large and small customers that was perceived to exist in 1989. Today, MSL's pricing is driven by market dynamics and a competitive landscape. Our customers push for the best price, often citing alternative sources of supply by manufacturers based outside of the UK to negotiate our prices down. That is the case whether the customer is seeking to purchase large or small quantities of product from MSL. MSL has not sold a relevant product to any UK customer at the price stated in the maximum price list for a number of years.

Intense competitiveness in the market has eroded MSL's profit margin to such an extent that it has regrettably withdrawn from production of a third of the "reference products" that are the subject of the Undertaking (a reduction driven by both commercial viability and regulatory withdrawals of the products themselves[5]). We continue to face intense

[3] Paragraph 1.5 of Part 1 (Executive Summary) of the 2006 OFT report *Opium derivatives, a review of the undertaking given by Macfarlan Smith Limited.*

[4] *R v Licensing Authority ex parte Cox Pharmaceuticals* [1994].

[5] Pholcodine was withdrawn from the UK market by the MHRA in 2023, making compliance with the Undertaking impossible for that product.

pressure in relation to the remaining “reference products” (and, indeed, on the rest of our portfolio).

Any benefit of the Undertaking has been superseded by changes in circumstances since 1989. It is no longer relevant or appropriate, nor does it remedy the original perceived customer detriment it was meant to address.

4. Conclusion

The competitive constraints on MSL today come from global market forces, not domestic regulation. Retaining the Undertaking serves only to impose a disproportionate administrative burden on a UK manufacturer. We respectfully request that the CMA confirms its provisional view and terminates the elements of the Undertaking that still remain in force. MSL believes that such action, in light of the active market-based competition described above, is consistent with the CMA’s current mandate to eliminate obsolete regulatory barriers and support business efficiency.

This response is submitted for and on behalf of Macfarlan Smith Limited by Andrew James, Deputy General Counsel of Veranova.

9 March 2026