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Bibliography

- Abbott, F.A. (2011) Trends in Local Production of Medicines and Related Technology Transfer, Geneva: World Health Organization Department of Public Health Innovation and Intellectual Property [Online]. Available from: http://www. who.int/phi/publications/local_production_trends/en/ [accessed 10 January 2015].
- Abraham, J. (2002) 'Making Regulation Responsive to Commercial Interests', BMJ, 325, 1164–69.
- Abrol, D. & Guha, A. (1986) 'Production and Price Controls: The Achilles Heel of National Drug Policy', in *Drug Industry and the Indian People*, A.S. Gupta (ed.), proceedings and papers presented at the 'All India Seminar of National Drug Policy', held in New Delhi, on 28 and 29 April 1986, A Delhi Science Forum (DSF) and Federation of Medical Representatives Association of India (FMRAI) publication.
- AfDB (1994) Project Completion Report: First Line of Credit to Zimbabwe Development Bank; Republic of Zimbabwe, African Development Bank, Tunis.
- AfDB (1997) Zimbabwe: Economic Structural Adjustment Programme: Project Performance Evaluation Report (PPER), African Development Bank Group, Tunis.
- AfDB (1998) Zimbabwe First Line of Credit to Zimbabwe Development Bank: Project Performance Evaluation Report (PPER), African Development Bank Group, Tunis.
- AfDB (2009) *Zimbabwe Short-Term Strategy: Concept Note*, African Development Bank: Regional Department, South Region A, Tunis.
- African Union (AU) (2007) *Pharmaceutical Plan for Africa*. Available from: www. unido.org/fileadmin/user_media/Services/PSD/BEP/Pharmaceutical%20manufacturing%20plan%20for%20Africa-English.pdf [accessed 22 May 2010].
- African Union (AU) (2012a) *Pharmaceutical Manufacturing Plan for Africa Business Plan*, Addis Ababa, Ethiopia. Available from: http://sa.au.int/en/sites/default/files/pmpa%20bp%20ebook.pdf [accessed 30 April 2015].
- African Union (AU) (2012b) Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, Addis Ababa, Ethiopia, available from: http://www.au.int/en/sites/default/files/Shared_Res_Roadmap_ Rev_F%5B1%5D.pdf [accessed 30 April 2015].
- Anders, S.M. & Caswell, J.A. (2009) 'Standards as barriers versus standards as catalysis: Assessing the impact of HACCP implementation of US seafood imports', *American Journal of Agricultural Economy*, 91 (2), 310–21.
- Anderson, K. (1996) 'Environmental standards and international trade', *Proceedings* of the World Bank Annual Conference on Development Economics, 317–18.
- Aragão, E., Loureiro, S. & Temporão, J.G. (2014) 'Trajetórias tecnológicas na indústria farmacêutica: desafios para a equidade no Brasil' in Silva Paim, J. & Almeida-Filho, N. (Eds.) Saúde Coletiva: Teoria e Prática, Medbook, Rio de Janeiro.
- Aspen Holdings (2013) *Aspen Pharmacare Holdings Limited Integrated Report 2013* [Online]. Available from: http://financialresults.co.za/2013/aspen_ir2013/ IR2013/1_about_this_report.php [accessed 30 April 2015].

- Assefa, H., Bienen, D. & Ciuriak, D. (2013) 'Ethiopia's investment prospects: A sectoral overview', *African Review of Economics and Finance*, 4 (2), 203–46.
- Astley, W.G. & Fombrun, C.J. (1983) 'Collective strategy: social ecology of organizational environments', *Academy of Management Review*, 8, 576–87.
- Athreye, S. (2004) 'Trade policy, industrialization and growth in India' in Bromley, S., Mackintosh, M., Brown, W. & Wuyts, M. (eds.) *Making the International: Economic Interdependence and Political Order*, Milton Keynes: The Open University In association with Pluto Press.
- Bagachwa, M.S.D. & Mbelle, A.M.Y. (1995) 'Tanzania' in Wangwe (ed.) *Exporting Africa: Technology, Trade and Industrialisation in Sub-Saharan Africa*, UNU/ INTECH and Routledge, London.
- Bajpai, V. & Saraya, A. (2012) 'Understanding the syndrome of techno-centrism through the epidemiology of vaccines as preventive tools', *Indian Journal of Public Health*, 56 (2), 133–39.
- Banda, G. (2013) 'Finance as a "forgotten technological capability" for promoting African local pharmaceutical manufacture', *International Journal of Technology Management & Sustainable Development*, 12 (2), 117–35.
- Bao, Q. (2000) 'Paying the price of medicines', *The China Business Review* [Online]. Available from: https://chinabusinessreview.com/ [accessed 15 November 2014]
- Barker, C. (1983) 'The Mozambique pharmaceutical policy', *The Lancet*, 2 (8353), 780–82.
- Basant, R. (2010) Intellectual Property Protection, Regulation and Innovation in Developing Economies-The Case of Indian Pharmaceutical Industry, Indian Institute of Management-Ahmedabad, Working Paper Series.
- Bate, R. (2008) *Local Pharmaceutical Production in Developing Countries*. Available from: www.libinst.ch/publikationen/LI-LocalPharmaceuticalProduction.pdf [accessed 3 May 2015].
- Bateman, C. (2014) 'Exchange rate hurting chronic drug suppliers but ARV pipeline safe, says govt', *South African Medical Journal*, 104 (7), 461–63.
- Bell, M. & Pavitt, K. (1993) 'Technological accumulation and industrial growth: contrasts between developed and developing countries', *Industrial and Corporate Change*, 2 (1), 157–210.
- Berger, M., Murugi, J., Buch, E., Ijsselmuiden, C., Kennedy, A., Moran, M., Guzman, J., Devlin, M. & Kubata, B. (2009) *Strengthening Pharmaceutical Innovation in Africa*, Council on Health Research for Development (COHRED), New Partnership for Africa's Development (NEPAD).
- Berlin, M. (2003) 'Trade credit: why do production firms act as financial intermediaries?' *Business Review*, 3, 21–28.
- BMI (2013) Ghana Pharmaceuticals and Healthcare Report Q3 2013, Business Monitor International, London.
- BMI Espicom (2013) World Pharmaceutical Markets Fact Book 2013, Espicom Business Intelligence Ltd.
- BMI Research (2015) 'Kenya pharmaceuticals and healthcare report Q1 2015', 1 January 2015 [Online]. Available from: http://www.marketresearch.com/Business-Monitor-International-v304/Kenya-Pharmaceuticals-Healthcare-Q1–8494874/ [accessed 3 May 2015].
- Bolu, R.B., Ketavarapu, N.R., Indukuri, V.S.K., Gorantia, S.R. & Chava, S. (2012) *Efficient Process to Induce Enantioselectivity in Prochiral Carbonyl Compounds*, US Patent Application 2012/0264933, filed 22 June 2012.

- Bond, P. (1998) Uneven Zimbabwe: A Study of Finance, Development and Underdevelopment, Africa World Press, Trenton.
- Botanical Extracts EPZ (2015) *BEEPZ Project Milestones* [Online]. Available from: http://www.be-epz.com/page5.html [accessed 27 April 2015].
- Brasil (1988) Constituição da República Federativa do Brasil. Brasília, DF, Senado, 1998. Available from http://www.senado.gov.br/legislacao/const/con1988/ CON1988_16.02.1998/CON1988.shtm [accesses 13 February 2015].
- Brasil (1996) Lei de Patentes. Lei nº 9.279, de 14 de maio de 1996. Regula direitos e obrigações relativos à propriedade industrial. Available from http://www. planalto.gov.br/ccivil_03/leis/l9279.htm [accessed 3 February 2015].
- Brasil (1998) Ministério da Saúde. PORTARIA Nº 3.916, DE 30 DE OUTUBRO DE 1998. Available from http://bvsms.saude.gov.br/bvs/saudelegis/gm/1998/ prt3916_30_10_1998.html [accessed 16 April 2015].
- Brasil (2004a) Política Nacional de Assistência Farmacêutica (PNAF). Ministério da Saúde/Conselho Nacional de Saúde. Resolução nº. 338, de 6 de maio de 2004. Diário Oficial da União 2004.
- Brasil (2004b) Decreto n. 5.090, de 20 de maio de 2004. Regulamenta a Lei 10.858, de 20 de maio de 2004, institui o programa "Farmácia Popular do Brasil", e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, n. 97, seção 1, p. 6, 21 mai. 2004. Available from http://www2.camara.leg.br/ legin/fed/decret/2004/decreto-5090–20-maio-2004–532380-norma-pe.html [accessed 11 January 2015].
- Brasil (2004c) Lei no 10.973, de 2 de dezembro de 2004. Dispõe sobre incentivos à inovação e à pesquisa científica e tecnológica no ambiente produtivo e dá outras providências. Available from http://www.planalto.gov.br/ccivil_03/_ato2004–2006/2004/lei/l10.973.htm [accessed 3 April 2015].
- Brasil (2005) Lei do Bem. Lei 11.196/05 21 de novembro de 2005. Available from http://www.planalto.gov.br/ccivil_03/_ato2004–2006/2005/lei/l11196.htm [accessed 15 March 2015].
- Brasil (2010) Lei nº 12.349, de 15 de dezembro de 2010. Available from http://www. planalto.gov.br/ccivil_03/_Ato2007–2010/2010/Lei/L12349.htm [accessed 25 March 2015].
- Brasil (2011) Decreto nº 7.546, de 2 de agosto de 2011. Available from http:// www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/Decreto/D7546.htm [accessed 25 March 2015].
- Brasil (2012) Ministério da Saúde. Portaria Nº 837, de18 de abril de 2012. Define as diretrizes e os critérios para o estabelecimento das Parcerias para o Desenvolvimento Produtivo (PDP). Available from http://bvsms.saude.gov.br/bvs/saudelegis/gm/2012/prt0837_18_04_2012.html [accessed 3 April 2015].
- Brasil (2013) Brasil Maior. Acompanhamento das medidas setoriais. Conselho Nacional de Desenvolvimento Nacional.
- Brasil (2014) Ministério da Saúde. Aqui Tem Farmácia Popular. Available from http://portalsaude.saude.gov.br/index.php [accessed 13 March 2015].
- Bräutigam, D. (1997) 'Institutions, economic reform, and democratic consolidation in Mauritius', *Comparative Politics*, 30 (1), 45–62.
- Bräutigam, D., Rakner, L. & Taylor, S. (2002) 'Business associations and growth coalitions in Sub-Saharan Africa', *The Journal of Modern African Studies*, 40 (4), 519–47.
- Brautigam, B. (2009) *The Dragon's Gift: The Real Story of China in Africa*, Oxford University Press, Oxford.

