Principles to be used to facilitate fast-tracked introduction of biosimilars to the local health economy

MSEMOC recommended guidance

The addition of a biosimilar medicine to the MSE joint formulary no longer requires formal recommendation by MSEMOC prior to addition, providing the set of key standards have been met by that biosimilar.

Biosimilar medicines are not considered generic equivalents to their originator biological medicine because the two products are similar but not identical. However, they will have met regulatory requirements in terms of comparative quality, safety and efficacy. Because of the similarities between originator and biosimilar medicines as well as growing experience with the use of biosimilar medicines, it is accepted that generic principles can be applied to biosimilar medicines with regards to addition to drug formularies, providing the set of key standards have been met

MSEMOC recommended key standards:

All standards must be met by the biosimilar product before addition to MSE joint formulary. Should the biosimilar not meet all of these standards, the biosimilar must be taken through MSEMOC for a recommendation to be made.

- The biosimilar product has been approved by the MHRA.
- The biosimilar product has been shown to be equivalent to the originator medicine in terms of quality, safety and efficacy.
- The biosimilar product has been launched in the UK.
- The acquisition cost less than that of the originator medicine.
- The originator medicine is accepted for use within the local health economy (i.e. not classified as 'black' traffic light status).
- Identified within the drug formulary and prescribed by brand, in line with MHRA guidelines that state that biological medicines, including biosimilar medicines, must be prescribed by brand name to support on-going pharmacovigilance.

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