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FOLLOWING NORWAY, WHICH MARKET WILL BE NEXT TO SEE EXTREME BIOSIMILAR DISCOUNTING?

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OBJECTIVES: Biosimilar discount expectations are often quoted at 20-30% of the originator's price, but this benchmark was hugely underrated during recent tender bids in Norway. Orinon Oyj astounded many when it decreased the price of its infliximab by 72%, a 69% discount vs. the originator. In our study, we aim to evaluate the risk of similar discounting levels occurring in the EU5 markets for IV biosimilars in the hospital setting. METHODS: We evaluated IV biosimilar and originator therapies and the discounting policies across the EU5 markets to develop hypotheses on extreme biosimilar discounting risk levels. RESULTS: All EU5 markets require biosimilars to launch at a discounted net price to attain reimbursement and net pricing is negotiated at several levels. Regions and hospital purchasing groups are anticipated to attain the greatest discounts or rebates, which will likely be greatest during exclusive or single-biosimilar source tenders that can shape biosimilar uptake. CONCLUSIONS: In our study, we identified 64 brands (48 molecules) removed from the list between 2007 and 2015. Data from IMS MIDAS prescribing data, government ATIH data on “liste-en-sus” products and IMS MIDAS prescribing data, and the impact on healthcare spending of “liste-en-sus” removal.

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LISTE-EN-SUS REFORM IN FRANCE - WHAT ARE THE CONSEQUENCES?

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OBJECTIVES: Activity-based financing (T2A) reforms in France in 2004 led to the creation of a list of “liste-en-sus” -cost drugs reimbursed outside the hospital budget, the “liste-en-sus”. In 2013, this spending was over 2.8 billion Euro, with 7.5% growth. Consequently, the French government has adopted multiple measures to control spending on “liste-en-sus” drugs. The main measure taken was the list. Patients and manufacturers have claimed that without such financing, removal, drugs would not be prescribed, effectively denying access to certain products with marketing authorisation. We investigated the variability of the reimbursement claim and the impact of the healthcare spending of “liste-en-sus” removal. METHODS: Using government ATIH data on “liste-en-sus” products and IMS MIDAS prescribing data, we identified 64 brands (48 molecules) removed from the list between 2007 and 2015. We then measured prescribing before and after removal and categorized the removal decisions. RESULTS: Reasons for removal from the “liste-en-sus” can be categorised as follows: Price cut following launch of a generic or a biosimilar: 36 (20 molecules) Marketing authorization withdrawn: 3 Prescribing shift to retail setting: 4 Insufficient clinical value: 21 (of which 8 are announced for 2015/16). IMS MIDAS data analysis of the 13 products removed for insufficient clinical value between 2006-2013 shows that prescribing of half of these products was maintained or even increased, suggesting that removal did not deprive patients of authorized medicines. Sales of the remaining products fell after removal, as suitable alternatives were available for patients. For drug manufacturers, removal typically reduces sales; either through price discounts to achieve hospital reimbursement levels, or a fall in prescribing. CONCLUSIONS: The French “liste-en-sus” is meant to offer temporary funding for innovation, yet the number of removals is low. While removal has no negative consequences for patients, the real savings from such measures is limited and unlikely to reduce drug spending.

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THE MOST PROFITABLE HEALTH INSURANCE “COMPANY” IN TURKEY

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OBJECTIVES: The Health Transformation Program commenced in 2002 by Ministry of Health. Today, Turkey has a well-established health care system, mostly dominated by government as healthcare provider and payer. Social Security Institution (SSI) is the only government payer covering 99% of the Turkish population. There are private health insurance (PHI) companies covering only 3% of the population. The aim of the analysis is to compare the profitability of health insurance in Turkey. METHODS: The most updated data of revenue and cost of PHI data was obtained from Turkish Private Insurance Association for years 2009-2013. The official revenue and cost of government health insurance data was obtained from SSI for the same years. Descriptive analysis were conducted with the revenue and cost data of government and private health insurers. RESULTS: The total revenue and costs of PHI companies were 2.3 billion TL and 1.7 billion TL per capita and revenue and cost of private health insurance companies were 822 TL and 631 TL in 2013, respectively. The gross profit of all PHI companies was 0.6 billion or 26%. The SSI’s revenue and cost for health insurance were 53 billion and 49.9 billion TL per capita revenue and cost of health insurance were 691 TL and 650 TL in 2013, respectively. The gross profit of SSI health insurance was 4.1 billion and 5%. CONCLUSIONS: The SSI has become the monopsonic payer in the Turkish health system with mandatory health insur-

