# References

## Chapter 22


1 Organisation for Economic Co-operation and Development. Health at a Glance 2011: OECD Indicators. Pharmaceutical expenditure. OECD Publishing. Available from: http://www.oecd.org/els/health-systems/49105858.pdf (last accessed 18 November 2015).

2 Kaplan W, Wirtz V, Mantel-Teeuwisse A, Stolk P, Duthey B, Laing R. Priority Medicines for Europe and the World 2013 Update. Available from: http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf?ua=1 (lastaccessed 18 November 2015).

3 Godman B, Wettermark B, van Woerkom M, Fraeyman J, Alvarez-Madrazo S, Berg C, et al. Multiple policies to enhance prescribing efficiency for established medicines in Europe with a particular focus on demand-side measures: findings and future implications. *Frontiers in Pharmacology.* 2014;**5**:106.

4 Wettermark B. The intriguing future of pharmacoepidemiology. *European Journal of Clinical Pharmacology.* 2013;**69**(Suppl. 1):43–51.

5 Wettermark B, Persson ME, Wilking N, Kalin M, Korkmaz S, Hjemdahl P, et al. Forecasting drug utilization and expenditure in a metropolitan health region. *BMC Health Services Research.* 2010;**10**:128.

6 Holloway KA. Combating inappropriate use of medicines. *Expert Review of Clinical Pharmacology.* 2011;**4**(3):335–48.

7 Henshall C, Sansom L, Eichler H-G, Lemgruber A, Longson C, O'Rourke B, Tunis S. Understanding the role and evidence expectations of health technology assessment and coverage/payer bodies: what are they looking for, and how and why does this differ from what regulators require? *Therapeutic Innovation & Regulatory Science.* 2014;**48** (3):341–6.

8 Paris V, Belloni A. Value in Pharmaceutical Pricing. OECD Health Working Papers, No. 63: OECD Publishing. Available from: http://dx.doi.org/10.1787/5k43jc9v6knx-en (last accessed 18 November 2015).

9 Pammolli F, Magazzini L, Riccaboni M. The productivity crisis in pharmaceutical R&D. *Nature Reviews Drug Discovery.* 2011;**10**(6):428–38.

10 Eichler HG, Baird L, Barker R, Bloechl-Daum B, Borlum-Kristensen F, Brown J, et al. From adaptive licensing to adaptive pathways: delivering a flexible life-span approach to bring new drugs to patients. *Clinical Pharmacology and Therapeutics.* 2015;**97**(3):234–46.

11 European Federation of Pharmaceutical Industries and Associations. Health & Growth: Evidence Compendium. Available from: http://www.efpia.eu/uploads/Modules/Documents/health-and-growth_evidence-compendium.pdf (last accessed 18 November 2015).

12 Godman B, Finlayson AE, Cheema PK, Zebedin-Brandl E, Gutierrez-Ibarluzea I, Jones J, et al. Personalizing health care: feasibility and future implications. *BMC Medicine.* 2013;**11**:179.

13 Iskrov G, Stefanov R. Post-marketing access to orphan drugs: a critical analysis of health technology assessment and reimbursement decision-making considerations. *Orphan Drugs: Research and Reviews.* 2014;**4**:1–9.

14 Baird LG, Banken R, Eichler HG, Kristensen FB, Lee DK, Lim JC, et al. Accelerated access to innovative medicines for patients in need. *Clinical Pharmacology and Therapeutics.* 2014;**96**(5):559–71.

15 Forda SR, Bergström R, Chlebus M, Barker R, Andersen PH. Priorities for improving drug research development and regulation. *Nature Reviews Drug Discovery.* 2013;**12**:247–8.



*Drug Utilization Research: Methods and Applications*, First Edition. Edited by M. Elseviers et al. © 2016 John Wiley & Sons, Ltd.
Published 2016 by John Wiley & Sons, Ltd.

**16** Babar ZU, Francis S. Identifying priority medicines policy issues for New Zealand: a general inductive study. *British Medical Journal Open.* 2014;**4**(5):e004415.

**17** Drews J. Drug discovery: a historical perspective. *Science.* 2000;**287**(5460):1960–4.

**18** Lichtenberg F. Pharmaceutical innovation and longevity growth in 30 developing and high-income countries, 2000–2009. *Health Policy and Technology.* 2014;**3**:36–58.

**19** World Health Organization. Database on life expectancy. Available from: http://www.who.int/gho/mortality_burden_disease/life_tables/situation_trends/en/ (last accessed 18 November 2015).

