

How to Put Patients at the Center of the Regulatory Decision-Making Process: The MHRA's Patient Involvement Strategy

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While it remains the industry gold standard to involve patients systematically in regulatory decisions, many questions remain about how to do so. It was therefore significant that on Monday, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) launched its draft [Patient Involvement Strategy](#).

This is the first officially announced move by a European regulator to create a formalized framework for patient and public engagement in its regulatory procedures. The Patient Involvement Strategy, which is open for consultation until June 28, sets out the MHRA's five strategic objectives in relation to patient involvement in regulatory decisions:

- a) systematically involving patients and the public in MHRA decisions
- b) implementing a process that allows for more agile and regular review of high-risk issues
- c) changing MHRA culture so that its staff can deliver this change
- d) developing a clear patient outcome evaluation framework and measuring patient engagement
- e) developing a cross-sector partnership plan to facilitate insight exchange and patient engagement mechanisms

The MHRA has committed to delivering these targets by December 2022. It also seeks to ensure alignment with industry practices and so two months ago launched a voluntary pilot scheme to consult with life sciences companies about how they involve patients in their clinical drug development. The idea is that the MHRA will be able to update its own assessment procedures accordingly.

Companies have been reassured that their decision about whether to participate in the program will in no way affect the way in which their applications are assessed. Under the pilot scheme, companies submitting clinical trial and marketing authorization applications are being asked to provide evidence on the patient involvement activities they undertake when developing their products.

The Patient Involvement Strategy and pilot scheme are only two of many recent changes the regulator has been making, alongside adopting new licensing procedures for innovative treatments, producing

new guidance on the collection and use of real-world evidence, and publishing clearer guidelines for the use of digital health tools.

CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

Maria Isabel Manley, Partner

+44 20 7360 3660, mmanley@sidley.com

Zina Chatzidimitriadou,

Senior Managing Associate

+44 20 7360 2580, zchatzidimitriadou@sidley.com

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