

How Involved Should Payers be in the Developments of Target Product Profile (TPP), Product Development Plan (PDP) and Design of Clinical Trials (DOCT)

Fatoye C. Sendyona S. Fatoye F. Odeyemi I

Clara.fatoye@stu.mmu.ac.uk

Background: Payers are to be involved in the development of pharmaceutical products since they pay or reimburse these products. It is now a requirement by reimbursement authorities to involve payer's in pharmaceutical product development. Payers are increasingly demanding for them to be involved in early stage development of pharmaceutical products to ensure value i.e. economic and clinical value. The study investigated how involved payers should be in early stage of pharmaceutical product development i.e. Target Product Profile (TPP), Product Development Plan (PDP) and Design of Clinical Trials (DOCT).

Methods: Questionnaire was administered at two different settings: Market Access (MA) and Health Economics and Outcomes Research (HEOR) Conference ISPOR 2015, and market access educational course European Market Access University Diploma (EMAUD) held in Paris. Thematic analysis was used to investigate how involved payers should be in the development of TPP, PDP and DOCT. Responses were grouped under three headings:- 0–1 = not involved (NI), 2–3 = somewhat involved (SI), 4–5 = very involved (VI).

Results: At TPP level, 53% (26) said payers are very involved, 35% (17) said payers are somewhat involved while 12% (6) believed payers are not involved. At PDP level, 33% (16) believed payers are involved, 39% (19) stated that payers are somewhat involved and 28% (14) indicated that payers are not involved. At DOCT level, 41% (20) stated that payers are very involved, 43% (21) said s are somewhat involved and 16% (8) believed that they are not involved. Fifty participants took part in this study.

Conclusions: Payers are very involved (VI) or somewhat involved (SI) in early stage of pharmaceutical product development. Early involvement of payers at this stage may ensure smooth access to pharmaceutical products. Manufacturers are to incorporate payers' perspective early to ensure effective pricing and reimbursement, and efficient resource allocation.