security funding law, France is becoming the first country to allow biosimilars substi-
tuting when initiating treatment courses. This modern health care system, and the
Norwegian Medicines Agency announced in 2013 the funding of clinical studies with
infliximab originator and biosimilars in which patients would be switched from
originator to biosimilars forth and back. Moreover, increased price discounts of
about 1% were negotiated for infliximab. The purpose of this study was to measure the impact
for biosimilars are estimated around $12-33 billion in big EU5, Poland, Romania,
Sweden. CONCLUSIONS: While patent cliff of major biologic drugs is expected on the
market in the years to come, efforts to prescribe biosimilars and implementation of substitution rules, even if still raising some reluctance, might contribute to boost biosimilar uptake in Europe. Price competition will impose manufacturers of branded biologics to adopt new pricing strategies.

OBJECTIVES: In Turkey, a medicine pricing reference system has been in use since 2004. The price of pharmaceuticals is determined by the acceptance of the lowest ex-factory price in the reference countries (France, Italy, France, Portugal, Spain). We aimed to examine the first 100 medicines, having the annual maximum amount on the average Turkish Lira (TL) based medicine sales between the years 2008-2013 which have 15% value in the total pharmaceutical market, reference price changes in period. METHODS: While pharmaceutical sales data were obtained from the IMS Health-Turkey data base, medicine prices were obtained from the Medicine Price List published by Turkish Medicines and Medical Devices Agency. RESULTS: In 2009, 32 medicines showed 100% increase in determining reference price. The “liste-en-sus” is the reference country more common, France and Italy are to follow. In 2008, only one medicine price was increased, only one medicine price had decreased. In 2009 reference price. In 2009 and 2010 price increases did not seen. In 2009, 8 and in 2010, 3 medicines price had decreased. In 2011, 2012 and 2013 totally 27 medicines refer-
ence price had increased. 21 medicine’s price in 2011, 20 medicine’s price in 2012 and 2013 totally 102 medicines’ price in 2013 had decreased. In 2014 totally 13 medicines’
connected to the reference price increases, mostly Greece (58 medicines) has been
based reference price drop in the analyzed period. CONCLUSIONS: The application of reference prices, medicine prices to be reduced to a large extent. Greece based
reduction in the size of the retail pharmaceutical market during the period of
crisis. Volume had an impact as well but it was partially offset by switch towards
more expensive medicines.

IMPLICATIONS OF EXTERNAL PRICE REFERENCING OF PHARMACEUTICALS IN MIDDLE EAST COUNTIES

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OBJECTIVES: External price referencing (EPR) is a method to control pharmaceutical prices. In some countries, healthcare payers specify a basket of countries, whose prices they use to inform their national target price. EPR is practiced frequently worldwide, though countries vary substantially in how they execute EPR. The objective of our paper is to identify the key policy changes in the health care systems. RESULTS: EPR regulations are most stringent in Europe and Saudi Arabia (largest study countries), mandating the lowest pharmaceutical price out of a basket comprising more than 25 countries each. By contrast, Kuwait references the country of origin only. The average price corridor is +/-38% for pharmaceuticals and +/-78% for outpatient and hospital services compared to mean prices. CONCLUSIONS: EPR results in narrower price corridor for innovative pharmaceuticals compared to other health care se-
cures. Prices of innovative pharmaceuticals are the lowest in Egypt and Saudi Arabia, and the highest in Kuwait, indicating the importance of population size and EPR implementation on drug price levels. However, EPR results in higher pharmaceutical prices compared to other regions. Allowing a higher price corridor may timely access of patients to new medicines in these countries compared to global markets. Stakeholders should understand the implications of EPR and develop solutions to prevent its negative consequences.