- Brett, E.A. (2005) 'From corporatism to liberalisation in Zimbabwe: Economic policy regimes and political crisis, 1980–97', *International Political Science Review*, 26 (1), 91–106.
- Browne (1985) *White Paper on the Report of the Commission of Inquiry into Health Services,* Government Printer, Pretoria.
- Buss, P. (2011) 'Brazil: Structuring cooperation for health', *The Lancet*, 377 (9779), 1722–23.
- Cabral, L. (2010) 'Brazil's Development Cooperation with the South: A Global Model in Waiting', *Overseas Development Institute (ODI)*. Available from http://www.odi.org.uk/opinion/4952-brazils-development-cooperation-south-global-model-waiting [accessed 27 April 2015].
- Cabral, L., Russo, G. & Weinstock, J. (2014) 'Brazil and the shifting consensus on development co-operation: Salutary diversions from the 'aid-effectiveness' trail?' *Development Policy Review*, 32 (2), 179–202.
- Calì, M. & Sen, K. (2011) 'Do effective state business relations matter for economic growth? Evidence from India states', *World Development*, 39 (9), 1542–57.
- Cameron, A., Ewen, M., Auton, M. & Abegunde, D. (2011) The world medicines situation 2011 – Medicine prices, availability and affordability, World Health Organisation, Geneva. Available from http://www.who.int/medicines/areas/ policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf [accessed 30 April 2015].
- Camps-Walsh, G., Aivas, I. & Barratt, H. (2009) *Improving UK Patient Outcomes: How Can Value-Based Pricing Improve Access and Adoption of New Treatments?* Available from http://www.2020health.org/dms/2020health/downloads/ reports/2020vpcdoc-sep09.pdf [accessed 1 May 2015].
- Capanema, L.X. & Palmeira Filho, P.L. (2004) A cadeia farmacêutica e a política industrial: uma proposta de inserção do BNDES, BNDES Setorial, Rio de Janeiro, 19, 23–48.
- Cawson, A. (1982) *Corporative and Welfare: Social Policy and State Intervention in Britain,* London: Heinemann Educational Books.
- Cawson, A. (1986) Corporatism and Political Theory, Basil Blackwell, Oxford.
- Central Statistics of Ethiopia (CSA) (2014), *Report on Large and Medium Scale Manufacturing and Electricity Industries Survey, various issues*, Industry Minister, GTP Pharma sector performance report. Available from http://www.eeaecon. org/node/8118 [accessed 3 May 2015].
- Chang, H. (2004) 'Regulation of foreign investment in historical perspective', *The European Journal of Development Research*, 16 (3), 687–715.
- Chataway, J., Tait, J. & Wield, D. (2006) 'The governance of agro- and pharmaceutical biotechnology innovation: public policy and industrial strategy', *Technology Analysis and Strategic Management*, 18 (2), 169–85.
- Chataway, J., Chaturvedi, K., Hanlin, R., Mugwagwa, J., Wield, D. & Smith, J. (2009) 'Technological trends and opportunities to combat diseases of the poor in Africa', in Kalua, F., Awotedu, A., Kamwanja, L. & Saka, J. (eds.) *Science, Technology and Innovation for Public Health in Africa*, NEPAD Office of Science and Technology, Pretoria, 53–93.
- Chataway, J., Fry, C., Marjanovic, S. & Yaqub, O. (2012) 'Public private collaborations and partnerships in stratified medicine: making sense of new interactions', *New Biotechnology*, 29 (6), 732–40.
- Chaudhuri, S. (1986) 'Licensing Policies and Growth of Drug TNCs in India', in A. S.Gupta (ed.), *Drug Industry and the Indian People,*. New Delhi and Patna: Delhi

Science Forum and Federation of Medical Representatives Associations of India, pp. 243–54.

- Chaudhuri, S. (2008) 'Indian Generic Companies, Affordability of Drugs and Local Production in Africa with Special Reference to Tanzania', Milton Keynes: The Open University Research Centre on Innovation, Knowledge and Development, IKD Working Paper No. 37.
- Chaudhuri, S. (2012) 'Multinationals and monopolies: Pharmaceutical industry in India after TRIPS', *Economic and Political Weekly*, 47 (2), 46–54.
- Chaudhuri, S., Mackintosh, M. & Mujinja, P.G.M. (2010) 'Indian generics producers, access to essential medicines and local production in Africa: An argument with reference to Ghana', *European Journal of Development Research*, 22 (4), 451–68.
- Chaudhuri, S. & West, A. (2015) 'Can local producers compete with low cost imports? A simulation study of pharmaceutical industry in low-income Africa', *Innovation and Development, Industrial and Corporate Change*, 5 (1), 23–38.
- Chava. S., Gorantla, S.R., Indukuri, V.S.K. & Joga, R. (2014) Process for the preparation of tenofovir, US patent 8,791,259 issued 29 July 2014.
- Chege, J., Ngui, D. & Kimiyu, P. (2014) *Scoping paper on Kenyan manufacturing*, WIDER Working Paper 2014/136, October 2014, United Nations University – World Institute for Development Economics Research.
- Chifamba, R. (2003) *Analysis of Mining Investments in Zimbabwe*, PhD, Goteborg University.
- Chuma, J. & Okungu, V. (2011) 'Viewing the Kenyan health system through an equity lens: implications for universal coverage', *International Journal for Equity in Health*, 10 (22).
- CIMS (2013) CIMS Updated Prescribers' Handbook, Mumbai, UBM Medica India Private Ltd.
- Claxton, K., Briggs, A., Buxton, M.J., Culyer, A.J., McCabe, C., Walker, S. & Sculpher, M.J. (2008) 'Value based pricing for NHS drugs: an opportunity not to be missed?' *BMJ: British Medical Journal*, *336* (7638), 251–54.
- CMAM (2011) *Proposta de Necessidades E Alocação de Recursos Para Medicamentos,* Ministério da Saúde de Moçambique.
- Cochrane, G., Wooding, S., Taylor, J., Kamenetzky, A., Sousa, S. & Parks, S. (2015) Accelerated Access Review: An international review of emerging and effective practice in improving access to medicines and medical technologies, RAND Europe.
- Corbett, J. & Jenkinson, T. (1996) 'The financing of industry, 1970–1989: An international comparison', *Journal of The Japanese and International Economies*, 10, 71–90.
- Cordeiro, H. (1985) A Indústria da Saúde no Brasil, Edições Graal, Rio de Janeiro.
- Cornia, G.A., Jolly, R. & Stewart, F. (1987) *Adjustment with a Human Face,* Clarendon Press, Oxford.
- Council for Medical Schemes (2014) *Annual Report 2013/14*. Available from http://www.medicalschemes.com/files/Annual%20Reports/AR2013_2014LR. pdf [accessed: 4 December 2014].
- COWI (2012) Finalização Do Plano de Negócios Da SMM: Situação Dos Mercados Farmacêuticos Em Moçambique E Na Região Da SADC, COWI Consulting, Maputo.
- Datta, D., Vellanki, S.R.R., Salu, A., Balusu, R.B., Ravi, M.R., Nandipati, H.B., Rama, S., Vadali, L.R., Gorantla, S.S.C., Desari, S.R. & Mitapelly, N. (2014) *Process for*

the preparation of tenofovir disoproxil fumarate, US Patent 8,759,515 issued 24 June 2014.

- Davies, R. & Ratso, J. (2000) Zimbabwe: Economic adjustment, income distribution and trade liberalization, Centre for Economic Policy Analysis, New School University, New York.
- D'Ávila Viana, A.L. & Elias, P.E.M. (2007) 'Saúde e desinvolvimento', *Ciéncia & Saúde Coletiva*, 12, 1765–77.
- Deloitte (2012) Value-Based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value. Available from http://deloitte.wsj.com/cfo/files/2012/09/ ValueBasedPricingPharma.pdf [accessed 1 May 2015].
- De Oliveira, L. (2012) Nota Informativa Sobre a Iniciativa de Instaliação Da Fábrica de Antiretrovirrais E Outrs Medicamentos Em Moçambique, Farmanguinhos, Fundação Oswaldo Cruz.
- De Oliveira, L. (2013) *Inicitativa de Instalação Da Fábrica de Antiretrovirrais E Outros Medicamentos Em Moçambique; Avaliação Do Projecto,* Farmanguinhos, Fundação Oswaldo Cruz.
- Department of Health (1996) *National Drug Policy* for *South Africa*. Available from http://apps.who.int/medicinedocs/en/d/Js17744en/ [accessed 30 April 2015].
- DHMS (2012) *Discovery Health Medical Scheme Integrated Annual Report 2012*. Available from http://www.discovery.co.za/discovery_coza/web/linked_content/ pdfs/health/health_integrated_annual_report.pdf [accessed 30 April 2015].
- Dodd, S.A. (2007) *The Effect of the Drug Price Intervention on Retail Pharmacy in South Africa,* mini-dissertation submitted in partial fulfilment of the requirements for the degree Masters in Business Administration. North-West University. Available from http://dspace.nwu.ac.za/bitstream/handle/10394/4297/dodd_ sa(1).pdf?sequence=1 [accessed 30 April 2015].
- Doner, R.F. & Sheneider, B.R. (2000) 'Business associations and economic development: Why some associations contribute more than others', *Business and Politics*, 2 (3), 261–88.
- Dosi, G., Freeman, C., Nelson, R.R., Silverberg G. & Soete, L. (eds.) (1998) *Technical Change and Economic Theory*, Pinter Publishers, London and New York.
- DTI (2013) *Draft National Policy on Intellectual Property, 2013*, Available from: http:// ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf [accessed 29 April 2015].
- EACRPMPA (2011) *East African Community Regional Pharmaceutical Manufacturing Plan of Action 2012–2016*, Arusha, Tanzania; EAC Secretariat. Available from http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_ Pharmaceutical_Manufacturing_Plan_of_Action.pdf [accessed 3 May 2015].
- East African Community Secretariat (nd) Guidelines for Good Manufacturing Practice for Medicinal products within the EAC, Report: EAC/TF-MED/GMP/ PD/N2R0. Available from http://www.tfda.or.tz/index.php?option=com_ph ocadownload&view=category&download=129:guidelines-on-good-manufacturing-practice-for-medicinal-products-within-the-eac&id=69:good-manufacturing-practice&Itemid=440 [accessed 30 April 2015].
- Economist, The (2014) *The New Drug War Continued*. Available from http://www.economist.com/blogs/schumpeter/2014/01/new-drug-war-continued [accessed 29 April 2015].
- EIC (Ethiopian Investment Commission) (2014) Available from http://www. investethiopia.gov.et/images/pdf/incentives.pdf [accessed 12 January 2015].

