Author's response to reviews

Title: Review of risk sharing schemes for pharmaceuticals: considerations, critical evaluation and recommendations for European payers

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Version: 4 Date: 16 May 2010

Author's response to reviews: see over
Dear Editor

Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers by J Adamski, B Godman, G Ofierska-Sujkowska, B. Osinska, H Herholz, K Wendykowska, O Laius, S Jan, C Sermet, C Zara, M Kalaba, R Gustafsson, K. Garuoliene, A Haycox, S Garattini, L L Gustafsson

We believe this potential paper on the critical evaluation of risk sharing arrangements for pharmaceuticals and recommendations for the future will be of great interest to your readers for the following reasons:

- This is a developing field with new schemes being discussed and instigated across Europe between pharmaceutical companies, health authorities and hospitals
- There is considerable confusion with the terminology – not helped by the wide range of schemes currently included with the general umbrella ‘risk sharing’
- Payers and their advisers across Europe have deep concerns with a number of the schemes. This is not helped by the very limited number of peer reviewed papers discussing such schemes as well as including their overall costs and benefits
- Publication in your journal allows easy access to a wide range of payers and their advisers across the different countries to help stimulate the debate and provide insights in the future

We are also aware that such schemes are accelerating across Europe with growing pressure on resources exacerbated by the continued launch of new premium priced drugs especially in the cancer field. This includes the development of patient access schemes in England as well as price capping schemes in Sweden.

Consequently, myself and my colleagues believed there was a need to bring together a large group of payers and their advisers from across Europe and the US who are currently wrestling with these schemes to debate these important issues as well as provide suggestions to all key stakeholders for the future.

The contribution of the individual authors are as follows:

- Jakub Adamski – Lawyer with the Ministry of Health in Poland actually involved with developing new laws to include such schemes in the future. As part of this, Jakub has been involved with appraising schemes from across Europe and categorising them to provide direction. Kamila Wendykowska and Gabriella Ofierska-Sujkowska helped with this whilst both at the National Health Fund in Poland before recent moves
- Brian Godman – main author involved with constructing the general direction for the paper as well as producing the initial and subsequent drafts for comment
- Bogusliwa Osinska – helped to critique the discussions on Poland as well as the potential future direction from her perspective at the National HTA Agency in Poland
- Harald Herholz – heavily involved with advising ambulatory care physicians in the State of Hessen on ways to improve the quality and efficiency of their prescribing to stay within target budgets. Harald is also a leading member of the national KBV organisation.
Consequently, able to critique and provide practical advice on the situation regionally and nationally in Germany between the Sickness Funds and pharmaceutical industry

- Ott Laius – currently working at the State Agency of Medicines in Estonia. Ott provided advice and comment on the current schemes in Estonia and potential ways forward
- Saira Jan - Director of Clinical Pharmacy Management at Horizon Blue Cross Blue Shield of New Jersey. Saira is actively involved with critiquing clinical and economic issues for new and existing drugs in HBCBS. This includes potential ‘risk sharing’ arrangements as well as programmes to enhance compliance, which is also seen as a growing problem especially for patients with chronic diseases
- Catherine Sermet – provided feedback on current schemes in France
- Corrine Zara – helped to critique the recommendations based on her perspective as a payer in a leading region in Spain
- Marija Kalaba – provided data on current schemes in Serbia as well as helping to provide guidance to the future based on her experience
- Alan Haycox – Reader and leader of the Prescribing Research Group at Liverpool University. Alan was involved with developing the Velcade scheme in the UK, and is now a member of the NICE appraisal group evaluating such schemes. He utilised his considerable knowledge with developing and critiquing the various drafts
- Roland Gustafsson is a Consultant in the procurement of tenders for pharmaceutical products at the Karolinska University Hospital and Stockholm County Council. Roland was actively involved in the first risk sharing schemes for Stockholm and provided a different perspective when reviewing these schemes
- Kristina Garuolienė – provided feedback on current schemes in Lithuania as well as critiquing proposed recommendations
- Silvio Garattini – helped to critique a number of drafts based on his considerable experience in Italy (when heading the Italian Reimbursement Agency and providing members since from his Institute) and across Europe with his time at the EMEA and subsequently
- Lars Gustafsson has published extensively on key issues in Sweden through his chairmanship of the Regional Drugs and Therapeutics Committee as well as general experience with informatics and the evaluation of the rational use of drugs. Lars contributed significantly to the discussions and future direction

In addition, Jan Jones from the Scottish Medicines Consortium provided input from Scotland as well as inputting into current concerns and critiquing the suggestions on potential ways forward. Ines Teixeira critiqued the details of current schemes in Portugal based on her previous experience at INFARMED. Roberta Joppi helped to provide additional details on current schemes in Italy.

As you can see, all the affiliations and emails of the authors are included in the submitted paper. For your information, all the tables are originals – so there are no copyright issues.

In addition, there are no conflict of interest issues although, as stated above, a number of the authors are heavily involved with critique the various schemes in their countries. There are also no ethical considerations. Finally, there was no writing assistance with paper.

Yours faithfully

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