Payers Related Issues Arising From the Development of Pharmaceutical Products at Pre – Launch - Target Product Profile (TPP), Product Development Plan (PDP) and the Design of Clinical Trials (DOCT)

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Background: Pre-launch stage of pharmaceutical product development consists of 3 components; Target Product Profile (TPP), Product Development Plan (PDP) and Design of Clinical Trials (DOCT). Involving payers at this stage is now a requirement by some Health Technology Assessment (HTA) bodies, sponsors and policy-makers. The study investigated payer's related issues arising from involving payers at early stage of pharmaceutical product development.

Methods: Questionnaire was administered at two different settings: Market Access (MA) and Health Economics and Outcomes Research (HEOR) Conference ISPOR 2015 and MA educational course European Market Access University Diploma (EMAUD) held in Paris. They were asked payers' related issues arising from TPP, PDP and DOCT. Participants responded under four domains: evidence requirements, manufacturer's related issues, payer's related issues and unmet needs. Thematic analysis used to investigate payers' related issues arising from involving payers at this level, 50 professionals participated in this study.

Results: At DOCT level, it showed that the main issue experienced by payers was evidence requirements making 72% (31) other issues experienced were; unmet needs 14% (6); payers related issues 12% (5). Manufacturers' related issues had least percentage with only 2% (1). At TPP level, the main issue experienced was unmet needs 36% (16), followed by payers' issues 34% (15) and evidence generation 25% (11). Just like DOCT level, manufacturer's related issues was 5% (2) not a major issue at TPP. At PDP level, payers' related issue was the major issue 53% (18), while evidence requirements and manufacturers related issues had the same response with 18% (6).

Conclusions: Stakeholders are to work on evidence generation requirements at DOCT level, and should focus on payers' issues at PDP level and at TPP level. Attention are to be paid to unmet needs and payers' issues. This may help payers to be involved in early pharmaceutical products development effectively.