Brian Godman

- Brian currently works with Governments, WHO, health authorities and their advisers as well as academics across countries and continents to enhance the quality and efficiency of prescribing. This includes both new and established medicines

- Co-founder of the Piperska Group in 2008 (Pan-European group of health authority/ health insurance company personnel and their advisers) and the MURIA (Medicines Utilisation Research in Africa) group in 2015

- Brian has published over 350 papers in peer-reviewed journals with multiple colleagues since 2008 - many listed in Pub Med

- Brian has no conflicts of interest to declare

Value-Based Alternative Payment Models

ISPOR Europe 2020

Professor Brian Godman

Key issues and their implications

- Expenditure on complex treatments including biological medicines will soon exceed 50% of total expenditure on medicines worldwide. Expenditure will continue rising with a considerable number of new medicines for oncology and orphan diseases in development with premium price expectations
- Concerns with available resources especially in Europe exacerbated by ageing populations
- However any initiatives introduced must be balanced against providing incentives to develop new medicines to meet continued unmet need
- This has resulted in:
  - Greater pro-activity among payers including new models to better manage the entry of new medicines
  - Alternative payment methods including MEAs and MCDAs as well as potentially fair pricing models and indication based pricing
  - Increasing use of low-cost multiple-sourced medicines and biosimilars where pertinent
  - Growth in disinvestment activities

Further details regarding potential models for disinvestment – also using patient level data – can be found in:

International Journal of Technology Assessment in Health Care

cambridge.org/thc

An evidence-based framework for identifying technologies of no or low-added value (NLVT)

María Eugenia Esandi[1,2], Iñaki Gutiérrez-Ibarluzea[3,4], Nora Ibargoyen-Roteta[3] and Brian Godman[5,6,7]

International Journal of Technology Assessment in Health Care, 33:2 (2017), 279–287.

doi: 10.1017/S0266462317000435

HEALTH TECHNOLOGY PERFORMANCE ASSESSMENT: REAL-WORLD EVIDENCE FOR PUBLIC HEALTHCARE SUSTAINABILITY

Augusto Afonso Guerra-Júnior
SUS Collaborating Centre for Technology Assessment and Excellence in Health, Universidade Federal de Minas Gerais
Department of Social Pharmacy, School of Pharmacy, Universidade Federal de Minas Gerais

Lívia Lovato Pires de Lemos
SUS Collaborating Centre for Technology Assessment and Excellence in Health, Universidade Federal de Minas Gerais
Post-Graduation Program in Public Health, School of Medicine, Universidade Federal de Minas Gerais
[illegible]@gmail.com

Brian Godman

Aine Heaney
National Prescribing Service Medicinewise

Carlos Alberto Vassallo
Facultad de Ciencias Médicas, Universidad Nacional del Litoral

Björn Wettermark
Public Healthcare Services Committee, Department of Healthcare Development, Stockholm County Council
Department of Medicine Solna, Clinical Epidemiology/Clinical pharmacology, Karolinska Institutet and Karolinska University Hospital

Gotzika Bengurto-Arrate, Iñaki Gutierrez-Ibarluzea
Osteba, Basque Office for HTA Ministry for Health, Basque Government

This is the Swedish model to improve the managed entry of new medicines starting with horizon scanning and continuing post launch - worked well for hepatitis C and new medicines for ovarian cancer

FIGURE 1 | The Swedish national process for managed introduction and follow-up of new medicines. Source: The Swedish Association of Local Authorities and Regions (2017a). Reproduced with permission from Sofie Alvehed.

This was our published paper – available Open Access - and builds on the model we developed across Europe following the launch of DOACs