**20** World Bank. Database on life expectancy at birth. Available from: http://www.who.int/gho/mortality_burden_disease/life_tables/hale/en/ (last accessed 18 November 2015).

**21** Economic Intelligence Unit. Never too early: tackling chronic disease to extend healthy life years. Available from: https://www.ihpm.org/pdf/EIU-Abbott_TacklingChronicDisease_Web.pdf (last accessed 18 November 2015).

**22** Cramer JA, Benedict A, Muszbek N, Keskinaslan A, Khan ZM. The significance of compliance and persistence in the treatment of diabetes, hypertension and dyslipidaemia: a review. *International Journal of Clinical Practice.* 2008;**62**(1):76–87.

**23** Kiviniemi V, Peura P, Helin-Salmivaara A, Martikainen JE, Hartikainen J, Huupponen R, et al. Suboptimal use of statins at treatment initiation. *European Journal of Clinical Pharmacology.* 2011;**67**(9):971–3.

**24** Godman B, Bishop I, Campbell SM, Malmstrom RE, Truter I. Quality and efficiency of statin prescribing across countries with a special focus on South Africa; findings and future implications. *Expert Review of Pharmacoeconomics & Outcomes Research.* 2015;**15**(2):323–30.

**25** Pedersen TR, Kjekshus J, Berg K, Haghfelt T, Faergeman O, Faergeman G, et al. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S) 1994. *Atherosclerosis Supplements.* 2004;**5**(3):81–7.

**26** Bellosta S, Paoletti R, Corsini A. Safety of statins: focus on clinical pharmacokinetics and drug interactions. *Circulation.* 2004;**109**(23 Suppl. 1):iii50–7.

**27** Staffa JA, Chang J, Green L. Cerivastatin and reports of fatal rhabdomyolysis. *New England Journal of Medicine.* 2002;**346**(7):539–40.

**28** Furberg CD, Pitt B. Withdrawal of cerivastatin from the world market. *Current Controlled Trials in Cardiovascular Medicine.* 2001;**2**(5):205–7.

**29** Ewang-Emukowhate M, Wierzbicki AS. Lipid-lowering agents. *Journal of Cardiovascular Pharmacology and Therapeutics.* 2013;**18**(5):401–11.

**30** Toth PP. Drug treatment of hyperlipidaemia: a guide to the rational use of lipid-lowering drugs. *Drugs.* 2010;**70**(11):1363–79.

**31** Srinivasa Rao K, Prasad T, Mohanta GP, Manna PK. An overview of statins as hypolipidemic drugs. *International Journal of Pharmaceutical Sciences and Drug Research.* 2011;**3**(3):178–83.

**32** Kim JH, Zamorano J, Erdine S, Pavia A, Al-Khadra A, Sutradhar S, et al. Reduction in cardiovascular risk using proactive multifactorial intervention versus usual care in younger (< 65 years) and older (>/= 65 years) patients in the CRUCIAL trial. *Current Medical Research and Opinion.* 2013;**29**(5):453–63.

**33** Naci H, Brugts JJ, Fleurence R, Tsoi B, Toor H, Ades AE. Comparative benefits of statins in the primary and secondary prevention of major coronary events and all-cause mortality: a network meta-analysis of placebo-controlled and active-comparator trials. *European Journal of Preventive Cardiology.* 2013;**20**(4):641–57.

**34** Shepherd J, Kastelein JJ, Bittner V, Deedwania P, Breazna A, Dobson S, et al. Intensive lipid lowering with atorvastatin in patients with coronary heart disease and chronic kidney disease: the TNT (Treating to New Targets) study. *Journal of the American College of Cardiology.* 2008;**51**(15):1448–54.

**35** Bybee KA, Lee JH, O'Keefe JH. Cumulative clinical trial data on atorvastatin for reducing cardiovascular events: the clinical impact of atorvastatin. *Current Medical Research and Opinion.* 2008;**24**(4):1217–29.

**36** Grabowski DC, Lakdawalla DN, Goldman DP, Eber M, Liu LZ, Abdelgawad T, et al. The large social value resulting from use of statins warrants steps to improve adherence and broaden treatment. *Health Affairs (Project Hope).* 2012;**31**(10):2276–85.

**37** Gotto AM Jr, Boccuzzi SJ, Cook JR, Alexander CM, Roehm JB, Meyer GS, et al. Effect of lovastatin on cardiovascular resource utilization and costs in the

Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS). AFCAPS/TexCAPS Research Group. *American Journal of Cardiology.* 2000;**86**(11):1176–81.