- Emeje, M.O., Izuka, A., Isimi, C.Y., Ofoefule, S.I. & Kunle, O.O. (2011) 'Preparation and standardization of a herbal agent for the therapeutic management of asthma', *Pharmaceutical Development and Technology*, 16 (2), 170–78.
- Emeje, M.O. & Kunle, O.O. (2005) 'Effect of two surfactants and mode of incorporation on the compaction characteristics of the hot water leaf extract of Ficus Sur', Journal of Nutraceuticals and Functional Medical Foods, 4, 147–56.
- Emsely, R. & Booysen, F. (2004) 'Cost effectiveness of an atypical conventional antipsychotic in South Africa', South African Journal of Psychiatry, 10 (3), 58–66.
- Ernst, D. & Lundvall, B. (1997) *Information Technology in The Learning Economy Challenges for Developing Countries*, DRUID Working Paper No. 97–12, Danish Research Unit for Industrial Dynamics.
- European Union (EU) (2010) Zimbabwe-Vital Health Services Support Programme, Phase I and II. Draft Evaluation Report, Harare, Zimbabwe.
- Fafchamps, M. (1997) 'Trade credit in Zimbabwean manufacturing', World Development, 25 (5), 795–815.
- Farrell, J. & Saloner, G. (1986) 'Installed base and compatibility: Innovation, product preannouncements and predation', *American Economic Review*, 76, 940–55.
- FDA (2014) Facts about Good Manufacturing Practices (CGMPs). Available from http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ ucm169105.htm [accessed 3 November 2014].
- FDRE (2004) 'Labor Proclamation No. 377/2003', *Federal Negarit Gazeta*, Federal Democratic Republic of Ethiopia.
- FDRE (2007) 'Drug Fund and Pharmaceuticals Supply Establishment Proclamation No. 553/2007', *Federal Negarit Gazeta*, Federal Democratic Republic of Ethiopia.
- FDRE (2009) 'Food, Medicine and Healthcare Administration and Control Proclamation No 661/2009', *Federal Negarit Gazeta*, Federal Democratic Republic of Ethiopia.
- Fioramonti, L. (2005) 'Civil society and democratisation: Assumptions, dilemmas and the South African experience', *Theoria*, 107, 65–88.
- Fiotec/Fiocruz (2007) Estudo de Viabilidade Técnico-Económica Para a Instalação Da Fábrica de Medicamentos Em Moçambique Para Produção de Medicamentos Anti-Retrovirais E Outros, Relatório de Estudo, Fundação Oswaldo Cruz, Rio de Janeiro.
- Fischhoff, B. (1984) 'Setting standards: A systematic approach to managing public health and safety risks', *Management Science*, 30 (7), 823–43.
- Fisman, R. and Love, I. (2003) 'Trade credit, financial intermediary development, and industry growth', *The Journal of Finance*, 58 (1), 353–74.
- Flynn, M. (2008) 'Public production of anti-retroviral medicines in Brazil, 1990–2007', *Development and Change*, 39 (4), 513–36.
- Flynn, M. (2010) 'Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for Its National AIDS Program', in Shadlen, K. C., Guennif, S., Guzman, A. & Lalitha, N. (eds.) Intellectual Property, Pharmaceuticals, and Public Health: Access to Drugs in Developing, Cheltenham: Edward Elgar Publishing.
- FMHACA (2013a) *Medicine Manufacturing Establishment Directive Number 12/2013,* available from http://www.fmhaca.gov.et/documents/Directive%20%20for%20 Medicine%20Manufucturing%20Establishmen%20%202013.pdf [accessed 3 May 2015].

- FMHACA (2013b) The GMP Road Map Pharmaceutical Manufacturing, August, Addis Ababa.
- FMoH (2011) *Health and Health Related Indicators*, Policy Planning Directorate, Addis Ababa.
- FMoH (2012) 'Health Sector Development Programmes III, IV FMOH, Health Sector Development Programme Annual Performance Report 2011/12', available from: http://www.moh.gov.et/documents/26765/28899/Annual+Perfor mance+Report+2011/3ba3483a-9ee0-4a8b-bc39-4ca5acd8a9eb?version=1.2 [accessed 3 May 2015].
- Fojule, G. & Ogunyale, P.O. (2001) 'Efficacy of niprisan in the prophylactic management of patients with sickle cell disease', *Current Theory & Research*, 62(1), 26.
- Fortunak, J.M.D. (2014) 'Green Chemistry and Global Access to Medicines', Gordon Research Conference on Green Chemistry, Hong Kong, July 30.
- Fortunak, J.M.D., Byrn, S.R, Dyson, B., Ekeocha, Z., Ellison, T., King, C.L., Kulkarni, A., Lee, M., Conrad, C. & Fortunak, J.R. (2013) 'An efficient, green chemical synthesis of the malaria drug piperaquine', *Topical Journal of Pharmaceutical Research*, 12 (5), 791–798.
- Frankel, R. (2006) 'Associations in China and India: An overview', European Society of Association Executives. Available from http://www.esae.org/articles/2006_07_004.pdf [accessed 23 October 2014].
- Frost and Sullivan (2010) *The Pharmaceutical Industry in Key East African Countries*, Report No M57C-52, May.
- Frost and Sullivan (2012) Analysis of the Pharmaceutical Market of Kenya and Tanzania: Unpacking the Five Key Segments Driving Growth, Report No M72B-5G, April.
- Gadelha, C. A. G. (2006) 'Desenvolvimento, complexo industrial da saúde e política industrial' *Revista de Saúde Pública*, 40 (N Especial), 11–23.
- Gadelha, C.A.G. & Costa, L.S. (2012) 'A saúde na política nacional de desenvolvimento: um novo olhar sobre os desafios da saúde', in Fundação Oswaldo Cruz, et al. *A saúde no Brasil em 2030: diretrizes para a prospecção estratégica do sistema de saúde brasileiro*, Rio de Janeiro: Fiocruz.
- Gadelha, C.A.G, Costa, L.S. & Maldonado, J.O. (2012) 'O complexo econômicoindustrial da saúde e a dimensão social e econômica do desenvolvimento', *Revista de Saúde Pública (Impresso)*, 46, 21–28.
- Gadelha, C.A.G., Costa, L.S., Santos de Varge Maldonado, J.M., Barbosa, P.R. & Vargas, M.A. (2013) 'The health care economic-industrial complex: concepts and general characteristics', *Health*, 5 (10), 1607–21.
- Gadelha, C.A.G., Maldonado, J.M.S.V. & Costa, L.S. (2014)'Complexo produtivo da saúde: inovação, desenvolvimento e estado', in Silva Paim, J. & Almeida-Filho, N. (eds.), *Saúde Coletiva: Teoria e Prática*, Medbook, Rio de Janeiro.
- Gaffney, A. (2015) 'India's data integrity problems', *Regulatory Affairs Professionals Society*, 3 February 2015. Available from http://www.raps.org/Regulatory-Focus/News/2014/08/19/18980/Indias-Data-Integrity-Problems-Updated-17-June-2014/ [accessed 3 May 2015].
- Garwood, P. (2007) 'Kenya rejects bid to remove government's compulsory licensing flexibilities', *Intellectual Property Watch* .Available from http://www.ip-watch.org/2007/09/14/kenyan-parliament-rejects-bid-to-remove-governments-compulsory-licensing-option/ [accessed 27 April 2015].

- GAVI (2013) *The GAVI Alliance 2013 Annual Progress Report*. Available from http:// gaviprogressreport.org/2013/ [accessed 17 November 2014].
- Gebre-Mariam, T. & Nikolayev, A.S. (1993) 'Evaluation of starch obtained from Ensete ventricosum as a binder and disintegrant for compressed tablets', *Journal of Pharmacy and Pharmacology*, 45, 317–20.
- Gebre-Mariam, T. & Schmidt, P.C. (1996a) 'Isolation and physico-chemical properties of Enset starch', *Starch/Stärke*, 48, 208–14.
- Gebre-Mariam, T. & Schmidt, P.C. (1996b) 'Characterization of Enset starch and its use as a binder and disintegrant for tablets', *Pharmazie*, 51, 303–11.
- Gebre-Mariam, T. & Schmidt, P.C. (1998) 'Some physico-chemical properties of Dioscorea abyssinica starch', *Starch/Stärke*, 50, 241–46.
- Gebre-Mariam, T., Winnemöller, M. & Schmidt, P.C. (1996a) 'An evaluation of the disintegration efficiency of a sodium starch glycolate prepared from Enset starch in compressed tablets', *European Journal of Pharmaceuticals and Biopharmaceuticals*, 43, 124–32.
- Gebre-Mariam, T., Winnemöller, M. & Schmidt, P.C. (1996b) 'The use of a starch obtained from Dioscorea abyssinica in tablet formulations. Part (II): The sodium starch glycolate from Dioscorea abyssinica as a disintegrant', *Pharmaceutical Industry*, 58, 255–59.
- Gianetti, M., Burkart, M. & Ellingsen, T. (2011) 'What you sell is what you lend? Explaining trade credit contracts', *The Review of Financial Studies*, 24 (4), 1261–98.
- Goldman, D. & Smith, J. (2005) Socioeconomic Differences in the Adoption of New Medical Technologies, National Bureau of Economic Research. NBER Working Paper Series, no. 11218.
- Gomes, R., Pimentel, V., Lousada, M. & Pieroni, J.P. (2014) O novo cenário de concorrência na indústria farmacêutica brasileira, Complexo Industrial da Saúde BNDES Setorial 39, p. 97–134. Available from http://www.bndes.gov.br/ SiteBNDES/export/sites/default/bndes_pt/Galerias/Arquivos/conhecimento/ bnset/set3903.pdf [accessed 9 April 2015].
- Goodluck, C. (2014) 'Role of family resources in firm performance: Evidence from Tanzania', *Journal of African Business*, 15 (2), 122–35.
- Government of India (GOI) (1978) *New Drugs Policy*, Ministry of Chemicals and Fertilisers, New Delhi.
- Grabowski, H.G., Vernon, J.M. & Thomas, G.L. (1978) 'Estimating the effects of regulation on innovation: An international comparative analysis of the pharmaceutical industry', *Journal of Law and Economics*, 21 (1), 133–63.
- Greiner, W. (2011) 'Germany's drug pricing after AMNOG What comes next?' Presentation at the 7th America and German Healthcare Forum, Minneapolis. Available from http://cges.umn.edu/docs/Greiner.Workshop. GermanyDrugPricingafterAMNOG.pdf [accessed 1 May 2015].
- Griliches, Z. and Mairesse, J. (1995) 'Production functions: the search for identification', NBER Working Paper No. 5067, National Bureau of Economic Research, Cambridge, MA.
- Grindle, M. (2007) *Going Local: Decentralization, Democratization, and the Promise* of *Good Governance*. Princeton University Press, Princeton.
- Guardian, The (2001) 'Firms Split Over Deal in Cheap Drugs Lawsuit'. Available from http://www.theguardian.com/world/2001/apr/18/medicalscience.aids [accessed 29 April 2015].

