UK-wide licensing for human medicines

Updated 30 August 2024

UKMA (UK) Category 1	UKMA (UK) Category 2
Authorised products	
Products that were authorised in the EU through the centralised procedure and subsequently grandfathered at the time of EU Exit. Or Are within the mandatory scope of the centralised procedure but authorised by MHRA since 1 January 2021. Or Are within the optional scope of the centralised procedure but authorised by MHRA since 1 January 2021, unless authorised by one or more member states through EU national procedures (including mutual recognition or decentralised procedures).	Products that do not fall within the mandatory scope of the centralised procedure. Or In the case of the optional scope, products were authorised through national procedures. Or Products were authorised prior to the introduction of the centralised procedure.
New applications	
For products that fall within the mandatory or optional scope of the centralised procedure. This includes products authorised as conditional marketing authorisations.	For products that do not fall within Category 1 (products that do not fall within the mandatory or optional scope of the centralised procedure). This will not include products authorised as conditional marketing authorisations.
Generic, hybrid or biosimilar products of category 1 reference products: For already authorised products, this will apply regardless of whether the centralised procedure was used for the generic, hybrid or biosimilar application.	**Generic, hybrid or biosimilar products of Category 2 reference products**
These products will be authorised by the MHRA in accordance with UK law on a UK-wide basis.	These products will be authorised by the MHRA in accordance with UK law and applicable EU law on a UK-wide basis.