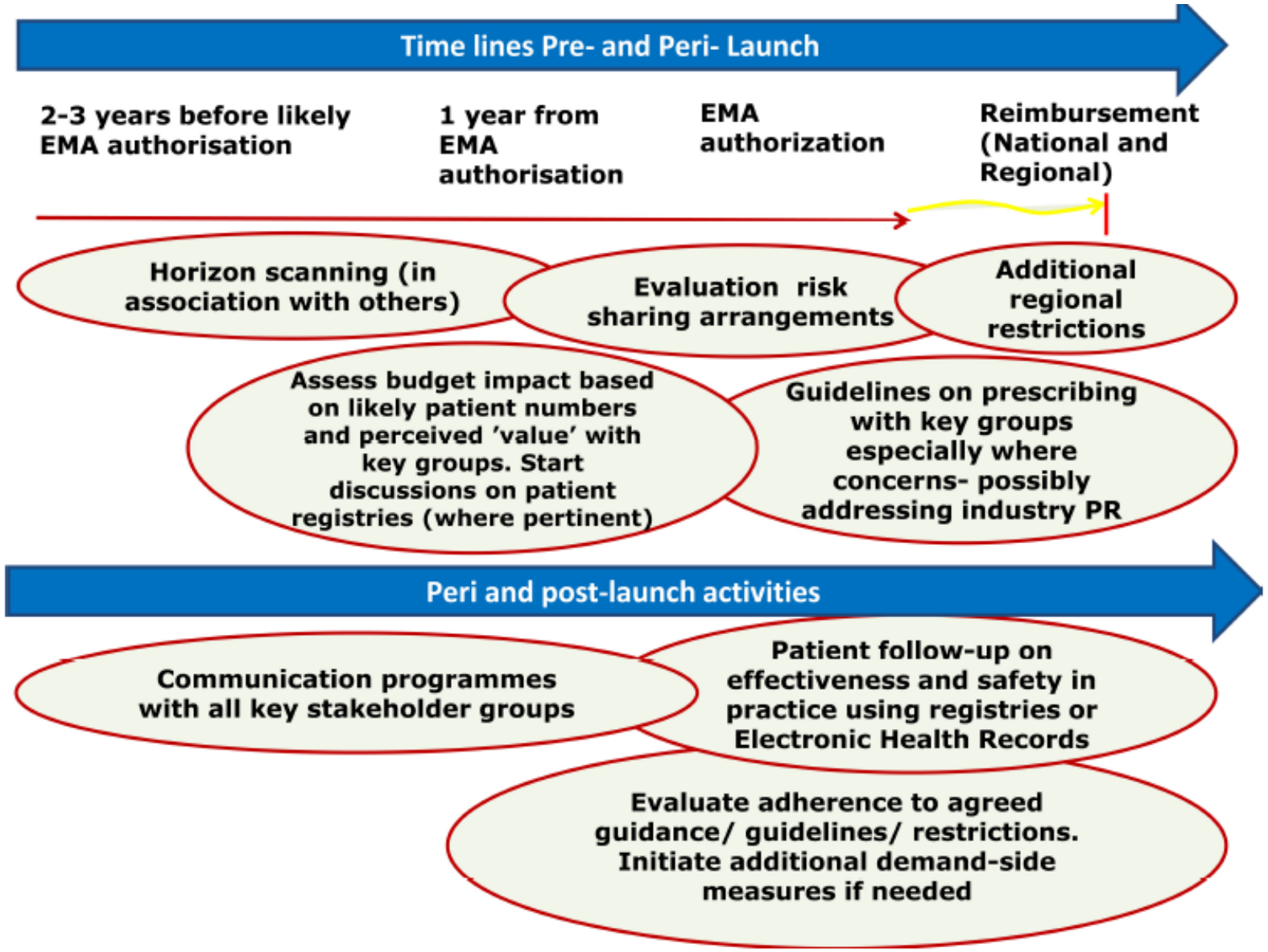
frontiers in Pharmacology

REVIEW
published: 05 October 2017
doi: 10.3389/fphar.2017.00674

The Early Awareness and Alert System in Sweden: History and Current Status

Irene Eriksson[1,2], Björn Wettermark[1,2], Marie Persson[3], Morgan Edström[4], Brian Godman[2,5,6,7], Anna Lindhé[8], Rickard E. Malmström[2,9], Helena Ramström[1], Mia von Euler[2,5,9] and Anna Bergkvist Christensen[10]*

[1] Department of Healthcare Development, Stockholm County Council, Stockholm, Sweden, [2] Department of Medicine Solna, Karolinska Institutet, Solna, Sweden, [3] Healthcare Administration, Stockholm County Council, Stockholm, Sweden, [4] Department of Clinical Pharmacology, County Council of Östergötland, Linköping University Hospital, Linköping, Sweden, [5] Health Economics Unit, University of Liverpool Management School, Liverpool, United Kingdom, [6] Clinical Pharmacology, Karolinska University Hospital, Stockholm, Sweden, [7] Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, Scotland, United Kingdom, [8] Department of Healthcare, Regional Head Office, Region Västra Götaland, Gothenburg, Sweden, [9] Department of Clinical Science and Education, Södersjukhuset, Karolinska Institutet, Solna, Sweden, [10] Department of Medicines Management and Informatics, Regional Head Office, Region Skåne, Malmö,



