The influence of "HAS" Haute Autorité de Sante in the Reimbursement decisions in Francophone countries: the Case of North Africa

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OBJECTIVE: France has large markets for pharmaceuticals in Algeria; moreover, Algerian authorities look to France for reference pricing. In recent times, the HAS is increasingly the influence health technology assessment (HTA) agency. French speaking countries are referencing and following the HAS decisions. The main objective of this study is to review the HAS in France (and Africa and particularly Algeria) in their reimbursement decisions. METHOD: To have a comprehensive study, a sample of medicines was determined, and these drugs had obtained positive recommendation by HAS during a period from January 2013 to December 2013. Then, the reimbursement from HAS were matched with the North African decision. RESULT: Drugs approved for their first prescription were 258, while one drug obtained ASRM II, 12 obtained ASRM III, 13 noted ASRM IV and 232 ASMR V. When we have analyzed the common reimbursement decision taken according the level of ASMR We have observed that Morocco reimburse the drugs product with ASRM III and ASMR IV. However Algeria and Tunisia reimburse less the medicines with ASRM IV and V. CONCLUSION: This study demonstrates that the discordance between the reimbursement decisions in the most cases may reflect the differences in the decision making process and in their constraint budget; Payers in Morocco are following HAS recommendation whereas Tunisia and Algeria there are following less HAS decisions.

Tracking Drug Utilization data to Enable Conditional Reimbursement of Medicines or Specific Indications in Romania: Analysis of the requirement for an effective implementation

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BACKGROUND INFORMATION: In 2014, Romania adopted a new law regulating the Health Technology Assessment (HTA) as mandatory step in the drug reimbursement listing. HTA as a score-card, the drug’s indication can include unconditional (80 – 145 points), or conditional approved (60-79 points). Conditional approved indications are reimbursed only if they are included in a cost-volume/cost-volume-result contract (CV/CVr) with the National Facility, requiring the tracking of drug use and reimbursement. This could be validated by the benefit the product provides in different indications (Multiple Indication Pricing-MIP). One single unit price could be not relevant for all indications (e.g. in oncology), especially when the same drug has both unconditional and conditional reimbursement. APPROACH: Under MIP, drug utilisation would be tracked; the price of medicine per indication would be defined according to the benefit of the drug in that indication. Two approaches could be used: leveraging existing national data collected by the National Facility, adding to collect data like indication, treatment status, result, etc. by a separate module in the Hospital Information System or use e-health/electronic patient records. Implications: Required minimum data fields, forms, definitions, attributes must be complete, consistent, available, allowing for validity checks. Marketing Authorization Holder (MAH) must receive reports containing information (anonymised and aggregated) on drug utilisation. To be tracked: timing between data capturing and data availability for payers, absorbing data for generation and capturing error handling. RECOMMENDATIONS: Conduct pilot with a representative oncology clinic, set a methodology for collection, validation and use of data, generate reports, demonstrate the utility in managing CV/CVR. Scale up the project on national level through the National Health Insurance House. CONCLUSION: Developing a system to identify drug utilisation on indication, could support implementing conditional reimbursement schemes by the Payer and increase patient access to drugs.

Targeted combination regimes in oncology challenges for pricing and reimbursement in Switzerland: An analysis of operational requirement for implementation of an indication code

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BACKGROUND INFORMATION: Targeted Combination Regimes (TCRs) could significantly improve outcomes for cancer patients in future as drugs with different and complementary mechanisms of action often act synergistically to improve treatment results. Despite the potential benefits of TCRs there are also challenges associated with them. Several combination therapies involve more than one Marketing Authorization Holder, adding the cost of two medicines on top of each component drug. To address this potential local market, an additional criteria for the funding of such TCRs unsustainable. The Federal Office of Public Health (FOPH) currently commands price negotiation at brand level, resulting in a single price per product approved. To overcome this limitation and to generate flexibility pricing negotiations might be required in order to enable faster patient access while maintaining TCRs remanence effective, expedient and economical. APPROACH: One approach could be the introduction of an indication code on the billing process. The indication code could help health insurers and physicians to identify TCRs and the potential local market. The new approach would be simple and standardised process. Flexible pricing models would make sure that TCRs remain economical. RECOMMENDATIONS: Patients would have to agree that information on the condition (e.g. indication, molecular profile, therapy) would be captured on the billing process. The indication code would have to be encrypted by the health insurer. The IT systems of health insurers and hospitals need to be modified. CONCLUSION: Patientcentric approach is a working group led by the pharma industry association and major health insurers (including pharma companies, hospital administration and oncologists) will set up pilots with oncology clinics to test the feasibility of implementing an indication code and work on sustainable pricing for TCRs. CONCLUSION: The reimbursement for TCRs would be standardised process for remuneration for TCRs based on indication code and the underlying pricing model. For scale up the FOPH would have to mandate the adoption of the approach at national level.

