carbohydrates (polynuclear iron (III)-oxyhydroxy cores stabilised by carbohydrates), glatiramoids (polypeptides) and liposomal drugs [1]. Like biological MPs, NBCDs are complex MPs consisting of non-HOMO molecular, partially nanoparticle, structures. Composition, in vitro and in vivo characteristics are defined by manufacturing. Subtle changes of the manufacturing modify quality, efficacy and safety of the MP. NBCDs are not fully characterised physicochemically. In contrast to biosimilars, a regulatory framework is not established.

**Purpose**

Intended copies of NBCDs such as the iron sucrose similars have been approved in several countries by the classical generic pathway. Growing scientific evidence in the non-clinical and clinical setting has raised doubts about interchangeability and/or substitutability.

**Material and Methods**

Science-based statements for comparability of intended copies and reference MPs were discussed among experts from regulatory science, clinicians, hospital pharmacists and industry in a Workshop at FIP 2012. The conclusions were used to propose regulatory requirements for NBCDs.

**Results**

The FIP 2012 consensus meeting confirmed the lack of an appropriate regulatory market authorization of intended copies of NBCDs. For liposomes, physicochemical equivalence testing seems to be more likely to be achievable, but clinical efficacy trials are needed on a case-by-case basis (EMA). Nanoparticle iron sucrose similars show almost no comparability and therapeutic equivalence has to go through quality, efficacy and safety assessments [2]. Glatiramoids, with a not-understood mode of action, also need a broad, as yet to be defined, regulatory approach. Nanoparticle assessment includes sizing and morphology (FDA) and also evaluation of in vivo biodisposition (EMA). The upcoming Terminology and a White Paper will integrate these conclusions.

**Conclusions**

For NBCDs and their specific characteristics a regulatory pathway is needed to assess comparability and eventually therapeutic equivalence of originator and intended copy MPs. In multiprofessional medicines management specific attention to the limits of interchangeability and substitutability is mandatory.

**References**


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