This was the model we developed across Europe to improve the managed entry of new medicines following concerns with the DOACs

It is based on three pillars starting pre-launch and ending post-launch

These models to improve the managed entry of new medicines have worked well for new medicines for hepatitis C and ovarian cancer in Sweden

European Journal of Clinical Pharmacology (2018) 74:971–978
https://doi.org/10.1007/s00228-018-2456-y

PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Introduction of the second-generation direct-acting antivirals (DAAs) in chronic hepatitis C: a register-based study in Sweden

P. Frisk[1,2] · K. Aggefors[1] · T. Cars[3] · N. Feltelius[4] · S. A. Loov[1] · B. Wettermark[1,5] · O. Weiland[6]

Targeted Oncology
https://doi.org/10.1007/s11523-018-0604-z

ORIGINAL RESEARCH ARTICLE

Real-World Use and Outcomes of Olaparib: a Population-Based Cohort Study

Irene Eriksson[1,2] · Björn Wettermark[1,2] · Kjell Bergfeldt[3]

Managed entry schemes are growing across Europe/ wider to enhance access to new medicines but still concerns

- There has been a growth in managed entry agreements (also called risk sharing arrangements) across countries to enhance access to new premium priced medicines
- MEAs can be divided into:
  - Financial-based models, e.g. discounts, rebates, price capping (typical approach)
  - Outcome-based models, e.g. reimbursed price/ funding maintained based on achieving agreed outcomes, e.g. lipid levels in patients with CVD or agreed viral load reductions in patients with hepatitis C; alternatively free goods or rebates if agreed outcome measures are not achieved
- However there are a number of issues/ concerns that need to be resolved going forward. These include:
  - confidential discounts (with financial-based MEAs), i.e. concerns with transparency between countries – not every country will gain optimal discounts. This has been one of the factors behind developing health authority consortia in Europe, e.g. Beneluxa and Valetta
  - lack of good patient-level databases in the public sector to monitor outcome-based schemes - although changing – e.g. SACT in England and CMOP in Scotland
  - yearly budget confines (although amortization models are being discussed more with the introduction of gene therapies - and this trend will continue)
  - who will fund subsequent treatment failures – unless robust agreements

The advantages and concerns with managed entry agreements were discussed in our recent paper including key personnel from across countries …

PharmacoEconomics (2020) 38:1165–1185
https://doi.org/10.1007/s40273-020-00943-1

REVIEW ARTICLE

Integrative Review of Managed Entry Agreements: Chances and Limitations

Carolina Zampirolli Dias[1,2] · Brian Godman[3,4,5,6] · Ludmila Peres Gargano[1,2] · Pâmela Santos Azevedo[1,2] · Marina Morgado Garcia[1,2] · Maurílio Souza Cazarim[7] · Laís Lessa Neiva Pantuzza[1] · Nelio Gomes Ribeiro-Junior[2] · André Luiz Pereira[8] · Marcus Carvalho Borin[1,2] · Isabella de Figueiredo Zuppo[1,2] · Roberto Iunes[9] · Tomas Pippo[10] · Renata Curi Hauegen[11] · Carlos Vassalo[12] · Tracey-Lea Laba[13] · Steven Simoens[14] · Sergio Márquez[15] · Carolina Gomez[16] · Luka Voncina[17] · Gisbert W. Selke[18] · Livio Garattini[19] · Hye-Young Kwon[20,21] · Jolanta Gulbinovic[22] · Aneta Lipinska[23] · Maciej Pomorski[23] · Lindsay McClure[24] · Jurij Fürst[25] · Rosana Gambogi[26] · Carla Hernandez Ortiz[26] · Vânia Cristina Canuto Santos[27] · Denizar Vianna Araújo[27] · Vânia Eloisa Araujo[1,28] · Francisco de Assis Acurcio[1,2] · Juliana Alvares-Teodoro[1,2] · Augusto Afonso Guerra-Junior[1,2]

