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

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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 which were granted EU approval between May 2015 and May 2018 and completed the P&R process in Italy were tracked and categorized by type and therapeutic area in a monthly updated database. Negotiated MEAs, applied confidential discounts and monitoring registries were evaluated through Official Journal publications. **RESULTS:** Categorization by type yielded 26.1% (23) orphan drugs (EU), 19.3% (17) innovative (AIFA), 5.7% (5) classified as orphan and innovative drugs and 48.9% (43) others; 14.8% (13) oncological drugs, 11.3% (10) oncohaematological and 73.9% (65) others by therapeutic area. Data analysis showed that 33% (29/88) of drugs had MEAs as approval condition; 26 (29.5%) drugs had one single MEA, 3 drugs (3.5%) had two MEAs (payment-by-results + budget cap or price-volume + capping) and the remaining 59 had none. Further analysis of the total 32 (31 and 1 undisclosed) MEAs showed that 31.3% (10) had price-volume agreements, 25% (8) budget cap, 15.6% (5) cost-sharing agreements, 12.5% (4) payment-by-results, 9.3% (3) had capping. Furthermore, AIFA set a market access agreement, a flat fee per patient, for Zalmoxis (3.1%). Twenty-two (75.9%) of the screened drugs with MEAs had monitoring registries and 16 (55.2%) had confidential discounts. **CONCLUSIONS:** Data evaluation showed an unbalance between outcome based and non-outcome based (financial) MEAs suggesting that regulatory attention is predominantly on the economic impact of new drugs; although AIFA recognised the added value of a new patient specific cell therapy by applying flat fee per patient. The low number of outcome based MEAs, though, are counterbalanced by the large number of monitoring registries requested. Budget cap and price-volume agreements are the most commonly negotiated MEAs.

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 representative 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. However, interviewees identified a range of challenges. 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 incentives for physicians as well as a lack of transparent and evidence-based methods of selection for the medicines to be listed in the NF. **CONCLUSIONS:** The e-Catalogue and the NF have not been fully utilized for achieving UHC in Indonesia. 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 greatly among countries. The United States (US) Food and Drug Administration (FDA) "breakthrough-therapy" designation created in 2012 expedites testing and approval. In France, Improvement of the Medical Benefit (ASMR) valued from I-III by the French National Authority for Health (HAS) qualify a drug as innovative and influence pricing. We aimed 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 developed a dataset of 2013-2018 approvals designated as "breakthrough-therapy" by the FDA and/or innovative by HAS. New indications were excluded. All data sources are publically available from government agencies. Variables included approval year, indication, market authorization type, FDA breakthrough designation, ASMR value obtained, and other FDA programs (orphan drug, fast track, and accelerated). **RESULTS:** We identified 57 drug approvals meeting study inclusion/exclusion criteria. More than half (n=30) were indicated for cancer. In the subset of drugs (n=37) classified by FDA and assigned an ASMR value by HAS (n = 37), an innovative designation was more common in the US (78% vs 49% in France). Yet, there was substantial discordance regarding which drugs were defined as innovative. Two of every three breakthrough-therapies approved in the US were not considered as innovative in France. 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

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OBJECTIVES: To retrospectively evaluate indicators of appropriate prescribing in an elderly population using Regional administrative prescription databases. **METHODS:** This study funded by the Italian Medicines Agency. We evaluated a set of explicit criteria, including a list of inappropriate drugs (ERD) in elderly (based on validated Beers, STOPP and EU-(7)-PIM criteria), a list of drugs with high anticholinergic burden (ACB) and with elevated sedative load (SL), has been selected, updated, and adapted to Italian context. The study population was composed by all patients over 65 years followed by a general practitioner (GP) of four local health units (LHUs) in Lombardy and Campania. These criteria were applied to the administrative databases of the outpatient drug prescriptions (reimbursable by the NHS) in 2016. **RESULTS:** The number of GPs for the four LHUs involved (Lecco, Bergamo, Napoli1 Centro and Napoli2 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 Lombardy, the percentages of elderly who received at least an ERD drug were 37.6% for Lecco (median 37.2; IQR 33.9-40.6) and 43.0% for Bergamo (median 42.7; IQR 38.6-47.5). For LHUs in Campania, more than 60% of patients were involved in the ERD list. In all LHUs, the most inappropriate drug prescribed was diclofenac. A high anticholinergic burden (ACB score$\geq$3) was found for 6.0%, 8.0%, 6.7% and 7.0% of patients belonging to the four LHUs, while an elevated sedative load (SL score$\geq$3) was observed in less than 1% of patients. **CONCLUSIONS:** These results show that the prescription of potentially inappropriate drugs in elderly patients is widespread, with some remarkable geographical differences. Therefore, it is necessary to implement local strategies to improve the rational use of drugs. This will enhance safe prescribing practices, reducing costs associated with inappropriate/unnecessary prescribing.