- Guimer, J., Lee, E. & Grupper, M. (2004) *Processes and Issues for Improving Access to Medicines: The Evidence Base for Domestic Production and Greater Access to Medicines,* DFID Health Systems Resource Centre, London.
- Handley, A. (2008) Business and the State in Africa: Economic Policy-making in the Neo-liberal Era, Cambridge University Press, Cambridge.
- Harper, I., Brhlikova, P. & Pollock, A. (2007) *Good Manufacturing Practice in the Pharmaceutical Industry Working Paper 3*, prepared for Workshop on 'Tracing Pharmaceuticals in South Asia', 2–3 July, University of Edinburgh.
- Hebrault, D. (2014) *New Continuous Flow Chemistry Webinar Recent Advances in Organic Chemistry Part 8.* Available from http://us.mt.com/us/en/home/events/webinar/ondemand/continuous-flow-chemistry-II-organic-chemistry.html [accessed 10 November 2014].
- Helmsing, A.H.J. (1990) 'Industrialization in Zimbabwe: A non-replicable model?' *Africa Focus*, 6, 267–82.
- Herzer, D. & Grimm, M. (2012) 'Does foreign aid increase private investment? Evidence from panel cointegration', *Applied Economics*, 44 (20), 2537–50.
- Himbara, D. (1993) 'Myths and realities of Kenyan capitalism', *Journal of Modern African Studies*, 31 (1), 93–107.
- Hirschman, A. O. (1967) *Development Projects Observed*. The Brookings Institution, Washington, DC.
- Hirschman, A. O. (1990). 'The case against "one thing at a time"', World Development, 18 (8), 1119-22.
- Immel, B. (2000) 'A brief history of the GMPs', *Regulatory Compliance Newsletter*, Winter.
- Immel, B. (2001) 'A Brief History of GMPs for Pharmaceuticals', *Pharmaceutical Technology*. Available from www.gmpnews.ru/wp-content/uploads/2010/05/ History-gmp.pdf [accessed 4 May 2015].
- IMS (2012) Africa: A Ripe Opportunity. Understanding the Pharmaceutical Market Opportunity and Developing Sustainable Business Models in Africa, IMS Health. Available from http://www.imshealth.com/ims/Global/Content/Insights/ Featured%20Topics/Emerging%20Markets/IMS_Africa_Opportunity_ Whitepaper.pdf [accessed 27 April 2015].
- IMS Health (2014a) Total Private Market, South Africa October 2014.
- IMS Health (2014b) Total Private Market, South Africa November 2014.
- IMS Institute for Healthcare Informatics (2014) Understanding the pharmaceuticals value chain. Available from http://www.imshealth.com/vgn-ext-templating/v/ index.jsp?vgnextoid=a64de5fda6370410VgnVCM10000076192ca2RCRD&vg nextchannel=a64de5fda6370410VgnVCM10000076192ca2RCRD# [accessed 3 May 2015].
- Interfarma (2014) *Associação da indústria farmacêutica de pesquisa Guia 2014.* Available from http://www.interfarma.org.br/biblioteca.php [accessed 21 March 2015].
- IPASA (2013) Draft National Policy on Intellectual Property, 2013: Submission by Innovative Pharmaceutical Association of South Africa (IPASA). Available from http://ipasa.co.za/wp-content/uploads/2014/01/Copy-of-IPASA-submissionon-the-draft-national-policy-on-IP-final-131016.pdf [accessed 04 November 2014].
- IPEA (2011) *Cooperação Brasileira Para O Desenvolvimento Internacional 2005–2009*, Administração Pública Federal, Brasília: Casa Civil, IPEA e ABC. Available from http://www.abc.gov.br/api/publicacaoarquivo/328 [accessed 05 April 2014].

- IRIN News Africa (2015) 'KENYA: Small farmers cash in on Artemisinin production'. Available from http://www.irinnews.org/report/82486/kenya-smallfarmers-cash-in-on-artemisinin-production [accessed 27 April 2015].
- Iyamu, E.W., Turner, E.A. & Asakura, T. (2003) 'Niprisan (Nix-0699) improves the survival rates of transgenic sickle cell mice under acute severe hypoxic conditions', *British Journal of Hematology*, 122 (6), 1001.
- Jacob, A.G. (2010) Steering the State: The Politics of Institutional Change in the *Pharmaceutical and Telecommunications Sectors in Post Reform India*, Ph.D. dissertation, Rutgers University, New Brunswick, NJ.
- Jaffe, S. & Henson, S. (2004) *Standards and Agro-Food Exports from Developing Countries: Rebalancing the Debate*, Policy Research Working Paper 3348, The World Bank, Washington, DC.
- Jain, S. (2012) 'Pragmatic agency in technology standards setting: The case of ethernet', *Research Policy*, 41, 1643–54.
- Jayaraman, K. (2012) 'Finding the right chemistry', Nature Medicine, 19, 1200-03.
- Jeffrey, R (2001) *Tracing pharmaceuticals in South Asia, University of Edinburgh,* Centre for Asian Studies Working Paper.
- Jeffrey, R., Pollock, A., Jeffrey, P., Harper, I. & Ecks, S. (2010) *Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption,* ESRC End of Award Report, RES-167–25–0110. ESRC, Swindon.
- Jenkins-Smith, H.C. & Sabatier, P.A. (1994) 'Evaluating the advocacy coalition framework', *Journal of Public Policy*, 14 (2), 175–203.
- Jian. B. & Si, Y. (2008) Amino Alcohol Ligand and Its Use in Preparation of Chiral Propargylic Alcohols and Tertiary Amines Via Enantioselective Addition Reaction, US Patent 7,439,400; issued October 21, 2008.
- Kaijage, F. & Tibaijuka, A. (1996) *Poverty and Social Exclusion in Tanzania*. International Institute for Labour Studies, Research Series 109, ILO, Geneva.
- Kaplan, W. & Laing, R. (2005) Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Future Research. Health, Nutrition and Population (HNP) Discussion Paper, The World Bank's Human Development Network, The International Bank for Reconstruction and Development / The World Bank, Washington, DC.
- Kaplan, W. A., Wirtz, V.J. & Stephens, P. (2013) 'The Market Dynamics of Generic Medicines in the Private Sector of 19 Low and Middle Income Countries between 2001 and 2011: a descriptive time series analysis', *Public Library of Science – One*. Available from http://www.plosone.org/article/ info%3Adoi%2F10.1371%2Fjournal.pone.0074399 [accessed 26 February 2015].
- Kaplinsky, R. & Masuma, F. (2010). What Are the Implications for Global Value Chains When the Market Shifts from the North to the South? The World Bank, Washington, DC.
- Kariuki, J., Njeru, M., Wamae, W. & Mackintosh, M. (2015) 'Local supply chains for medicines and medical supplies in Kenya: understanding the challenges', ACTS Working Paper. Available at http://iphsp.acts-net.org/publications/working-papers [accessed 08/09/15].
- Kattel, R. & Lember, V. (2010) 'Public procurement as an industrial policy tool: An option for developing countries?' *Journal of Public Procurement*, 10 (3), 368–404.
- Katz, M.L. & Shapiro, C. (1985) 'Network externalities, competition, and compatibility', *American Economic Review*, 75, 424–40.

- KEMRI (2015) *Background of KEMRI*. Available from http://www.kemri.org/index. php/about-kemri/background [accessed 27 April 2015].
- KEMSA Task Force (2008) KEMSA Task Force Report, KEMSA, Nairobi.
- Khan, M. (1995) 'State Failure in Weak States: A Critique of New Institutionalist Explanations', in J. Harris, J. Hunter and C. Lewis (eds.), *The New Institutional Economics and Third World Development*, Sage, London.
- Khan, M. (2000) 'Rent Seeking as a Process: Inputs, Rent-Outcomes and Net Effects', in M. Khan and K.S. Jomo (eds.), *Rents, Rent-Seeking and Economic Development*, Cambridge University Press, Cambridge.
- Khanna, T. & Palepu, K.G. (1997) 'Why focused strategies may be wrong for emerging markets', *Harvard Business Review*, 75 (4) (July–August), 41–51.
- Kim, J.Y., Farmer, P.E. & Porter, M.E. (2013) 'Redefining global health-care delivery', *Lancet*, 382, 1060–69.
- Kjöllerström, M. (2008) Public Procurement as a Tool for Promoting More Sustainable Consumption and Production Patterns, Sustainable Development Innovation Briefs. Issue 5. United Nations Department of Economic and Social Affairs. Available from http://esa.un.org/marrakechprocess/pdf/InnovationBriefs_no5. pdf [accessed 30 April 2015].
- Kotwani, A., Ewen, M., Dey, D., Iyer, S. Lakshmi, P.K., Patel, A., Raman, K., Singhal, G.L., Thawani, V., Tripathi, S. & Laing, R. (2007) 'Prices & availability of common medicines at six sites in India using a standard methodology', *Indian Journal of Medical Research*, 125, 645–54.
- Kragelund, P. (2008) 'The return of non-DAC donors to Africa: New prospects for African Development?' *Development Policy Review*, 26 (5), 555–84.
- Kshetri, N. & Dholakia, N. (2009) 'Professional and trade associations in a nascent and formative sector of a developing economy: A case study of the NASSCOM effect on the Indian offshoring industry', *Journal of International Management*, 15(2), 225–39.
- Laing, R., Waning, B., Gray, A., Ford, N. & Hoen, E.T. (2003) '25 years of the WHO essential medicines lists: progress and challenges', *The Lancet*, 361 (9370), 1723–29.
- Lall, A. (1992) 'Technological capabilities and industrialisation', *World Development*, 20 (2), 165–86.
- Lall, S. (2003) Reinventing Industrial Strategy: The Role of Government Policy in Building Industrial Competitiveness, QEH Working Paper Series-QEHWPS111.
- Lall, S. & Narula, R. (2004) 'Foreign direct investment and its role in economic development: Do we need a new agenda?' *The European Journal of Development Research*, 16 (3). *Harvard Business Review*, 75 (4), 41–51.
- Lall, S. & Wangwe S. (1998) 'Industrial policy and industrialisation in Sub-Saharan Africa', *Journal of African Economies*, 7 (Supp. 1), 70–107.
- Lazonick, W. & O'Sullivan, M. (1997a) 'Finance and industrial development. Part I: the United States and the United Kingdom', *Financial History Review*, 4, 7–29.
- Lazonick, W. & O'Sullivan, M. (1997b) 'Finance and industrial development: evolution to market control. Part II: Japan and Germany', *Financial History Review*, 4, 117–38.
- Lehman, H.P. (2008) 'The emergence of civil society organizations in South Africa', *Journal of Public Affairs*, 8(1–2), 115–27.