**38** World Economic Forum and Harvard School of Public Health. The Global Economic Burden of Non-communicable Diseases. Available from: http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf (last accessed 18 November 2015).

**39** Suhrcke M, Urban D. Are cardiovascular diseases bad for economic growth? Available from: http://www.cesifo-group.de/portal/page/portal/DocBase_Content/WP/WP-CESifo_Working_Papers/wp-cesifo-2006/wp-cesifo-2006-11/cesifo1_wp1845.pdf (last accessed 18 November 2015).

**40** European Commission; Directorate-General for Health and Consumers. Health of People of Working Age. Available from: http://ec.europa.eu/health/social_determinants/docs/final_full_ecorys_web.pdf (last accessed 18 November 2015).

**41** Salomon JA, Wang H, Freeman MK, Vos T, Flaxman AD, Lopez AD, et al. Healthy life expectancy for 187 countries, 1990–2010: a systematic analysis for the Global Burden Disease Study 2010. *Lancet.* 2012;**380**(9859):2144–62.

**42** European Commission; Directorate-General for Economic and Financial Affairs. The 2012 Ageing Report: Underlying Assumptions and Projection Methodologies – Joint Report Prepared by the European Commission (DG ECFIN) and the Economic Policy Committee (AWG). Available from: http://ec.europa.eu/economy_finance/publications/european_economy/2011/pdf/ee-2011-4_en.pdf (last accessed 18 November 2015).

**43** McKee M, Stuckler D, Martin-Moreno JM. Protecting health in hard times. *British Medical Journal (Clinical Research Edition).* 2010;**341**:c5308.

**44** Taylor L. NICE rejects 'wider societal benefit' test for new drugs. *PharmaTimes.* Available from: http://www.pharmatimes.com/article/14-01-26/NICE_rejects_wider_societal_benefit_test_for_new_drugs.aspx (last accessed 18 November 2015).

**45** Scottish Medicines Consortium. PACE (Patient & Clinician Engagement) Overview Document. Available from: https://www.scottishmedicines.org.uk/files/PACE/PACE_Overview_Document_FINAL.pdf (last accessed 18 November 2015).

**46** HM Government. Pharmaceutical Price Regulation Scheme (PPRS): Heads of Agreement. Available from: https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-pprs-heads-of-agreement (last accessed 18 November 2015).

**47** Sermet C, Andrieu V, Godman B, Van Ganse E, Haycox A, Reynier JP. Ongoing pharmaceutical reforms in France: implications for key stakeholder groups. *Applied Health Economics and Health Policy.* 2010;**8**(1):7–24.

**48** EFPIA. Pharmaceutical Body EFPIA and Lithuanian Ministry of Health Galvanise Future Innovation and Improvements to Public Health with Landmark Joint Working Agreement. Available from: http://www.efpia.eu/mediaroom/190/43/Pharmaceutical-Body-EFPIA-and-Lithuanian-Ministry-of-Health-Galvanise-Future-Innovation-and-Improvements-to-Public-Health-with-Landmark-Joint-Working-Agreement (last accessed 18 November 2015).

**49** Dymek C, Gingold J, Shanbhag A, Fridsma D, Yong PL. A national data infrastructure for patient-centered outcomes research. *Journal of Comparative Effectiveness Research.* 2015;**4**(1):75–87.

**50** Cars T, Wettermark B, Malmstrom RE, Ekeving G, Vikstrom B, Bergman U, et al. Extraction of electronic health record data in a hospital setting: comparison of automatic and semi-automatic methods using anti-TNF therapy as model. *Basic & Clinical Pharmacology & Toxicology.* 2013;**112**(6):392–400.

**51** Porter ME, Teusber EO. *Redefining Health Care: Creating Value-Based Competition on Results.* New York, Harvard Business School Press, 2006.

**52** Lawyer P, Soderlund N, Kent J, Larsson S. Health reform should focus on outcomes, not costs. *Boston Consulting Group Perspectives.* Available from: https://www.bcgperspectives.com/content/articles/health_care_payors_providors_health_reform_should_focus_on_outcomes/ (last accessed 18 November 2015).

**53** Porter ME. A strategy for health care reform – toward a value-based system. *New England Journal of Medicine.* 2009;**361**(2):109–12.

