**PHP133**

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**OBJECTIVES:** To describe reporting rates of gender-specific safety outcomes for new molecular entity (NME) drugs approved from the US Food and Drug Administration (US FDA) between 2009 and 2013 based on the clinical data summary (CDS) and the new drug application (NDA) files for all NME drugs that were approved for systemic use in men and women were surveyed from the US FDA database. Specific reviews and key word searches were made for descriptions or tabulation of gender-specific inferential statistics on the drug safety section. The rates of inclusion of explicit descriptions or reports of statistical significance were calculated. **RESULTS:** Of all 457 approved drugs during the study period, 118 NMEs were included for the evaluation. Of those, 52 NMEs were excluded due to gender specific indications or non-systemic route of administration, respectively, thereby remaining 97 NME drugs were further reviewed. On average, gender-specific safety outcome descriptions were included in 74% (72/97) of the reviews. Gender-specific statistical significance was documented in 48% (45/97) of the reviews. Further, women were surveyed from the US FDA database. **CONCLUSIONS:** The survey suggested there is an inadequate understanding of the role of patients and payers in the development and commercialization by all stakeholders in the healthcare delivery system. Further research is needed into this field as it has important health policy implications for patient care.

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**PHP136**

**HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs**

**OBJECTIVES:** To compare trends of single versus multiple technology appraisals (STA versus MTA recommendations) for new technologies conducted by NICE. Analysis was also conducted for products with European Union (EU) orphan designation. Further analysis was conducted to identify any disease areas that could be particularly challenging for companies planning a European launch of any new products, aiming to support planning for sequencing across the EU. **RESULTS:** A longitudinal study was conducted by searching all technology appraisals published by NICE since the formation of the organization was analyzed. Analysis of products by disease area was conducted by classification into British National Formulary (BNF) categories. All published guidance was included thus reviews were made for each condition. STA recommendations were more common than MTA recommendations. **CONCLUSIONS:** The ratio of guidance published for STAs to MTAs decreased from 3:1 (54 versus 17) in 2000-2007 to 1:1 in 2008-2014.

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**PHP137**

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**OBJECTIVES:** To explore the impact of orphan designation on the SMC's evaluation of orphan medicinal products. **RESULTS:** A total of 200 orphan medicinal products were evaluated by the SMC from 2000 to 2014. Of these, 118 products were included for the evaluation. **CONCLUSIONS:** The SMC recommendation rate for orphan products, particularly malignant disease and immunosuppressive drugs, has improved from 2013 to 2014 suggesting the revised SMC appraisal process may be more effective in enabling the SMC to provide positive recommendations for orphan products.