- Losse, K., Schneider, E. & Spennemann, C. (2007) *The Viability of Local Production in Tanzania,* Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), Eschborn, Germany.
- Loureiro, S.A.L.S., Simões, B., Aragão, E., Mota, F., Moura, H. & Damasceno, L. (2007) 'Diffusion of medical technology and equity in health in Brazil: An exploratory analysis', *European Journal of Development Research*, 19, 66–80.
- Loyola, M.A. (2008) 'Medicamentos e saúde pública em tempos de AIDS: metamorfoses de uma política dependente', *Ciênc. Saúde Coletiva*, 13, 763–78.
- MacDonald, R. & Yamey, G. (2001) 'The cost to global health of drug company profits', *Western Journal of Medicine*, 174 (5), 302–03.
- Mackintosh, M., Chaudhuri, S. & Mujinja, P.G.M. (2011) 'Can NGOs regulate medicines markets? Social enterprise in wholesaling, and access to essential medicines', *Globalization and Health*, 7 (4).
- Madhavi, Y. (2003) 'The manufacture of consent? Hepatitis B vaccination', *Economic and Political Weekly*, 38 (24), 2417–24.
- Madhavi, Y. (2013) 'Vaccines and vaccine policy for universal health care', *Social Change*, 43 (2), 263–91.
- Malerba, F. (2002) 'Sectoral systems of innovation and production', *Research Policy*, 31(2), 247–64.
- Maluka, S.O. (2013) 'Why are pro-poor exemption policies in Tanzania better implemented in some districts than in others?' *International Journal for Equity in Health*, 12 (80).
- Manning, R. (2006) 'Will "Emerging Donors" Change the Face of International Co-Operation?' *Development Policy Review*, 24 (4), 371–85.
- Maree, J. (1993) 'Trade unions and corporatism in South Africa', *Transformation*, 21 (1993), 24–54.
- Maskus, K., Otsuki, T. & Wilson, J. (2004) *The Costs of Complying with Foreign Product Standards for Firms in Developing Countries: An Econometric Study*, Research Program on Political and Economic Change, Working Paper PEC2004–0004.
- Maskus, K.E. & Wilson, J.S. (2001) 'A Review of Past Attempts and the New Policy Context', in K. E. Maskus and J. S. Wilson (eds.), *Quantifying the Impact of Technical Barriers to Trade: Can It Be Done?* University of Michigan Press, Ann Arbor.
- Maxon, R.M. (1992) 'Multinational Corporations', in Ochieng, W.R. and R.M. Maxon (eds.), *An Economic History of Kenya*, East African Publishers, pp. 383–88.
- McIntyre, D., Garshong, B., Mtei, G., Meheus, F., Thiede, M., Akazili, J., Ally, M., Aikins, M., Mulligan, J.H. & Goudge, J. (2008) 'Beyond fragmentation and towards universal coverage: insights from Ghana, South Africa and the United Republic of Tanzania', *Bulletin of the World health Organization*, 86, 871–76.
- Mckinsey and Company (2013) *Pharmaceutical Sector in Africa*, presentation at the African Pharmaceutical Summit, Hammamet, Tunisia, September 23.
- Medical Chronicle (2012) Medical Schemes Should Plan Properly to Address Rising Demand for Biologics. Available from http://www.medicalchronicle. co.za/medical-schemes-should-plan-properly-to-address-rising-demand-forbiologics/ [accessed 30 April 2015].
- MEDS (Mission for Drugs and Essential Supplies) (2013) 2012 Annual Report and Financial Statements for the Year Ended 31st December 2012, Nairobi.

- Mhamba, M.R. & Mbirigenda, S. (2010) *The Pharmaceutical Industry and Access to Essential Medicines in Tanzania, EQUINET Discussion Paper* 83. Available from http://equinetafrica.org/bibl/docs/DIS83TZN%20medicines%20mhamba.pdf [accessed 30 April 2015].
- Ministry of Industrialization (2010) Kenya National Industrialization Policy Framework, Draft Five. Available from http://industrialization.eac.int/index. php?option=com_docman&task=doc_download&gid=115&Itemid=70 [accessed 27 April 2015].
- Mitra, S. (1986) 'Actual Drug Needs: Facts and Fallacies', in A. S. Gupta (ed.), *Drug Industry and the Indian People*, Delhi Science Forum and Federation of Medical Representatives Associations of India, New Delhi and Patna, pp. 59–68.
- Mkandawire, T. (2001) 'Thinking about development states in Africa', *Cambridge Journal of Economics*, 25, 289–313.
- Mlambo, A.S., Pangeti, E.S. & Phimister, I. (2000) Zimbabwe: A History of Manufacturing 1890–1995, University of Zimbabwe Press, Harare.
- MoFED (2006) Building on Progress A plan for Accelerated and Sustained Development to End Poverty (PASDEP) 2005/06–2009/10, Ministry of Finance and Economic Development Ethiopia. Available from http://www.mofed.gov.et/English/ Pages/Home.aspx [accessed 3 May 2015].
- MoFED (2012) *Growth and Transformation Plan (2010/11–2014/15) Annual Progress Report for F.Y. 2010/11*, Ministry of Finance and Economic Development Ethiopia. Available from http://www.mofed.gov.et/English/Pages/Home.aspx [accessed 3 May 2015].
- MoHSW (Ministry of Health and Social Welfare) (2006) *Strategies for Promotion of Local Production of Pharmaceuticals in Tanzania 2006–2016*, Dar es Salaam.
- MoHSW (Ministry of Health and Social Welfare) (2008) *Mapping of the Medicines Procurement and Supply Management System in Tanzania*, Dar es Salaam. Available from: http://www.who.int/medicines/areas/coordination/tanzania_mapping_ supply.pdf [accessed 4 May 2015].
- MoHSW (Ministry of Health and Social Welfare) (2009) *Annual Health Statistical Tables and Figures: Tanzania Mainland,* Dar es Salaam.
- MoHSW (Ministry of Health and Social Welfare) (2012) *Tanzania National Health Accounts Year 2010*, Dar es Salaam. Available from https://www.hfgproject.org/ tanzania-national-health-accounts-year-2010-sub-accounts-hiv-aids-malariareproductive-child-health/ [accessed 4 May 2015].
- MoHSW (Ministry of Health and Social Welfare) (2013) *Mid Term Review of the Health Sector Strategic Plan III 2009–2015*, Main Report, Ministry of Health and Social Welfare, United Republic of Tanzania, p. 34. Available from http://digitallibrary.ihi.or.tz/2643/ [accessed 30 April 2015].
- MoMS (Ministry of Medical Services) (2010) *Kenya Pharmaceutical Country Profile,* Nairobi, November. Available from http://www.who.int/medicines/areas/coordination/kenya_pharmaceuticalprofile_december2010.pdf [accessed 4 May 2015].
- MoMS & MPHS (Ministry of Medical Services and Ministry of Public Health and Sanitation) (2010) *Sessional Paper on National Pharmaceutical Policy*, Government of Kenya, Nairobi. Available from http://apps.who.int/medicinedocs/en/d/ Js18697en/ [accessed 4 May 2015].
- MoMS & MPHS (Ministry of Medical Services and Ministry of Public Health and Sanitation) (nd) *Kenya National Health Accounts 2009/10* Government of Kenya,

Nairobi. Available from http://www.who.int/pmnch/media/events/2013/ kenya_nha.pdf [accessed 4 May 2015].

- Moon, S. (2011) *Pharmaceutical Production and Related Technology Transfer*, World Health Organization Department of Public Health Innovation and Intellectual Property, Geneva.
- Moore, M. & Schmitz, H. (2008), *Idealism, Realism and the Investment Climate in Developing Countries*, Institute of Development Studies, Working paper series, no. 307. IDS, Brighton.
- Morgan Jones, M., Castle-Clarke, S., Brooker, D., Nason, E., Huzair, F. & Chataway, J. (2014) The Structural Genomics Consortium: A knowledge platform for drug discovery, A RAND research report. Available from http://www.rand.org/pubs/ research_reports/RR512.html [accessed 1 May 2015].
- MoST (2012) The Green Paper on Science, Technology and Innovation Policy of Ethiopia Building Competitiveness through Innovation of the Ministry of Science and Technology, Ministry of Science and Technology Ethiopia. Available from http:// www.most.gov.et/ [accessed 3 May 2015].
- MoST (2013) *National Science, Technology and Innovation Policy of Ethiopia*, Ministry of Science and Technology Ethiopia. Available from http://www.most.gov.et/ [accessed 3 May 2015].
- MS/DECIIS (2015) Departamento do Complexo Industrial e Inovação em Saúde. Available from http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/secretarias/sctie [accessed 22 April 2015].
- MS/PFPB (2014) Farmácia Popular do Brasil. Available from http://portalsaude. saude.gov.br/index.php/o-ministerio/principal/secretarias/sctie/farmaciapopular [accessed 12 February 2015].
- MSD (Medical Stores Department) (2013) *Medium Term Strategic Plan II: 2014–2020*, Dar es Salaam. Available from http://msd.or.tz/index.php/medium-term-strategic-plan-2014–2020/category/6-medium-term-strategic-plan [accessed 30 April 2015].
- MSF (2015) The Right Shot: Bringing Down Barriers to Affordable and Adapted Vaccines. Available from http://www.msf.org.br/sites/default/files/msf_the_right_shot_ report_2nded_2015.pdf [accessed 1 May 2015].
- MSH (Management Sciences for Health) (2010) *International Drug Price Indicator Guide 2009*. Available from http://erc.msh.org/mainpage.cfm?file=1.0.htm&m odule=DMP&language=English [accessed 30 April 2015].
- MSH (Management Sciences for Health) (2013) *International Drug Price Indicator Guide 2012*. Available from http://erc.msh.org/dmpguide/pdf/ DrugPriceGuide_2012_en.pdf [accessed 30 April 2015].
- MTDP (2010) *Medium Term Development Plan January 2010–December 2015,* Government of Zimbabwe, Harare.
- Mugwagwa J., Kale D. & Banda, G. (2015) *Standards and Their Role in Pharmaceutical Upgrading in Low- and Middle-Income Countries*, Innogen Institute Policy Brief, March.
- Mujinja, P.G.M., Mackintosh, M., Justin-Temu, M. & Wuyts, M. (2014) 'Local production of pharmaceuticals in Africa and access to essential medicines: "Urban bias" in access to imported medicines in Tanzania and its policy implications', *Globalization and Health*, 10 (12), 1–12.
- Muller, K.M., Gempeler, M.R., Scheiwe, M. & Zeugin, B.T. (1996) 'Quality assurance for biopharmaceuticals: An overview of regulations, methods and problems', *Pharmaceutics Acta Helvetiae*, 71, 421–38.

