

EMA Q&A document on biosimilars

The EMA has just published on its website the final versions of the Q&A documents on biosimilars and generics, making these two documents official. The text of the final draft Q&A on biosimilars (dated 22 June but posted on 12 July) is nearly identical to the draft text we received in April and which was welcomed by our European industry federation, via supporting letters. The somewhat vague, but very important text for the automatic substitution debate is still in the text:

"Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional."

Links:

<http://www.emea.europa.eu/pdfs/human/pcwp/39390506en.pdf>

<http://www.emea.europa.eu/pdfs/human/pcwp/7456206en.pdf>