How Do Hospital Pharmacists Approach Substitution of Nanomedicines? Insights from a Qualitative Pilot Study and a Quantitative Market Research Analysis in Five European Countries

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Abstract

We conducted research to assess hospital pharmacists' familiarity with/interpretation of data requirements for the different regulatory approval frameworks and the impact of this on their approach to substitution in the formulary. The online questionnaire included a small molecule (acetylsalicylic acid—follow-ons approved via the generic pathway), two biologic drugs (insulin glargine and etanercept—follow-ons approved via the biosimilar pathway), a non-biologic complex drug (NBCD; glatiramer acetate—follow-ons approved via the hybrid pathway) and a nanomedicine, ferric carboxymaltose (no follow-ons approved as yet). The study was conducted in two phases: an initial qualitative pilot study with 30 participants, followed by a quantitative stage involving 201 pharmacists from five European countries. Most expected negligible safety/efficacy differences between reference and follow-on products. Head-to-head clinical data showing therapeutic equivalence as a prerequisite for reference product/follow-on substitution was perceived to be needed most for biologics (47%), followed by NBCDs (44%)/nanomedicines (39%) and small molecules (23%). Overall, 28% did not know the data requirements for follow-on approval via the hybrid pathway; 16% were familiar with this pathway, compared with 50% and 55% for the generic and biosimilar pathways, respectively. Overall, 19% of respondents thought the European Medicines Agency (EMA) was responsible for defining the substitutability of follow-ons. Education is required to increase hospital pharmacist's knowledge of regulatory approval frameworks and their relevance to substitution practices.
Keywords: drug substitution; hospital formulary; hospital pharmacy; hybrid approval pathway; nanomedicines; nanosimilars; non-biologic complex drugs

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