**54** Stausberg J, Hasford J. Drug-related admissions and hospital-acquired adverse drug events in Germany: a longitudinal analysis from 2003 to 2007 of ICD-10-coded routine data. *BMC Health Services Research.* 2011;**11**:134.

**55** Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *British Medical Journal (Clinical Research Edition).* 2004;**329**(7456):15–19.

**56** Brvar M, Fokter N, Bunc M, Mozina M. The frequency of adverse drug reaction related admissions according to method of detection, admission urgency and medical department specialty. *BMC Clinical Pharmacology.* 2009;**9**:8.

**57** Rottenkolber D, Schmiedl S, Rottenkolber M, Farker K, Salje K, Mueller S, et al. Adverse drug reactions in Germany: direct costs of internal medicine hospitalizations. *Pharmacoepidemiology and Drug Safety.* 2011;**20**(6):626–34.

**58** Miller I, Ashton-Chess J, Spolders H, Fert V, Ferrara J, Kroll W, et al. Market access challenges in the EU for high medical value diagnostic tests. *Personalised Medicine.* 2011;**8**:137–48.

**59** Food and Drug Administration. Table of Pharmacogenomic Biomarkers in Drug Labeling. Available from: http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm (last accessed 18 November 2015).

**60** Abramson EL, Barron Y, Quaresimo J, Kaushal R. Electronic prescribing within an electronic health record reduces ambulatory prescribing errors. *Joint Commission Journal on Quality and Patient Safety/Joint Commission Resources.* 2011;**37**(10):470–8.

**61** Troncoso A, Diogene E. Dabigatran and rivaroxaban prescription for atrial fibrillation in Catalonia, Spain: the need to manage the introduction of new drugs. *European Journal of Clinical Pharmacology.* 2014;**70**(2):249–50.

**62** Bjorkhem-Bergman L, Andersen-Karlsson E, Laing R, Diogene E, Melien O, Jirlow M, et al. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. *European Journal of Clinical Pharmacology.* 2013;**69**(Suppl. 1): 73–8.

**63** European Federation of Pharmaceutical Industries and Associations. Health & Growth: Working Together for a Healthy Europe. A Vision Towards a Life Sciences Strategy for Europe. Brussels, European Federation of Pharmaceutical Industries and Associations, 2014. Available from: http://www.efpia.eu/uploads/documents/EFPIA-health&growth_MANIFESTO_V11_pbp.pdf (last accessed 18 November 2015).

**64** Toumi M, Rémuzat C; Executive Agency for Health and Consumers. EU Pharmaceutical Expenditure Forecast. Available from: http://ec.europa.eu/health/healthcare/docs/creativ_ceutical_eu_pharmaceutical_expenditure_forecast.pdf (last accessed 18 November 2015).

**65** Godman B, AbuelkhairM, Vitry A, Abdu S, Bennie M, Bishop I, et al. Payers endorse generics to enhance prescribing efficiency; impact and future implications, a case history approach. *Generics and Biosimilars Initiative Journal.* 2012;**1**(2):21–35.

**66** Jack A. Balancing Big Pharma's books. *British Medical Journal (Clinical Research Edition).* 2008;**336**(7641):418–19.

**67** Haustein R, de Millas C, Höer H, Häussler B. Saving money in the European healthcare systems with biosimilars. *Generics and Biosimilars Initiative Journal.* 2012;**1**(3–4):120–6.

**68** PharmaFutures. PharmaFutures Global Conclusions. Pathways to Value: Pharma in a Changing World. Available from: http://apps.who.int/medicinedocs/documents/s20202en/s20202en.pdf (last accessed 18 November 2015).

**69** Henshall C, Schuller T. Health technology assessment, value-based decision making, and innovation. *International Journal of Technology Assessment in Health Care.* 2013;**29**(4):353–9.

**70** van de Vooren K, Duranti S, Curto A, Garattini L. A critical systematic review of budget impact analyses on drugs in the EU countries. *Applied Health Economics and Health Policy.* 2014;**12**(1):33–40.

**71** Godman B, Campbell S, Suh HS, Finlayson A, Bennie M, Gustafsson L. Ongoing measures to enhance prescribing efficiency across Europe: implications for other countries. *Journal of Health Technology Assessment.* 2013;**1**:27–42.

**72** Carlson JJ, Gries KS, Yeung K, Sullivan SD, Garrison LP Jr. Current status and trends in performance-based risk-sharing arrangements between healthcare payers and medical product manufacturers. *Applied Health Economics and Health Policy.* 2014;**12**(3):231–8.