… which built on our earlier papers regarding MEAs among Central and Eastern European countries and wider

PharmacoEconomics (2017) 35:1271–1285
DOI 10.1007/s40273-017-0559-4

ORIGINAL RESEARCH ARTICLE

The Implementation of Managed Entry Agreements in Central and Eastern Europe: Findings and Implications

Alessandra Ferrario[1] · Diāna Arāja[2] · Tomasz Bochenek[3] · Tarik Čatić[4] · Dávid Dankó[5] · Maria Dimitrova[6] · Jurij Fürst[7] · Ieva Greičiūtė-Kuprijanov[8] · Iris Hoxha[9] · Arianit Jakupi[10] · Erki Laidmäe[11] · Olga Löblová[12] · Ileana Mardare[13] · Vanda Markovic-Pekovic[14,15] · Dmitry Meshkov[16] · Tanja Novakovic[17] · Guenka Petrova[18] · Maciej Pomorski[19] · Dominik Tomek[20] · Luka Voncina[21] · Alan Haycox[22] · Panos Kanavos[1] · Patricia Vella Bonanno[23,] · Brian Godman[22,23,24]

… which built on our earlier papers regarding MEAs among Central and Eastern European countries and wider (continued)

Adamski *et al. BMC Health Services Research* 2010, **10**:153
http://www.biomedcentral.com/1472-6963/10/153

CORRESPONDENCE Open Access

Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers

Jakub Adamski*[1], Brian Godman*[2,3,4], Gabriella Ofierska-Sujkowska[5], Bogusława Osińska[5], Harald Herholz[6], Kamila Wendykowska[7], Ott Laius[8], Saira Jan[9], Catherine Sermet[10], Corrine Zara[11], Marija Kalaba[12], Roland Gustafsson[13], Kristina Garuolienè[14], Alan Haycox[4], Silvio Garattini[3] and Lars L Gustafsson[2]

Good databases and all oncologists working together in Catalonia in Spain enabled the successful introduction of an outcome based MEA for gefitinib

Journal of Medical Economics

Taylor & Francis
Taylor & Francis Group

ISSN: 1369-6998 (Print) 1941-837X (Online) Journal homepage: http://www.tandfonline.com/loi/ijme20

Financial consequences of a payment-by-results scheme in Catalonia: gefitinib in advanced EGFR-mutation positive non-small-cell lung cancer

Ana Clopes, Montse Gasol, Rosana Cajal, Luis Segú, Ricard Crespo, Ramón Mora, Susana Simon, Luis A Cordero, Candela Calle, Antoni Gilabert & Josep R Germà

We will see the growth in outcome based schemes in countries including the UK with improved collection of patient level data

- NICE has instigated 256 commercial in confidence agreements by October 2020 to enhance funding for new premium-priced medicines (https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit). Typically easier and quicker to apply a confidential discount
- However, NICE has also instigated new arrangements for the cancer drugs fund (CDF) which requires pharmaceutical companies applying to the CDF for funding for their new cancer medicine to provide additional data
- These include submitting an MEA as part of the justification incorporating details of potential data collection via the Systemic Anti-Cancer Therapy (SACT) Data (mandated dataset as part of the Health and Social Care Information Standards in England) to address issues of uncertainty – especially with immature data - https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf
- NHS Scotland has also instigated the CMOP programme in cancer to address issues of routine data collection during outpatients to improve knowledge

Details of the England SACT database can be found in the recent paper of Bright et al (2020)

International Journal of Epidemiology, 2020, 15–15l
doi: 10.1093/ije/dyz137
Advance Access Publication Date: 24 July 2019
Data Resource Profile

Data Resource Profile

Data Resource Profile: The Systemic Anti-Cancer Therapy (SACT) dataset

Chloe J Bright,[1]* Sarah Lawton,[1] Stephen Benson,[1] Martine Bomb,[1] David Dodwell,[2] Katherine E Henson,[1] Sean McPhail,[1] Louise Miller,[1] Jem Rashbass,[1] Alice Turnbull[1] and Rebecca Smittenaar[1]

[1]National Cancer Registration and Analysis Service, Public Health England, London, UK and [2]Nuffield Department of Population Health, University of Oxford, Oxford, UK

