ABSTRACTS

ACCESS AND DRUG USE STUDIES

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

Adunani D1, Lanuzi FP, Niedeccker S, Iezonia M, Rosco V1

1MA Provider Srl, Milano, Italy, 2MA Provider Sagl, Lugano, Switzerland

OBJECTIVES: To track and analyse the economic negotiated conditions (Managed Entry Agreements [MEAs], monitoring, registries, discounts) of novel drugs reimbursed in Italy through official sources. METHODS: Eighty-eight drugs 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 incentive programs were extracted and indexed. RESULTS: Twenty-three (26.1%) novel drugs had MEAs as approval condition, 26 (29.5%) had single MEA, 3 drugs (3.5%) had two MEAs (payment-by-results + indications) 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, 19% (4) set a market access agreement, a flat fee per patient, for Zalmoxis (3.1%). Twenty-two (75.9%) had the lowest form of MEAs had monitoring registries and 16 (55.2%) had confidential discounts. CONCLUSIONS: Data evaluation showed an unbalanced between outcome based and non-outcome based (financial) MEAs suggesting that regulatory attention is predominantly on the economic impact of new drugs, although some MEAs are incentivized to seek breakthrough and innovative designations.}

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

Wasih U1, Irwati S1, Makadu A, Postma MJ2, Goetsch W1, Feenstra T1, Buskens E1

1University Medical Center Groningen, Groningen, The Netherlands, 2University of Groningen, Groningen, The Netherlands, 3The National Healthcare Institute (ZIN), Diemen, The Netherlands, 4The National Healthcare Institute (ZIN), Utrecht University, Diemen, The Netherlands

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 Chairman 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, but they 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 in reporting the findings included the 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 and adapted. 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 VS THE UNITED STATES

Erin F1, Adamson B2, Garrison L3

1French Healthcare products Pricing Committee (CEPS), French Ministry of Health, Paris, France, 2The Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute, University of Washington, Seattle, WA, USA, 3University of Washington, Seattle, WA, USA

OBJECTIVES: Approaches to identify and encourage new innovative, breakthrough drugs vary between the US and France. METHODS: The United States Food and Drug Administration (FDA) “breakthrough-therapy” designation created in 2012 expedited 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 a “breakthrough therapy” (median 37.2; IQR 33.9-41.9) to evaluate the consistency of FDA and HAS designations and frequency of discordant decisions. RESULTS: We conducted a retrospective analysis of approved drug innovation classifications. We included all drugs approved in 2018. Concordant (“breakthrough-therapy” approval 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, ASMR value obtained, and other FDA programs (orphan drug, fast track, and accelerated). CONCLUSIONS: 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

Galionbemer F1, Casula M1, Olmastroini E1, Rosco V1, Fucinielli A, Orlando V1, Mendoza F1, Tragis E1

1Department of Pharmaceutical and Biomolecular Sciences (DISFB), University of Milan, Milan, Italy, 2University of Naples Federico ll, Naples, Italy

OBJECTIVES: To retrospectively evaluate indicators of inappropriate 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 validsted Beers, STOPP and EU-II-HM 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. Those data were applied to the administrative databases of the outpatient drug prescriptions (reimbursable by the NHS) in 2016. RESULTS: The number of ADs (n = 27) classified by FDA and assigned an ASMR value by HAS (n = 37) was found for the four LHUs (LHUs involved (Lecco, Bergamo, Napoli Centre and Napoli2 Nord) were 205, 661, 744 and 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.