**73** Ferrario A, Kanavos P. Managed entry agreements for pharmaceuticals: the European experience. Available from: http://core.ac.uk/download/

pdf/16379320.pdf (last accessed 18 November 2015).

**74** Morel T, Arickx F, Befrits G, Siviero P, van der Meijden C, Xoxi E, et al. Reconciling uncertainty of costs and outcomes with the need for access to orphan medicinal products: a comparative study of managed entry agreements across seven European countries. *Orphanet Journal of Rare Diseases.* 2013;**8**:198.

**75** Grimaldi-Bensouda L, Zureik M, Aubier M, Humbert M, Levy J, Benichou J, et al. Does omalizumab make a difference to the real-life treatment of asthma exacerbations?: Results from a large cohort of patients with severe uncontrolled asthma. *Chest.* 2013;**143**(2):398–405.

**76** National Institute of Health and Care Excellence. Omalizumab for treating severe persistent allergic asthma. Available from: https://www.nice.org.uk/guidance/ta278 (last accessed 18 November 2015).

**77** NBHW. Osteoporos, artros, inflammatorisk ryggsjukdom och ankyloserande spondylit, psoriasisartrit och reumatoid artrit. Available from: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/18665/2012-5-1.pdf (last accessed 18 November 2015).

**78** CVS Caremark. CVS caremark medication adherence report identifies significant opportunities for health care cost-savings across all 50 US states. Available from: http://www.prnewswire.com/news-releases/cvs-caremark-medication-adherence-report-identifies-significant-opportunities-for-health-care-cost-savings-across-all-50-us-states-213288371.html (last accessed 18 November 2015).

**79** Business Wire. Humana and Pfizer form research partnership to improve health care delivery for seniors. Available from: http://www.businesswire.com/news/home/20111013006441/en/Humana-Pfizer-Form-Research-Partnership-Improve-Health (last accessed 18 November 2015).

**80** Keegan BM. Natalizumab for multiple sclerosis: a complicated treatment. *Lancet Neurology.* 2011;**10**(8):677–8.

**81** Kappos L, Bates D, Edan G, Eraksoy M, Garcia-Merino A, Grigoriadis N, et al. Natalizumab treatment for multiple sclerosis: updated recommendations for patient selection and monitoring. *Lancet Neurology.* 2011;**10**(8):745–58.

**82** Raaschou P, Simard JF, Holmqvist M, Askling J. Rheumatoid arthritis, anti-tumour necrosis factor therapy, and risk of malignant melanoma: nationwide population based prospective cohort study from Sweden. *British Medical Journal (Clinical Research Edition).* 2013;**346**:f1939.

**83** International Society for Pharmacoeconomics and Outcomes Research. ISPOR Good Practices for Outcomes Research Index. Available from: http://www.ispor.org/workpaper/practices_index.asp (last accessed 18 November 2015).

**84** Drummond M, Helfand M, Mullins CD. Note from the editors. *Medical Decision Making.* 2012;**32**(5):653–5.

**85** Cosman F, de Beur SJ, LeBoff MS, Lewiecki EM, Tanner B, Randall S, Lindsay R. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis International.* 2014;**25**(10):2359–81.

**86** Wysowski DK. Reports of esophageal cancer with oral bisphosphonate use. *New England Journal of Medicine.* 2009;**360**(1):89–90.

**87** Cardwell CR, Abnet CC, Cantwell MM, Murray LJ. Exposure to oral bisphosphonates and risk of esophageal cancer. *Journal of the American Medical Association.* 2010;**304**(6):657–63.

**88** Green J, Czanner G, Reeves G, Watson J, Wise L, Beral V. Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort. *British Medical Journal.* 2010;**341**:c4444.

**89** Food and Drug Administration. FDA Drug Safety Communication: Ongoing Safety Review of Oral Osteoporosis Drugs (Bisphosphonates) and Potential Increased Risk of Esophageal Cancer. Available from: http://www.fda.gov/drugs/drugsafety/ucm263320.htm (last accessed 18 November 2015).

**90** Food and Drug Administration. FDA Drug Safety Podcast for Healthcare Professionals: Ongoing Safety Review of Oral Osteoporosis Drugs (Bisphosphonates) and Potential Increased Risk of Esophageal Cancer. Available from: http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm264096.htm (last accessed 18 November 2015).

**91** de la Maisonneuve COM. *Public Spending on Health and Long-Term Care: A New Set of Projections.* Paris, Organisation for Economic Co-operation and Development, 2013.