*Corresponding author. National Cancer Registration and Analysis Service, Public Health England, 2 Rivergate, Temple Quay, Bristol BS1 6EH, UK. E-mail: chloe.bright@phe.gov.uk

The CMOP programme was developed in Scotland to improve future care of oncology patients with better outcome information

- In 2017, the Scottish Government announced it was investing GB£300,000 in a programme to investigate whether medicines are as effective in the 'real world' as they are in clinical trials
- The Cancer Medicines Outcome Programme (CMOP) is a collaboration between NHS Greater Glasgow and Clyde and the University of Strathclyde (https://cancerchallengescotland.com/sites/default/files/documents/event_item/PROMsPREMs_Info_Session_190417/cic_info_session_190417_marion_bennie.pdf)
- This involves developing, agreeing and implementing data sets for cancer to help better manage patients – CMOP's vision is '**to develop a process which provides feedback to our cancer care clinicians on local outcomes. This real life data on the benefits, and side effects, of cancer medicines can then be used to identify supportive care needs as well as inform shared clinical decision-making between clinicians and patients**'. As such will help inform future investment/ disinvestment decisions in cancer care
- A study in prostate cancer was the first published outcome of CMOP

A study using patient level data in Scotland to evaluate treatment outcomes in patients with prostate cancer is the first published output of the CMOP programme

Received: 16 August 2019 | Revised: 31 January 2020 | Accepted: 18 March 2020

DOI: 10.1002/pds.4998

Check for updates

WILEY

ORIGINAL REPORT

Use of record linkage to evaluate treatment outcomes and trial eligibility in a real-world metastatic prostate cancer population in Scotland

Kelly Baillie[1] | Tanja Mueller[2] | Jiafeng Pan[3] | Jennifer Laskey[1] | Marion Bennie[2,4] | Christine Crearie[1] | Kimberley Kavanagh[3] | Samantha Alvarez-Madrazo[2] | David Morrison[5] | Julie Clarke[1] | Aileen Keel[6] | David Cameron[7] | Olivia Wu[5] | Amanj Kurdi[2] | Robert J. Jones[1,8]

Key areas for the future especially with new oncology medicines often launched with limited clinical trial data are agreements over funding and data collection – this was an issue with olaratumab

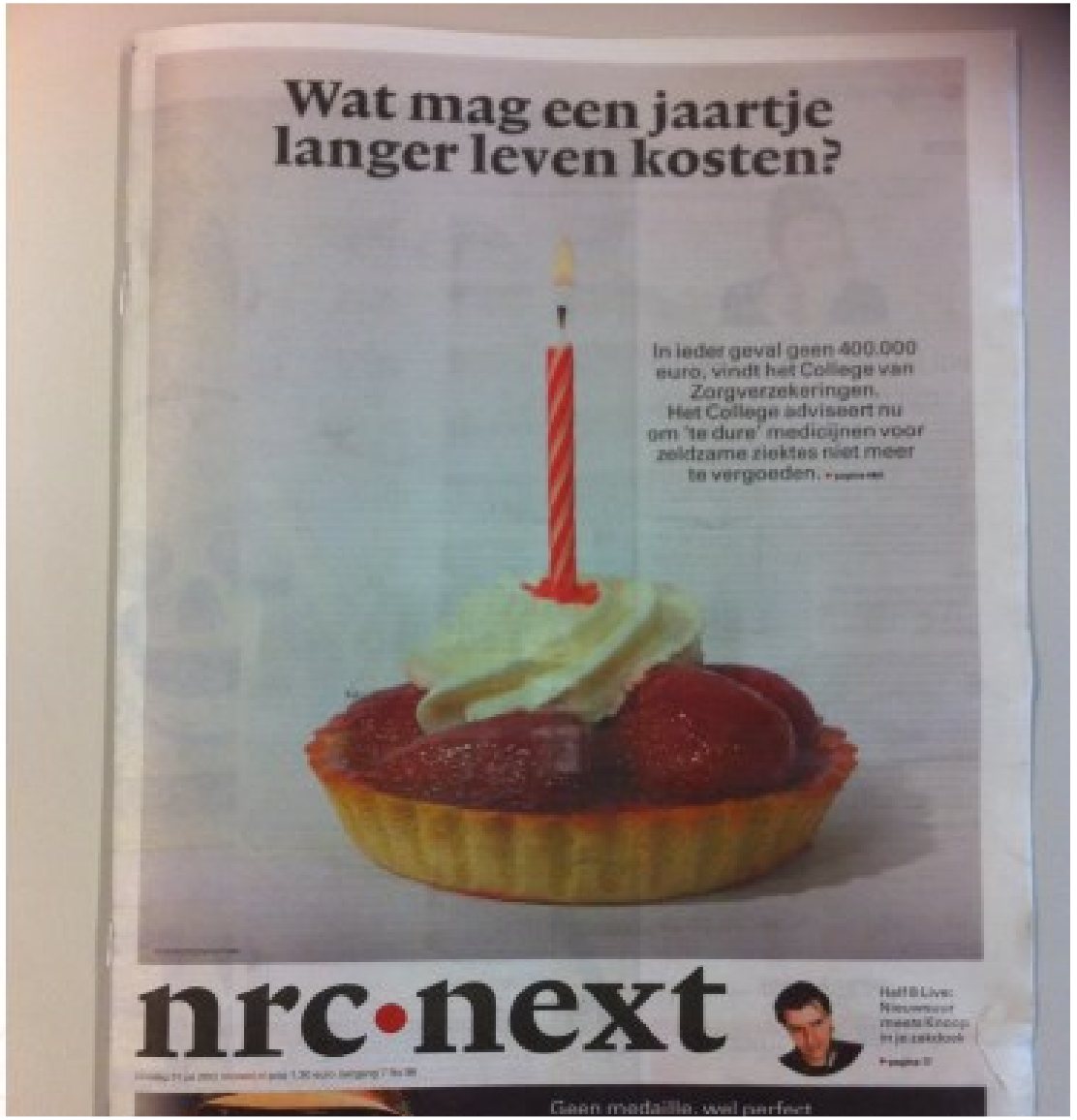
Applied Health Economics and Health Policy (2020) 18:5–16
https://doi.org/10.1007/s40258-019-00527-x