- Myers, S.C. (1984) 'The capital structure puzzle', *The Journal of Finance*, 39 (3), 575–92.
- Myers, S. & Majluf, N. (1984) 'Corporate financing and investment decision when firms have information investors do not have', *Journal of Financial Economics*, 13, 187–221.
- Nadvi, K. (1999) 'Collective efficiency and collective failure: the response of Sialkot surgical instrument cluster to global quality pressures', *World Development*, 27 (9), 1605–26.
- Nadvi, K. & Halder, G. (2007) 'Local clusters in global value chains: Exploring dynamic linkages between Germany and Pakistan', *Entrepreneurship & Regional Development*, 17 (5), 339–63.
- Nadvi, K.M. & Waltring, F. (2004) 'Making Sense of Global Standards', in H. Schmitz (ed.), *Local Enterprises in the Global Economy: Issues of Governance and Upgrading*, Edward Elgar. Cheltenham.
- Narayanan, V. & Chen, T. (2012) 'Research on technology standards: Accomplishment and challenges', *Research Policy*, 41, 1375–1406.
- National Bureau of Statistics (NBS) (2009) *Annual Survey of Industrial Production*. Available from http://nbs.go.tz/takwimu/Industry/ASIP_2009_Statistical.pdf [accessed 30 April 2015].
- Ndlela, D.B. (2007) 'Africa's Industrialisation: An Alternative Approach', in Senghor, J. & Poku, N.K. (eds.), *Towards Africa's Renewal*, Ashgate, Hampshire and Burlington.
- NECF (National Economic Consultative Forum) (2011) The NECF Health Task Force Report On The Current Status Of The Pharmaceutical Industry Of Zimbabwe And Factors Affecting Its Growth Prospects, Harare, Zimbabwe.
- Nelson, R.R. & Winter S.G. (1982) An Evolutionary Theory of Economic Change, Belknap Press, Cambridge, MA.
- Nguyen, T.A., Knight, R., Roughead, E.E., Brooks, G. & Mant, A. (2014) 'Policy options for pharmaceutical pricing and purchasing: issues for low-and middle-income countries', *Health Policy and Planning*, 30 (2), 267–80.
- Nickerson, J.V. & zur Muehlen M. (2006) 'The ecology of standards processes: Insights from internet standards making', *MIS Quarterly*, 30, 467–88.
- Nigussu, E., Belete, A. & Gebre-Mariam, T. (2013) 'Acetylation and characterization of enset starch and evaluation of its direct compression and drug release sustaining properties', *International Journal of Pharmacological Science and Research*, 4, 4397–4409.
- Nilsen, J.H. (2002) 'Trade credit and the bank lending channel', *Journal of Money, Credit and Banking*, 34 (1), 226–53.
- Ogonda, R.T. (1992) 'Kenya's Industrial Progress in the Post-Independence Era', in Ochieng, W.R. and Maxon, R.M. (eds.), *An Economic History of Kenya*, East African Publishers, 297–312. Nairobi.
- Ogot, M., Nyandemo, S., Kenduiwo, J., Mokaya, J., Iraki, W., Muriuki, R. & Mulinge, M. (2009) *The Long Term Policy Framework for Public Procurement in Kenya*, PPOA, University of Nairobi.
- Olcay, M. & Laing R. (2005) Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation? Paper prepared for The Commission on Intellectual Property Rights, Innovation and Public Health. Available from http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines. pdf [accessed 19 February 2015].

- Oliveira, E. A., Labra, M.E. & Bermudez, J. (2006) 'A produção pública de medicamentos no Brasil: uma visão geral', *Cad. Saúde Pública*, 22 (11), 2379–89.
- Olson, M. (1982) The Rise and Decline of Nations, Yale University Press, New Haven.
- Organisation of Economic Cooperation and Development (OECD) (nd) *Public Procurement for Sustainable and Inclusive Growth.* Available from http://www. oecd.org/gov/ethics/PublicProcurementRev9.pdf [accessed 25 April 2015].
- Osewe, P.L., Nkrumah, Y.K. and Sackey, E. (2008) *Improving Access to HIV/AIDS Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities Utilization*, World Bank, Washington, DC.
- Page, J. (2012) 'Can Africa industrialise?' *Journal of African Economies*, 21 (Suppl. 2), ii86–ii125.
- Paim, J.S. (2009) 'Uma análise sobre o processo da Reforma Sanitária Brasileira', *Saúde em Debate*, 33, 27–37.
- Palmeira-Filho, P.L., Pieroni, J.P., Antunes, A. & Bomtempo, J.V. (2012) 'O desafio do financiamento à inovação farmacêutica no Brasil: a experiência do BNDES Profarma', *Revista do BNDES*, 37, 69–90.
- Pangeti, E.S. (2000) 'The Economy Under Siege: Sanctions and the Manufacturing Sector, 1965–1979', in Mlambo, A.S., Pangeti, E.S. & Phimister, I. (eds.), *Zimbabwe: A History of Manufacturing 1890–1995*, University of Zimbabwe Press, Harare.
- Patwardhan, B. & Mashelkar, R.A. (2009) 'Traditional medicine-inspired approaches to drug discovery: Can Ayurveda show the way forward?' *Drug Discovery Today*, 14, 804.
- Pavignani, E. & Durão, J. R. (1999) 'Managing external resources in Mozambique: Building new aid relationships on shifting sands?' *Health Policy and Planning*, 14 (3), 243–53.
- Perampaladas, K., Masum, H., Kapoor, A., Shah, R., Daar, A.S. & Singer, P.A. (2010) 'The road to commercialization in Africa: Lessons from developing the sicklecell drug Niprisan', *BMC International Health and Human Rights*, 10 (Suppl. 1), S11.
- Persson, U. (2012) Value Based Pricing in Sweden: Lessons for Design? Seminar Briefing 12. Office of Health Economics, London. Available from https://www. ohe.org/news/value-based-pricing-sweden-lessons-design [accessed 1 May 2015].
- Persson, U., Willis, M. & Odegaard, K. (2010) 'A case study of ex ante, value-based price and reimbursement decision-making: TLV and rimonabant in Sweden', *European Journal of Health Economics*, 11 (2), 195–203.
- Petersen, M.A. and Rajan, R.G. (1997) 'Trade credit: Theories and evidence', *The Review of Financial Studies*, 10 (3), 661–91.
- Pharmaceutical Society of South Africa (2014) *PSSA Submission: Market Enquiry into the Private Healthcare Sector.* Available from http://www.healthinquiry. net/Public%20Submissions/PSSA%201%20submission%20to%20Market%20 Inquiry.pdf [accessed 30 April 2015].
- Phimister, I. (1988) An Economic and Social History of Zimbabwe, 1890–1948, Longman, London.
- Phimister, I. (2000) 'The Origins and Development of Manufacturing in Southern Rhodesia, 1894 – 1939', in Mlambo, A.S., Pangeti, E.S. & Phimister, I. (eds.),

Zimbabwe: A History of Manufacturing 1890–1995, University of Zimbabwe Press, Harare.

- Pinheiro, E., Vasan, A., Kim, J.Y., Lee, E., Guimier, J.M. & Perriens, J. (2006) 'Examining the production costs of antiretroviral drugs', *AIDS*, 20 (13), 1745–52.
- Pinho, V.D., Gutmann, B., Miranda, L.S.M., de Souza, R. & Kappe, C.O. (2014) 'Continuous flow synthesis of a-halo ketones: essential building blocks of antiretroviral agents', J. Org. Chem., 79, 1555–1562.
- PINTEC/ Instituto Brasileiro de Geografia e Estatística IBGE (2011) *Pesquisa de Inovação Tecnológica*, IBGE, Rio de Janeiro. Available from Pesquisa de Inovação PINTEC, http://www.pintec.ibge.gov.br/index.php?option=com_content_extjs &view=article&id=17&Itemid=6 [accessed 1 March 2015].
- Portal Fiocruz (2014) *Produção e Inovação*. Available from http://portal.fiocruz.br/ pt-br/content/produ%C3%A7%C3%A3o-e-inova%C3%A7%C3%A3o [accessed 20 March 2015].
- Portelli, B. & Narula, R. (2004) Foreign direct investment through acquisitions and implications for technological upgrading: Case evidence from Tanzania, Research Memoranda 008, MERIT, Maastricht Economic Research Institute on Innovation and Technology, Maastricht.
- Private Sector Innovation Programme for Health (2014). Overview of Experiences in the Pharmaceutical Supply Chain; Implications of the Poor in Kenya. Available from http://www.psp4h.com/ [accessed 3 May 2015].
- Progenerico (2014) *Associação Brasileira das Indústrias de Medicamentos Genéricos*. Available from http://www.progenericos.org.br/index.php/noticias [accessed 15 March 2015].
- Puliyel, J. M. & Madhavi, Y. (2008) 'Vaccines: Policy for public good or private profit?' *Indian Journal of Medical Research*, 127 (1), 1–3.
- Rai, R.K. (2009) 'Effect of the TRIPS-mandated intellectual property rights on pharmaceutical industry', *The Journal of World Intellectual Property*, 11 (5–6), 404–31.
- Rajagopal, D. (2013) 'Cipla completes the Medpro deal, buys 100% stake in the South African company', *The Economic Times*, 28 February. Available from http://articles.economictimes.indiatimes.com/2013–02–28/news/37352125_1_cipla-medpro-cipla-chairman-subhanu-saxena [accessed 27 April 2015].
- Rajan, R.G. & Subramanian, A. (2011) 'Aid, Dutch disease, and manufacturing growth', *Journal of Development Economics*, 94 (1), 106–18.
- Reich, M. (1990) 'Why the Japanese don't export more pharmaceuticals: Health policy as industrial policy', *California Management Review*, Winter, 124–50.
- Richardson, C.J. (2005) 'How the loss of property rights caused Zimbabwe's collapse', *CATO Institute Economic Development Bulletin*, Project on Global Economic Liberty 4.
- Riddell, R. (1990) Manufacturing Africa: Performance and Prospects of Seven Countries in Sub-Saharan Africa, James Curry, London.
- Rietveld, A.H. & Haaijer-Ruskamp, F.M. (2002) 'Policy options for cost containment of pharmaceuticals', *International Journal of Risk and Safety in Medicine*, 15, 29–54.
- Ripin, D.H.B., Teager, D.S., Fortunak, J., Basha, S.M., Bivins, N., Boddy, C.N., Byrn. S., Catlin, K.K., Houghton, S.R. & Jagadeesh, S.T. (2010) 'Process improvements

for the manufacture of tenofovir disoproxil fumarate at commercial scale', *Organic Process R&D Journal*, 14, 1194–1201.