MULTI-STAKEHOLDER (PHYSICIAN, PAYER, PATIENT, AND INDUSTRY) QUALITATIVE ANALYSIS OF THE POLICIES THAT WOULD SUPPORT A SUSTAINABLE EUROPEAN BIOLOGIC MARKET

Whitehouse TC1, Teale CW1, Glover JC2, Taylor C3, Lino Mendonca V4

1 CCR Market Access, Melton Mowbray, UK 2 European Generic Medicines Association (EGA)

OBJECTIVES: To establish the key policy areas that will drive the establishment of a sustainable biosimilar medicines market. To outline the benefits that these will bring to Physicians, Payers, Patients, and Industry, with particular focus on the benefits for European National Health systems. METHODS: 71 qualitative in-depth interviews were conducted across 7 European markets: France, Germany, Hungary, Italy, Poland, Spain and the UK. Collecting insight from experts and policy influencers at pan-European, National and Regional levels, Physicians, Payers, Pharmacists, Patients, and Industry. Quantitative modelling used a systems dynamics approach with in-depth analysis of 3 representative biologic products: trastuzumab, bevacizumab, and adalimumab. Dynamics were based on a delphi panel of expert opinions. The five forces of supplier power, buyer power, impact of new entrants, impact of substitutes, and competitive rivalry were addressed. A ranking of the attractiveness of policy combinations from a sustainability and benefit perspective was developed using a best-case scenario for the “multi-stakeholder” policy combination, measured in terms of the sustainability index, the calculation of the magnitude of the benefit. RESULTS: The qualitative analysis has shown that a European biosimilars medicines market based on stakeholder and policy alignment in four key policy areas: Education and understanding 2. Innovation in use 3. Affordable pricing, 4. Decision making will be sustainable and deliver benefits to all stakeholders. The quantitative analysis demonstrated that the most efficient policy combination, measured in terms of the sustainability index, was the same for all policy areas and would deliver cumulative 10 year cost savings of between 24% and 26%.

PHASE 2

A MULTISTAKEHOLDER (PHYSICIAN, PAYER, PATIENT, AND INDUSTRY) QUALITATIVE ANALYSIS OF THE POLICIES THAT WOULD SUPPORT A SUSTAINABLE EUROPEAN BIOLOGIC MARKET WOULD DELIVER

Whitehouse TC1, Teale CW1, Glover JC2, Taylor C3, Lino Mendonca V4

1 CCR Market Access, Melton Mowbray, UK 2 European Generic Medicines Association (EGA)

OBJECTIVES: To identify the key policy areas that will drive the establishment of a sustainable biosimilar medicines market. To outline the benefits that these will bring to Physicians, Payers, Patients, and Industry, with particular focus on the benefits for European National Health systems. METHODS: 71 qualitative in-depth interviews were conducted across 7 European markets: France, Germany, Hungary, Italy, Poland, Spain and the UK. Collecting insight from experts and policy influencers at pan-European, National and Regional levels, Physicians, Payers, Pharmacists, Patients, and Industry. Quantitative modelling used a systems dynamics approach with in-depth analysis of 3 representative biologic products: trastuzumab, bevacizumab, and adalimumab. Dynamics were based on a delphi panel of expert opinions. The five forces of supplier power, buyer power, impact of new entrants, impact of substitutes, and competitive rivalry were addressed. A ranking of the attractiveness of policy combinations from a sustainability and benefit perspective was developed using a best-case scenario for the “multi-stakeholder” policy combination, measured in terms of the sustainability index, the calculation of the magnitude of the benefit. RESULTS: The qualitative analysis has shown that a European biosimilars medicines market based on stakeholder and policy alignment in four key policy areas: Education and understanding 2. Innovation in use 3. Affordable pricing, 4. Decision making will be sustainable and deliver benefits to all stakeholders. The quantitative analysis demonstrated that the most efficient policy combination, measured in terms of the sustainability index, was the same for all policy areas and would deliver cumulative 10 year cost savings of between 24% and 26%.

CONCLUSIONS: Greater stakeholder alignment and the combina-
tion of specific policies will increase the sustainability of the European biosimilar
medicines market. A sustainable biosimilar medicines market will deliver signifi-
cant benefits to all stakeholders.