CURRENT OPINION

Check for updates

Time to Review Authorisation and Funding for New Cancer Medicines in Europe? Inferences from the Case of Olaratumab

Caridad Pontes[1,2] · Corinne Zara[1] · Josep Torrent-Farnell[1,2] · Merce Obach[1] · Cristina Nadal[3] · Patricia Vella-Bonanno[4] · Michael Ermisch[5] · Steven Simoens[6] · Renata Curi Hauegen[7] · Jolanta Gulbinovic[8] · Angela Timoney[4,9] · Antony P. Martin[10] · Tanja Mueller[4] · Anna Nachtnebel[11] · Stephen Campbell[12,13] · Gisbert Selke[14] · Tomasz Bochenek[15] · Celia C. Rothe[15] · Ileana Mardare[16] · Marion Bennie[4] · Jurij Fürst[17] · Rickard E. Malmstrom[18] · Brian Godman[4,10,19,20]



Pressure from the media in the Netherlands resulted in pressure on the Ministry of Health to ignore the advice of the Dutch reimbursement agency about funding enzyme replacement therapy for Fabrys' disease (up to €3.3 million incremental cost / QALY) and up to €15million for alglucosidase alfa to treat Pompe's disease

The payers in the Netherlands realised this situation could not continue for the sustainability of European healthcare systems – led to the development of MCDAs for new biological medicines for orphan diseases involving all key stakeholder groups (TVF)

European payers together with Pharmaceutical Companies and patient groups are developing MCDAs including those for orphan diseases. One output to date is the Transparent Value Framework (TVF) as part of the MOCA process

Criterion	Lower Degree	Medium Degree	High Degree
Available Alternatives/ Unmet Need, including non-pharmaceutical treatment options	yes, new medicine does not address unmet need	yes, but major unmet need still remains	no alternatives except best supportive care - new drug addresses major unmet need
(Relative) Effectiveness, Degree of Net Benefit (Clinical Improvement, QoL, etc. vs. side effects, societal impact, etc.) relative to alternatives, including no treatment.	incremental	major	curative
Response Rate (based on best available clinically relevant criteria)	<30%	30-60%	>60%
Degree of Certainty (Documentation)	promising but not well-documented	plausible	unequivocal