The trends in orphan drug authorisation and approval in Europe and in the United States - A retrospective study (2005-2014)

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BACKGROUND: There are differences across the world in the definitions used to classify an orphan drug (OD), especially with respect to the prevalence of the disease justifying the orphan status and, the estimation of the population affected. OBJECTIVE: To identify the number of medicines which have been granted orphan designation in the United States (US) and European Union (EU), and analyse the approval trends over a ten-year time horizon. METHODS: All ODs authorised by the European Medicines Agency (EMA) and approved by the US Food and Drug Administration (FDA) were identified on the 1st May 2015 by downloading the databases available from their respective websites. Duplicates were removed if the names using non-proprietary name and the lists were filtered to capture the period from 01/01/2005 to 31/12/2014. RESULTS: The databases downloaded from FDA and EMA had n=93 and n=237 reports respectively. Resulting duplicates reduced these to n=91 and n=197 respectively. Filtering the list to select ODs authorised between the 01/01/2005 and 31/12/2014 gave final values of n=74 and n=189 respectively. ANALYSIS: The number of ODs approved significantly increased in numbers between the years 2005 and 2014 in the US and in the EU. In 2014 the EMA authorised 5 times as many ODs as they did in 2005 (15 vs 3 respectively) and a similar trend was observed in the US, where in 2014 the FDA authorised twice as many ODs as they did in 2005 (30 vs 14). CONCLUSIONS: In 2005 the number of ODs authorised was significantly lower than that of 2014 and the designation of orphan diseases and approval of ODs was rare. 10 years on and gaining OD status for orphan diseases and approval of ODs was rare. 10 years on and gaining OD status for orphan diseases and approval of ODs is rare. 10 years on and gaining OD status for orphan diseases and approval of ODs is rare. 10 years on and gaining OD status for orphan diseases and approval of ODs is rare. 10 years on and gaining OD status for orphan diseases and approval of ODs is rare.
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ous health care providers to offer a new kind of competition as a real challenge to gener-
ing the local NHIF capacity. Legislation changes should be made in chapter 12 of
the Drug act, article 45 of the Insurance act and to be created new section within
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PHP334 HEALTH CARE COVERAGE THROUGH PRIVATE HEALTH INSURANCE
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BACKGROUND: Achieving universal health coverage (UHC) is a common goal world-
wide. As off today only some rich countries have succeeded to provide publically
funded UHC to all their citizens. However, many low- and middle-income countries
are still struggling with financial access to the health. Today, only 60% of the
world’s population has access to at least basic health services. The main reason is
the scarce NHIF budget will be preserved within endorsed limits. CONCLUSIONS: RSA
seems promising solution for balancing uncertainties for payers with market access
for new drugs. In the future, this model will allow PHI efficiently to control and spend
their limited budget while preserving quality treatment to more patients in need.

PHP335 COMPARISON OF PHARMACEUTICAL PRICING AND REIMBURSEMENT SYSTEMS
IN TURKEY AND CERTAIN OTHER EU COUNTRIES
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This is an expository analysis, along with current situation in Turkey, pharmaceutical pricing
methods, reimbursement methods and basic health indicators, within the scope of
changing pharmaceutical policies, in Turkey, reference countries and the United
Kingdom; the implementations of which are of utmost importance for other coun-
tries. As long as a country is developing, it is very important to review the phar-
mazeutical pricing system which has been developed in Turkey on the basis of reference
pricing system. At the same time, the factors that cause price increase in these coun-
tries are identified and recognized by all stakeholders. A political incidence and advocacy
was estimated in USD 6.1 million; of which the GFATM would cover USD 3.6 million

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PHP338 PATIENT BEHAVIOUR AS A COST DRIVER IN THE MANAGEMENT OF CHRONIC DISEASE PATIENTS
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BACKGROUND: Maintaining chronic disease patients clinically stable after dis-
charge is an important imperative for avoiding costly hospital readmissions. A good
understanding of the clinical risk drivers in chronic disease patients is considered
as the most important factor predictive of unfavorable patient outcomes. However,
an often overlooked risk factor is patient behavior and patient decision drivers.
Insight from the behavioral sciences can shed light on how individuals actu-
ally make decisions. Behavioral sciences have been used in marketing for years
but are rarely used in the medical field. Recent studies from the UK have shown
that up to 60% of the costs incurred over the reference price and the frequency of Euro is fixed at 2. Moreover, it has been
recognized that certain drugs have been hard to find within the market and the
patients’ access to medicines has become hindered. Although it is natural for Turkey to
raise restrictions on drugs budget to ensure sustainable drug financing, in order to
maintain the existence of pharmaceutical industry and protect the patients’ access
to medicines; it would be more favorable in the development of the industry that
the expectations of the stakeholders in the industry are taken into account in the policy
making process. This would also help the already supported R&D activities to be
sustainable as well. The positive and negative aspects of Turkey’s offering the least
expensive medicine should be examined. Whether being the country to supply the
least expensive medicine is the correct objective or not in the international arena should
seriously be discussed. It is recommended that how this situation affects
Turkey’s image in the outer world should be scrutinized.

PHP336 CLOSING THE FINANCIAL GAP OF ANTIRETROVIRAL AND HIV SUPPLIES FOR SUSTAINABILITY OF HIV NATIONAL RESPONSE IN THE DOMINICAN REPUBLIC
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Since the first HIV/AIDS pandemic was first announced in 1981, the production of ARVs in the world has
been funded, by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Until
2005, there was a gross correspondence between the increase in the number of treated
patients and the increase in the number of new patients. Since 2004 public provision of ARV in Dominican
Republic (DR) has been funded, since 2008, by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

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