- Roa, A.C. & Baptista e Silva, F.R. (2015) 'Fiorruz as an actor in Brazilian foreign relations in the context of the community of Portuguese-speaking countries: An untold story', *História, Ciências, Saúde-Manguinhos*, 22 (1), 153–69.
- Rosen, D. & Rickwood, S. (2014) "Supply Chain Optimisation in Africa's Private Sector – Reducing the Price to Patient", IMS Health. Available from http:// www.imshealth.com/deployedfiles/imshealth/Global/Content/Healthcare/ Driving%20Healthcare%20Performance/High%20Growth%20Markets/IMSH_ Africa Supply Chain WP.pdf [accessed 30 April 2015].
- Rosenberg, N. (1976) *Perspectives on Technology*, Cambridge University Press, Cambridge.
- Rowe, R.C., Sheskey, P.J., Cook, W.G. & Fenton, M.E. (2012) Handbook of *Pharmaceutical Excipients*, 7th ed., Pharmaceutical Press, London.
- Russo, G. & Banda, G. (forthcoming) 'Re-thinking pharmaceutical production in Africa; Insights from the analysis of the local manufacturing dynamics in Mozambique and Zimbabwe', *Studies in Comparative International Development*.
- Russo, G., Cabral, L. & Ferrinho, P. (2013) 'Brazil-africa technical cooperation in health: What's its relevance to the post-busan debate on "aid effectiveness"?' *Globalization and Health*, 9, 2.
- Russo, G., de Oliveira, L., Shankland, A. & Sitoe, T. (2014) 'On the margins of aid orthodoxy: The Brazil-Mozambique collaboration to produce essential medicines in Africa', *Globalization and Health*, 10 (1), 70.
- Russo, G. & McPake, B. (2010) 'Medicine prices in urban Mozambique: A public health and economic study of pharmaceutical markets and price determinants in low-income settings', *Health Policy and Planning*, 25 (1), 70–84.
- Sabatier, P.A. (1991) 'Toward better theories of the policy process', *PS: Political Science & Politics*, 24 (2), 147–56.
- Sahu, S.K. (1998) Technology Transfer, Dependence, and Self-Reliant Development in Third World: The Pharmaceutical and Machine Tool Industries in India, Praeger Publishers, London.
- Sala de Situação em saúde (2015) Available from http://189.28.128.178/sage/ paineis/aqt/tabelaFP.php?ufcidade=Brasil&ufs=&ibges=&cg=&tc=&re_ giao=&rm=&qs=&ufcidade=Brasil&qt=5570%20munic%C3%ADpios&pop=20 2799518&cor=005984&output=html&title= > [accessed 7 March 2015].
- Schmitter, P.C. (1974) 'Still the century of corporatism?', *The Review of Politics, 36* (1), 85–131.
- Schmitter, P. & Streeck, C. (1999), The Organization of Business Interests: Studying the Associative Action of Business in Advanced Industrial Societies. No. 99/1. MPIfG discussion paper.
- Schneider, B. R. & Maxfield, S. (1997) 'Business, the State, and Economic Performance in Developing Countries', in S. Maxfield and B.R. Schneider (eds.), *Business and the State in Developing Countries*, Cornell University Press, Ithaca.
- Seekings, J. & Nattrass, N. (2011) 'State-business relations and pro-poor growth in South Africa', *Journal of International Development, 23* (3), 338–57.
- Seiter, A. & Gyansa-Lutterodt, M. (2009) Policy Note: The Pharmaceutical sector in Ghana. Available from http://apps.who.int/medicinedocs/en/m/abstract/ Js16765e/ [accessed 28 April 2015].

- Shadlen, K. & Massard da Fonseca, E. (2013) 'Health policy as industrial policy: Brazil in comparative perspective', *Politics & Society*, 41 (4), 561–87.
- Sheldon, R.A. (2007) The E factor: Fifteen years on', *Green Chemistry*, 9, 1273–83.
- Shelys Pharmaceuticals. (2008) Company Profile, Shelys Pharmaceuticals, Dar es Salaam.
- Sidibé M., Yong L. & Chan, M. (2014) 'Commodities for better health in Africa: Time to invest locally.' Bulletin of the World Health Organization, 92, 387–387A.
- SMM and Farmanguinhos (2013) *Plano de Negócios Da SMM*, Sociedade Moçambicana de Medicamentos, Matola.
- Snyman, H.W. (1962) Report of the Commission of Inquiry Into High Cost of Medical Services and Medicines, R.P. no. 59/1962, Government Printer, Pretoria.
- Srinivas, S. (2004) *Technological Learning and the Evolution of the Indian Pharmaceutical and Biopharmaceutical Sectors,* Unpublished Dissertation, Massachusetts Institute of Technology, Cambridge, MA.
- Srinivas, S. (2006) 'Industrial development and innovation: Some lessons from vaccine procurement', *World Development*, 34 (10), 1742–64.
- Srinivas, S. (2011) Well Beyond Market Failure: Development States in Indian pharmaceuticals and biotech, paper presented at the American Political Science Association annual meeting (APSA) 2011, Seattle, 1–4 September 2011.
- Srinivas, S. (2012) Market Menagerie. Health and Development in Late Industrial States, Stanford University Press, Stanford.
- Srinivas, S. (2014a) Development planning criteria in local pharmaceutical production, Paper prepared for the Open University-UNIDO workshop on "Making Medicines in Africa", 15–16 December, London.
- Srinivas, S. (2014b) 'Demand and Innovation: Paths to Inclusive Development', in Ramani, S. (ed.), Innovation in India: Combining Economic Growth with Inclusive Development, Cambridge University Press, Cambridge.
- Steenkamp, W.F.J. (1978) *The Steenkamp Commission. Report of the Commission of Inquiry into the Pharmaceutical Industry*, Government Printer, Pretoria.
- Stephenson, S. (1997) *Standards and conformity assessment as non-tariff barriers to trade*, World Bank Development Research Group Policy Research Working Paper No 1826, World Bank, Washington DC, September.
- STERP (2009) Short Term Emergency Recovery Programme (STERP): Getting Zimbabwe Moving Again, Government of Zimbabwe, Harare.
- Steyn, R., Burger, J.R., Hendrik, J., Serfontein, P. & Lubbe, M.S. (2007) 'Influence of a new reference based pricing system in South Africa on the prevalence and cost of antidiabetic medicines: A pilot study', *International Journal of Pharmacy Practice*, 15 (4), 307–11.
- Stoker, A. & Jeffery, R. (1988) 'Pharmaceuticals and health policy: An Indian example', *Social Science and Medicine*, 27 (5), 563–67.
- Sutton, J. (2012) *Competing in Capabilities: The Globalization Process*, Oxford University Press, Oxford.
- Sutton, J. & Kellow, N. (2010) 'An Enterprise Map of Ethiopia', International Growth Centre. Available from http://personal.lse.ac.uk/sutton/ [accessed 3 May 2015].
- Sutton, J. & Olomi, D. (2012) An Enterprise Map of Tanzania, International Growth Centre, London.

- Tassey, G. (2000) 'Standardization in technology-based markets', *Research Policy*, 29 (4–5), 587–602.
- Tempest, B. (2011) The Structural Changes in the Global Pharmaceutical Marketplace and Their Possible Implications for Intellectual Property, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Policy Brief Number 10, July. Available from http://ictsd.org/i/publications/111430/ [accessed 28 April 2015].
- TGE (1993a) National Health Policy of the Transitional Government of Ethiopia, Addis Ababa.
- TGE (1993b) National Drug Policy of the Transitional Government of Ethiopia. Available from http://apps.who.int/medicinedocs/en/m/abstract/Js17823en/ [accessed 3 May 2015].
- Thomas C.S. (ed.) (2004) Research Guide to U.S. and International Interest Groups, Praeger, Westport.
- Thomas, G.L. (1994) 'Implicit industrial policy: The triumph of Britain and the failure of France in global pharmaceuticals', *Industrial and Corporate Change*, 3 (2), 541–48.
- Tibandebage, P., Mackintosh, M., Israel, C., Mhede, E. & Mujinja, P.G.M. (2014) 'The Tanzanian health sector as buyer and user of medicines and other essential supplies, Working Paper 1', in *Industrial Productivity, Health Sector Performance and Policy Synergies for Inclusive Growth (IPHSP) research project*. Available from http://www.repoa.or.tz/documents/REPOA_WP_14_5.pdf [accessed 4 May 2015].
- Tsebelis, G. (2002) *Veto Players: How Political Institutions Work*, Princeton University Press, Princeton.
- Turshen, M. (2001) 'Reprivatizing pharmaceutical supplies in Africa', *Journal of Public Health Policy*, 22 (2), 198–225.
- UNCTAD (2009) *The Least Developed Countries Report 2009: The State and Development Governance*, United Nations Conference on Trade and Development, Geneva.
- UNCTAD (2011) Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: a Series of Case Studies by the UNCTAD Secretariat, United Nations Conference on Trade and Development, Geneva.
- UNIDO (United Nations Industrial Development Organisation) (2007) 'Pharmaceutical Sector Profile: Zimbabwe', *Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries,* Vienna, Austria.
- UNIDO (United Nations Industrial Development Organisation) (2010a) 'Pharmaceutical Sector Profile: Kenya', *Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries*, Vienna, Austria.
- UNIDO (United Nations Industrial Development Organisation) (2010b) 'Pharmaceutical Sector Profile: Uganda', *Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries*, Vienna, Austria.
- UNIDO (United Nations Industrial Development Organisation) (2011a) 'Pharmaceutical Sector Profile: Nigeria', *Global UNIDO Project: Strengthening the Local Production of Essential Generic Drugs in Least Developed and Developing Countries*, Vienna, Austria.
- UNIDO (United Nations Industrial Development Organisation) (2011b) 'Pharmaceutical Sector Profile: Zimbabwe', *Global UNIDO Project: Strengthening*

the Local Production of Essential Generic Drugs in Least Developed and Developing Countries, Vienna, Austria.

