procurement procedures in 38 European Countries. *Haemophilia*. 2015;21:436-43.

3. Porter ME. What is value in health care? *N Engl J Med*. 2010; 363(26):2477–2481.

OP19 Unlocking The Potential Of Established Products: Need For Incentives

AUTHORS:

Gabrielle Nayroles, Sylvie Gabriel, Mondher Toumi, Åsa Kornfeld, Patrycja Jaros, Sandrine Frybourg, Fernando Antoñanzas, Jaime Espín, Claudio Jommi (claudio.jommi@unibocconi.it), Nello Martini, Gérard de Pouvourville, Keith Tolley, Jürgen Wasem

INTRODUCTION:

Re-purposing of established products (EPs) – defined as marketed for 8 years or more – may represent a high value for patients and society. It has been recognized by the European Commission as an important factor contributing to greater access to new therapies. Due to a lower development cost, it could also represent a cost-effective alternative and help to reduce pressure on healthcare budgets. However, it is perceived that no financial incentives exist for the pharmaceutical industry to invest in new indications for EPs. The objective of this research was to review current European regulations and propose strategies stimulating development in this field.

METHODS:

We performed a targeted literature review and held two international expert panel workshops to discuss current policies and their implications, and issue recommendations for changes.

RESULTS:

Within the current regulatory framework EPs face price cuts due to generic competition, reference pricing (RP), price re-negotiations or systematic price cuts, after a period of marketing presence. Extension of indications does not permit to increase or maintain the price. Generic substitution regardless of indication poses another challenge. Limited incentives in the form of an additional year of market protection exists only for new indication(s) registered within the first 8 years following initial approval. The expert panel proposed several strategies to stimulate development in this field, including: (i) extending the period in which registering a new indication results in additional market protection beyond 8 years and extending the duration of additional market protection; (ii) delaying inclusion in RP for EPs with a new value adding indication; (iii) establishing a differential pricing by indication; (iv) preventing temporarily generic substitution when an EP is prescribed for a new indication.

CONCLUSIONS:

Current regulations represent a serious disincentive to develop new indications for EPs. Regulatory and pricing policy changes are needed to stimulate development in this important field.

OP21 Involving Clinical Experts In Prioritizing Topics For Health Technology Assessment: A Randomized Controlled Trial

AUTHORS:

Andrew Cook (andrewc@soton.ac.uk), Elke Streit, Gill Davage

INTRODUCTION:

The National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme commissions research to inform health services in the United Kingdom. The program prioritises research ideas from literature, guidelines, patients, and clinicians, to decide which research should be funded. We get clinical input on these ideas through (i) committees of clinicians and patients and (ii) seeking written advice from multiple clinicians — a refereeing process. Chairs of our committees suggested that the material we sent to clinicians was too extensive and the method of

https://doi.org/10.1017/S0266462317001222 Published online by Cambridge University Press