ABSTRACTS

ACCESS AND DRUG USE STUDIES

AC1 OUTCOME OF NEW DRUG NEGOTIATION PROCESS IN ITALY: APPROVAL CONDITIONS (2015-2018)

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OBJECTIVES: To track and analyse the economic negotiated conditions (Managed Entry Agreements [MEAs], monitoring, registries, discounts) of novel drugs reimbursed in Italy through Official Journal publications. METHODS: Eighty-eight drugs identified, which were granted EU approval between May 2015 and May 2018 and completed the F&R process in Italy were tracked and categorized by type and therapeutic area in a monthly updated database. Negotiated MEAs, applied confidential discounts and discounts and registries were evaluated and indicated. RESULTS: A total of 23 drugs had monitoring registries. The main MEA applied was price-volume agreements (27.3% of the total assessed drugs) followed by budget cap (20.5%) and cost-sharing agreements (14.1%). Twenty-two (75.9%) of the screened drugs with MEAs had monitoring registries and reimbursement policies in Indonesia for achieving universal health coverage.

AC2 USE OF MEDICINE PRICING AND REIMBURSEMENT POLICIES FOR UNIVERSAL HEALTH COVERAGE IN INDONESIA

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OBJECTIVES: This study aimed to define the problems of the current use of the e-Catalogue and the National Formulary (NF), two elements of medicine pricing and reimbursement policies in Indonesia for achieving universal health coverage (UHC) - by examining the knowledge and attitudes of stakeholders. Specifically, to investigate (1) the perceived challenges involved in the further implementation of the e-Catalogue and the NF, (2) the reasons of prescribing medicines not listed in the NF, and (3) possible improvements in the acceptance and use of the e-Catalogue and the NF.

METHODS: Semi-structured interviews were conducted with stakeholders (policymakers, healthcare providers, pharmaceutical industry representatives and experienced patients) to collect the qualitative data. The data were analysed using directed content analysis, following the guidelines of the Consolidated criteria for Reporting Qualitative studies (COREQ) in reporting the findings.

RESULTS: Interestingly, 20 of 45 participants decided to withdraw from the interview due to their lack of knowledge of the e-Catalogue and the NF. All 25 stakeholders who fully participated in this research were in favor of the e-Catalogue and the NF. A major issue was the lack of harmonization between the lists of medicines in the e-Catalogue and the NF. Several system and personal reasons for prescribing medicines not listed in the NF were identified. Important reasons were a lack of transparency and evidence-based selection for the medicines to be listed in the NF. CONCLUSIONS: The e-Catalogue and the NF have not been fully utilized due to lack of harmonization and evidence-based methods of selection of the medicines to be listed in the NF. Some possible improvements suggested were harmonization of medicines listed in the e-Catalogue and the NF, restructuring incentive programs for prescribing NF medicines, and increasing the transparency and evidence-based approach for selection of medicines listed in the e-Catalogue and the NF.

AC3 DISCORDANT DESIGNATIONS OF BREAKTHROUGH DRUG INNOVATION: FRANCE VERSUS THE UNITED STATES

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OBJECTIVES: Approaches to identify and encourage new innovative, breakthrough drugs vary among countries. The United States of CPGs for the Food and Drug Administration (FDA) “breakthrough-therapy” designation created in 2012 expedited testing and approval. In France, Improvement of the Medical Benefit (ASMIR) value from I-III by the French National Authority for Health (HAS) qualifies a drug as 96% for Lecco (median 37.2; IQR 32.9-41.6) to evaluate the consistency of FDA and HAS designations and frequency of discordant decisions.

METHODS: We conducted a retrospective analysis of approved drug innovation classifications. We included all breakthrough-therapy approvals designated by the FDA and/or innovative by HAS. New indications were excluded. All data sources are publicly available from government agencies. Variables included approval year, indication, market authorization type, FDA breakthrough-therapy designation, ASMI value and others.

RESULTS: In the sample, 73% had discordant designations in FDA versus HAS. In French review, 44% considered innovative were not classified as breakthrough-therapy in the US. In the sample, 73% had discordant designations in FDA versus HAS. CONCLUSIONS: Classification of the innovativeness of new drugs led to substantially different conclusions in France compared to the US. As pharmaceutical companies are incentivized to seek breakthrough and innovative designations during market access, these mixed signals may affect their investments and thus, ultimately, both innovation and access to medicines.

AC4 RETROSPECTIVE ANALYSIS OF INAPPROPRIATE MEDICATION PRESCRIPTION INDICATORS IN ELDERLY POPULATION IN ITALY


1Department of Pharmacological and Biomolecular Sciences (DiSFB), University of Milan, Milan, Italy, 2University of Naples Federico II, Naples, Italy

OBJECTIVES: To retrospectively evaluate indicators of inappropriate prescription in an elderly population using Regional administrative prescription databases.

METHODS: This study was conducted in the Italian Medicines Agency. We evaluated a set of explicit criteria, including a list of inappropriate drugs (ERD) in elderly based on validated tools. STOPP and EU (H)-KIM criteria, and were identified through medical records. An expert committee agreed on the criteria.

RESULTS: The sample included 794, with a mean of 369, 324, 225, 170 patients over 65 for each GP, respectively. For LHUs in Campania, more than 60% of patients were involved (Lecco, Bergamo, Napoli Centro and Napoli Nord) were 205, 661, 744 and 794, with a mean of 369, 324, 225, 170 patients over 65 for each GP, respectively. For LHUs in Campania, more than 60% of patients were involved (Lecco, Bergamo, Napoli Centro and Napoli Nord) were 205, 661, 744 and 794, with a mean of 369, 324, 225, 170 patients over 65 for each GP, respectively.

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