The European Commission Proposes First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years

 On 26 April 2023, the European Commission published two legislative proposals – a new **Regulation 2023/0131** and a new **Directive 2023/0132** – to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children).

The Directive contains all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at the EU and national level. The Regulation sets specific rules (on top of the ones in the Directive) for medicines authorised at the EU level, in particular the most innovative ones.

The proposals aim to reduce costs, expedite the introduction of new medicines and prevent medicine shortages.

Read the key points in the client alert **here**.