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COMPARISON OF CURRENT AND PREFERRED STATUS OF HTA IMPLEMENTATION IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

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OBJECTIVES: To assess current status of HTA implementation in Central-Eastern European (CEE) countries and to identify long-term objectives considering country specific aspects and regional commonalities. METHODS: An HTA implementation survey was designed and distributed to 22 Central-Eastern European countries. The survey was conducted among participants at the Fifth Adriatic Congress of Pharmacoeconomics and Outcomes Research (Sibenik) and at the Pilot ISPOR HTA Training Conference (Zagreb). Opinion of respondents on current and preferred status of HTA implementation as well as influencing factors, current and preferred future status of HTA implementation in their own country were described to capacity building, HTA financing, process and organisational structure, HTA methodology, use of local data, scope of mandatory HTA, and decision criteria. RESULTS: 41 participants (78% public sector employees) from 11 CEE countries filled in the survey. 75% of respondents would prefer postgraduate training for HTA capacity building, however, only 15% reported a current HTA implementation protocol. 13% reported difficulties in finding key persons in their country. Participants would increase public funding on HTA research (6% current vs. 65% preferred) and on critical appraisal of HTA submissions (15% current vs. 64% preferred). 73% of participants would prefer establishment of public health agency with academic support, however only 10% reported the existence of such agency. 92% of respondents would mandate the use of local data with need for assessing the transferability of international evidence (vs. 34% currently). 86% would prefer development and access to databases for HTA (vs. 11% currently). CONCLUSIONS: Our results must be viewed as an initial step in a multi-stakeholder dialogue on HTA implementation. Each CEE country should develop its own HTA roadmap, as such roadmaps are not fully transferable with- out taking into account country size, GDP per capita, major social values, public health priorities and fragmentation of health care financing.

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IMPACT OF A PAYMENT BY RESULTS Access Scheme in Italy: Better Value for Money?

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OBJECTIVES: The Italian Medicine Agency (AIFA) has recently introduced conditional reimbursement schemes to promote access to oncology therapies, and reduce the risk of funding treatment with lower effectiveness than observed in clinical trials. These schemes are designed to be terminated after few years once treatment value is reassessed based on available real world data. Payment by Results (PbR) is frequent applied, manufacturers would be asked to pay back the treatment costs for patients receiving the new therapy if progression occurs before a pre-specified threshold. METHODS: A simulation tool was built to assess the impact of the implementing PbR scheme and quantify the resulting increase in clinical value of a new treatment. Progression Free Survival (PFS) curves have been simulated using parametric distributions and hazard ratios to generate various scenarios that may be observed in clinical trials. Patients receiving the new treatment and experiencing a recurrence before the PbR threshold were censored within the survival curve. PbR was also investigated considering Bevacizumab (Bev) in cervical cancer (CC). RESULTS: The improvement in mPFS resulting from PbR was significant and meaningful in every scenario generated. The magnitude of the benefit depended mostly of the shape of parametric distribution. When applied to Bev in CC, a 3-month PbR scheme resulted in an improvement of Bev mPFS from 3.2 to 5.0 months (leading to a 4.1 months median incremental benefit over chemotherapy). CONCLUSIONS: Based on this simulation study and the underlying assumptions, the patient access scheme proposed by AIFA would, in most scenarios, be associated with an increase in median incremental benefit for the patients, fewer costs for the payers and therefore better value for money.

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PREFERRED ACCESS SCHEMES WITHIN THE UK: A RETROSPECTIVE ANALYSIS

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OBJECTIVES: In recent years there has been an increasing strain on healthcare budgets due to the fact that many new medicines so manufacturers need to demonstrate additional benefit and value for money to achieve reimbursement. One of the key policy tools available are managed entry agreements. In the UK these are assessed as patient access schemes (PAS) which have been successfully used to obtain cost effectiveness since 2007.