- UNIDO (2012) Kenya Pharmaceutical Sector Development Strategy Strengthening the Local Production of Essential Medicines in Least Developed and Developing Countries, UNIDO.
- UNIDO (2014) Kenya GMP Roadmap: A Stepwise Approach for the Pharmaceutical Industry to Attain WHO GMP Standards – Strengthening the Local Production of Essential Medicines in Least Developed and Developing Countries, UNIDO.
- UNIDO (2015) *Industrial Pharmacy Advanced Training (IPAT)*. Available from http://www.unido.org/en/what-we-do/poverty-reduction-through-productive-activities/business-investment-and-technology-services/ competitiveness-business-environment-and-upgrading/pharmaceuticals/ industrial-pharmacy-advanced-training-ipat.html [accessed 27 April 2015].
- UNIDO/GoT (2012) *Tanzania Industrial Competitiveness Report*, United Nations Industrial Development Organization (UNIDO) and Government of Tanzania, Ministry of Industry and Trade (GoT). Available from http://www.unido.org/ fileadmin/user_media/Services/PSD/TanzaniaIndustrialCompetitivenessRepor t2012-ebook.pdf [accessed 30 April 2015].
- UNITAID (2013) *Malaria Medicines Landscape*, WHO, UNITAID, Geneva. Available from http://www.unitaid.eu/images/marketdynamics/publications/UNITAID-MalariaMedicinesLandscape-2013_DEC.pdf [accessed 18 May 2015].
- URT (United Republic of Tanzania) (2009) Speech by the Minister for Finance and Economic Affairs, Hon. Mustafa Haidi Mkulo MP, Introducing to the National Assembly the Estimates of Government Revenue and Expenditure for the Financial Year 2009/10. Available from http://www.mof.go.tz/mofdocs/budget/BUDGET%20SPEECH%20ENGLISH%20FINAL%20VERSION.pdf [accessed 30 April 2015].
- USFDA (2008) *Warning letter WL: 320–08–02*, Centre for Drug Evaluation and Research, Development of Health and Human Services, Washington, DC. Available from http://www.fiercebiotech.com/press-releases/fda-issues-warning-letter-ranbaxy-regarding-march-inspections [accessed 3 May 2015].
- USNLM (2014) Artemisinin derivatives, *United States National Library of Medicine*. Available from http://livertox.nih.gov/ArtemisininDerivatives.htm [accessed 8 November 2014].
- Uyarra, E. & Flanagan, K. (2009) Understanding the Innovation Impacts of Public *Procurement*, Manchester Business School Working Paper, Number 574. Available from www.mbs.ac.uk/research/workingpapers/ [accessed 1 December 2014].
- Verhoef ,T.I. & Morris, S. (2015) 'Cost-effectiveness and pricing of antibacterial drugs', *Chemical and Biological Drug Research*, 85 (1), 4–13.
- Vokes, S. (2007) 'Trade dynamics affecting the face of retail pharmacy in South Africa', *South African Pharmaceutical Journal*, 74 (7), 6–9.
- von Hippel, E. (1982) 'Get new products from customers', *Harvard Business Review*, 60 (2), 117–22.
- Wafula, F., Molyneaux, C., Mackintosh, M. & Goodman, C. (2013) 'Protecting the public or setting the bar too high? Understanding the causes and consequences of regulatory actions of frontline regulators and specialized drug shop operators in Kenya', *Social Science & Medicine*, 97, 220–27.
- Wamae, W. and Kariuki Kungu, J. (2014) 'Pharmaceutical Manufacturing in Kenya: Key trends and Developments', *ACTS Working Brief No.3*, African Centre

for Technological Studies. Available from http://iphsp.acts-net.org/publications/policy-briefs [accessed 14 May 2015].

- Wamae, W., Kariuki Kungu, J. & Clark, N. (2014) 'Value Added Tax in the Pharmaceutical Industry: What Does It Really Mean for Kenya's Industrialisation?' ACTS Working Brief No.1, African Centre for Technological Studies. Available from http://iphsp.acts-net.org/publications/policy-briefs [accessed 14 May 2015].
- Wamai, R.G. (2009) 'Reviewing Ethiopia's health system development: International medical community', *Japanese Medical Association Journal*, 52 (4), 279–86.
- Wambebe, C.O., Bamgboye, E.A., Badru, B.O., Khamofu, H., Momoh, J.A., Ekpeyong, M., Audu, B.S., Njoku, S.O., Nasipuri, N.R., Kunle, O.O., Okogun, J.I., Enwerem, N.M., Gamaniel, S.K., Obodozie, O.O., Samuel, B., Fojule, G. & Ogunyale, P.O. (2001a) 'Efficacy of niprisan in the prophylactic management of patients with sickle cell disease', *Current Theory & Research*, 62 (1), 26.
- Wambebe, C., Khamofu, H., Momoh, J.A.F., Ekpeyong, M., Audu, B.S., Njoku, O.S., Bamgboye, E.A., Nasipuri, R.N., Kunle, O.O., Okogun, J.I., Enwerem, M.N., Audam, J.G., Gamaniel, K.S., Obodozie, O.O., Samuel, B., Fojule, G. & Ogunyale, O. (2001b) 'Double-blind, placebo-controlled, randomised cross-over clinical trial of NIPRISAN® in patients with Sickle Cell Disorder', *Phytomedicine*, 8 (4), 252.
- Wangwe, S. (ed.) (1995) *Exporting Africa: Technology, Trade and Industrialisation in Sub-Saharan Africa,* UNU/INTECH and Routledge, London.
- Wangwe, S. (2003) *Exporting Africa: Technology, Industrialism and Trade*, Routledge, London.
- Wangwe, S., Tibandebage, P. Mhede, E., Israel, C., Mujinja P.G.M. & Mackintosh, M. (2014a) 'Reversing Pharmaceutical Manufacturing Decline in Tanzania: Policy Options and Constraints', *REPOA Brief* 43, July. Available from http:// www.repoa.or.tz/documents/REPOA_BRIEF_43.pdf [accessed 30 April 2015].
- Wangwe, S., Tibandebage, P., Mackintosh, M., Israel, C., Mhede, E. & Mujinja P.G.M. (2014b) 'From Passive to Active Industrial Policy: Improving Locally Manufactured Supplies to the Tanzanian Health Sector', *REPOA Brief* 46, September. Available from http://www.repoa.or.tz/documents/REPOA_ BRIEF_46.pdf [accessed 1 May 2015].
- Waning, B., Maddix, J., Tripodis, Y., Laing, R., Leufkens, H.G.M. & Gokhale, M. (2010) 'Towards equitable access to medicines for the rural poor: analyses of insurance claims reveal rural pharmacy initiative triggers price competition in Kyrgyzstan', *International Journal for Equity in Health*, 8 (43).
- Warren-Rodríguez, A. (2010) 'Uncovering trends in the accumulation of technological capabilities and skills in the Mozambican manufacturing sector', *Oxford Development Studies*, 38 (2), 171–98.
- WHO (World Health Organization) (1995) *Essential Drugs Monitor* No 019. Available from http://apps.who.int/medicinedocs/en/d/Js16518e/4.7.html#Js16518e.4.7 [accessed 11 April 2015].
- WHO (World Health Organization) (2004a) WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems, WHO Press, Geneva.
- WHO (World Health Organization) (2004b) 'WHO good manufacturing practices: main principles for pharmaceutical products', in WHO Expert Committee on

Specifications for Pharmaceutical Preparations, 37th report, Geneva, WHO 2003. Annex 4 (WHO Technical Report Series, No. 908).

- WHO (World Health Organization) (2005) *Local Production of Essential Medicines, including Antiretrovirals: Issues, Challenges and Perspectives in the African Region,* Report of the Regional Director, regional Committee for Africa, Maputo, Mozambique.
- WHO (World Health Organization) (2007a) WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues, WHO Press, Geneva.
- WHO (World Health Organization) (2007b) WHO Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines, WHO Press, Geneva.
- WHO (World Health Organization) (2012) *Estatísticas da Saúde Mundial*. Available from http://www.who.int/gho/publications/world_health_statistics/2012/en/ [accessed 13 March 2015].
- Willcox, M.L., Graz, B., Falquet, J., Diakite, C., Giani, S. & Diallo, D. (2011) 'A "reverse pharmacology" approach for developing an anti-malarial phytomedicine', *Malaria Journal*, 10 (Suppl. 1), S8.
- Wilson, J.S. & Abiola, V. (2003) *Standards & Global Trade: A Voice for AFRICA*, The World Bank, Washington, DC.
- Wolff, J. (2012) *The Human Right to Health*, W.W. Norton & Company, New York and London.
- World Bank (2005) *Food safety and agricultural health standards: Challenges and opportunities for developing country exports,* Report no. 31027, Poverty Reduction & Economic Management Trade Unit, Agriculture and Rural Development Department, The World Bank, Washington, DC.
- World News (2013) Cipla Ups Stake in Ugandan Firm, Acquires 14.5% for \$15 Million. Available from http://article.wn.com/view/2013/11/21/Cipla_ups_stake_in_ Ugandan_firm_acquires_145_for_15_million_l/ [accessed 27 April 2015].
- World Trade Organisation (2001) *Declaration on the TRIPS Agreement and Public Health.* Available from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [accessed: 29 April 2015].
- Yadav P. (2014) Kenya Medical Supplies Authority (KEMSA): A case study of the ongoing transition from an ungainly bureaucracy to a competitive and customer focused medical logistics organization, The World Bank, Washington, DC.

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