Payers in Italy are also using an MCDA approach to determine the level of innovation for new medicines as part of their reimbursement discussions

Received: 20 May 2019 | Revised: 4 September 2019 | Accepted: 15 September 2019

DOI: 10.1111/bcp.14138

ORIGINAL ARTICLE

BJCP BRITISH PHARMACOLOGICAL SOCIETY

Using GRADE methodology to assess innovation of new medicinal products in Italy

Filomena Fortinguerra[1] | Giovanni Tafuri[1] | Francesco Trotta[1] | Antonio Addis[2]

[1] Italian Medicines Agency (AIFA), Rome, Italy

[2] Department of Epidemiology, Lazio Regional Health Service, Rome, Italy

Aim: In April 2017 the Italian Medicine Agency (AIFA) developed new criteria to grant any new medicinal product with an innovative designation. The aim of this study is to describe this new model and how it works.

We are also seeing a growth in fair pricing models – enhanced by recent WHO deliberations (2020). However, this needs to be balanced against necessary incentives – acknowledged to some extent in the AIM (European payer body) approach

AIM Healthcare and social benefits for all

AIM PROPOSES TO ESTABLISH
A EUROPEAN DRUG PRICING MODEL FOR FAIR AND TRANSPARENT PRICES
FOR ACCESSIBLE PHARMACEUTICAL INNOVATIONS

ACCESS TO MEDICINES
AND HEALTH PRODUCTS

WHO guideline on country pharmaceutical pricing policies

In conclusion

- We will continue to see the growth in alternative pricing models including MEAs and MCDAs to enable health authorities to fund new premium priced medicines/ use existing resources more wisely
- In addition, we will see a growth in health authority IT/ EHR systems to improve data collection especially in priority areas including cancer, e.g. SACT and CMOP in the UK. This will help Pharma Companies and health authorities promote optimal treatment approaches when multiple choices exist, e.g. different NOACs and anti-TNFs as well as potentially introduce different pricing by indication and outcome
- Concurrent with this will increasingly be a re-evaluation of the prices/ discounts/ rebates of existing patented medicines when the medicine used in the initial negotiations loses its patent and becomes available either as a low cost oral generic or biosimilar under value-based pricing approaches
- This will necessarily require Pharmaceutical Companies to provide additional data to support prices/ new formulations or delivery systems to enhance their value. The same will happen with ongoing discussions regarding fair pricing models

Public database studies such as these enhance our understanding of the relative place of different DOACs without head-to-head RCTs

British Journal of Clinical Pharmacology

Br J Clin Pharmacol (2019) **85** 422–431 422

ORIGINAL ARTICLE

Comparative safety and effectiveness of direct oral anticoagulants in patients with atrial fibrillation in clinical practice in Scotland

Correspondence Tanja Mueller, The Farr Institute of Health Informatics Research, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, UK. Tel.: +44 (0)141 548 2367; E-mail: tanja.muller@strath.ac.uk

Received 27 April 2018; Revised 6 November 2018; Accepted 8 November 2018

Tanja Mueller[1], Samantha Alvarez-Madrazo[1], Chris Robertson[2,3], Olivia Wu[4] and Marion Bennie[1,5]

[1]The Farr Institute of Health Informatics Research, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, UK, [2]Department of Mathematics and Statistics, University of Strathclyde, Glasgow, UK, [3]Health Protection Scotland, NHS National Services Scotland, Glasgow, UK, [4]Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK, and [5]Public Health and Intelligence Strategic Business Unit, NHS National Services Scotland, Edinburgh, UK

Similarly for different subcutaneous biologic medicines for patients with RA with such studies growing to provide future robust guidance when multiple choices are available and no RCTs

Open access Research

BMJ Open

Discontinuation, persistence and adherence to subcutaneous biologics delivered via a homecare route to Scottish adults with rheumatic diseases: a retrospective study

Samantha Alvarez-Madrazo,[1,2] Kimberley Kavanagh,[3] Stefan Siebert,[4] Yvonne Semple,[5,6] Brian Godman,[7,8] Alessandra Maciel Almeida,[9] Francisco de Assis Acurcio,[9] Marion Bennie[1,10]

Thank You

Happy to answer questions!

Brian.Godman@ ki.se; Brian.godman@strath.ac.uk;
briangodman@outlook.com