Life Sciences for Europe

An integrated strategy for healthcare innovation(2019-2024)

List of references and literature reviewed







CRA conducted a literature review of numerous sources, document and reports to identify overlapping issues affecting all areas of the life sciences sector. This was done using search terms or keywords such as 'trends', 'barriers', 'challenges' for 'life sciences', 'medicines', 'diagnostics', 'medical devices' and 'digital health'.

This covered a variety of different sources/authors:

- Public policy documents from stakeholders (including regulators, policy-makers and payers, eg, the European Commission);
- Academic articles;
- · Press articles and insight pieces; and
- Trade association and market intelligence reports.

Below is the full list of the documents reviewed as part of the research conducted for *Life Sciences for Europe:* An integrated strategy for healthcare innovation (2019-2024).

Regulators/policy-makers

European Commission

- 1. European Commission (2018) 'Proposal for a Regulation of the European Parliament and of the council on health technology assessment and amending Directive 2011/24/EU'. COM (2018) 51 final 2018/0018(COD).
- 2. European Commission (2018) 'Press releases: database European Commission Fact Sheet. The digital transformation of healthcare' Brussels, 25 April 2018.
- 3. European Commission (2017) Communication from the European Commission to the European Parliament, the European Council, the Council, the European Economic and social committee, the committee of the Regions and the European Investment Bank. 'Investing in a smart, innovative and sustainable Industry A renewed EU Industrial Policy Strategy' COM/2017/0479 final.
- 4. European Commission (2016) 'White Paper: The Future of Health Care: deep data, smart sensors, virtual patients and the Internet-of-Humans'.
- 5. European Commission (2016) 'Business Innovation Observatory: Internet of Things: Smart health Case study 46 Internal Market, Industry, Entrepreneurship and SMEs'.
- 6. European Commission (2016) 'Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability, Volume 1'. Economic and Financial Affairs Economic Policy Committee ISSN 2443-8014 Institutional paper 037. October 2016.
- 7. Juncker, J.C. (2014). 'A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change'. Political Guidelines for the next European Commission.
- 8. European Commission (2014) 'Widespread Deployment of Telemedicine Services in Europe Report of the eHealth Stakeholder Group on implementing the Digital Agenda for Europe Key Action 13/2 "Telemedicine".' Version 1.0.
- 9. European Commission (2014) 'The existing EU legal framework applicable to lifestyle and wellbeing apps Commission staff working document Brussels', 10.4.2014 SWD (2014) 135 final.
- 10. European Commission (2014) 'Green Paper on mobile health (mHealth)'.
- 11. European Commission (2014) 'Pharmaceutical Industry: A Strategic Sector for the European Economy'. http://ec.europa.eu/growth/content/pharmaceutical-industry-strategic-sector-european-economy-0_en.
- 12. European Commission (2013) 'The use of '-omics' technologies in the development of personalised medicine'. Brussels, 25.10.2013 SWD (2013) 436 final.

13. Official Journal of the European Union (2008) 'Commission recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (notified under document number C(2008) 3282)'. (2008/594/EC).

European Council

- 14. Council of the European Union (2018). 'EU industrial policy strategy: Council adopts conclusions'. http://www.consilium.europa.eu/en/press/press-releases/2018/03/12/eu-industrial-policy-strategy-council-adopts-conclusions/pdf.
- 15. Council of the European Union (2017). 'Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices'.

Others

- 16. Haute Autorité de Santé (2016) 'How to assess co-dependent technologies' Dr Mira Pavlovic-Ganascia, Deputy Director for HTA, Haute Autorité de Santé, France.
- 17. Innovative medicines initiative Project Factsheets: 'PRO-active Physical Activity as a Crucial Patient Reported Outcome in COPD'. https://www.imi.europa.eu/projects-results/project-factsheets/proactive.

International/multilateral organisations

Organisation for Economic Co-operation and Development (OECD)

- 18. OECD (2017) 'New Health Technologies: Managing Access, Value and Sustainability'.
- 19. OECD (2017) 'OECD Data Pharmaceutical Spending'.
- 20. OECD (2016) 'OECD Health Working Papers Pharmaceutical Expenditure and Policies Past Trends And Future Challenges'.
- 21. OECD (2016) 'New Health Technologies: Managing access, value and sustainability'.
- 22. OECD (2016) 'Health at a Glance: Europe 2016 state of health in the EU cycle'.
- 23. OECD (2015) 'Healthcare costs unsustainable in advanced economies without reform'.
- 24. OECD (2015) 'OECD Health Statistics 2015: Focus on Health Spending', July 2015. https://www.oecd.org/health/health-systems/Focus-Health-Spending-2015.pdf.

Others

- 25. World Health Organization (WHO) (2016) 'From innovation to implementation: eHealth in the WHO European Region'.
- 26. The World Bank (2018) 'How Managed Equipment Services in Kenya help the private sector contribute to healthcare' accessible at http://blogs.worldbank.org/ppps/how-managed-equipment-services-kenya-help-private-sector-contribute-healthcare.

Consultant/market intelligence reports

- 27. Boston Consulting Group (2014) 'The Challenge of Pricing Combination Therapies'.
- 28. Charles River Associates (2014) 'A comparative analysis of the role and impact of Health Technology Assessment: 2013 Final report'.
- 29. Deloitte (2016) 'Global life sciences outlook Moving forward with cautious optimism'.
- 30. Deloitte (2016) 'Preparing for the future: The new European Union medical devices regulation'.
- 31. Deloitte (2018). '2018 Global life sciences outlook innovation life sciences in the fourth industrial revolution'.
- 32. Ernst & Young (2018) 'A Road Map to Strategic Drug Pricing'. In Vivo The business and medicine report.

- 33. Ernst & Young (2016) 'Medical technology report 2016: Pulse of the industry'.
- 34. KPMG (2016) 'Collaboration the future of innovation for the medical device industry'.
- 35. KPMG (2017) 'Pharma outlook 2030: From evolution to revolution'.
- 36. McKinsey (2016) 'The age of analytics: Competing in a data-driven world'.
- 37. PwC (2016) 'Five distinct trends are converging to determine how artificial intelligence (AI) and robotics will define New Health'.
- 38. QuintilesIMS Institute (2016) 'Outlook for Global Medicines through 2021. Balancing Cost and Value'.
- 39. Roland Berger (2016) 'Digital health market to average 21 percent growth per year through 2020'.
- 40. Roland Berger (2016) 'Digital and disrupted: All change for healthcare'.
- 41. TaylorWessing. 'Personalised medicine challenges of authorisation and reimbursement'.

Academic/think tanks literature

- 42. Azzopardi-Muscat, N., et al (2018) 'The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems'. Health Policy, 122(3): 279–283.
- 43. Bajwa, M. (2014) 'Emerging 21st century medical technologies'. Pakistan journal of medical sciences, 30(3), 649.
- 44. Brigid Pike and Deirdre Morgan (2014) 'The integration of health and social care services'. Health Research Board.
- 45. Campling, N. C., Pitts, D. G., Knight, P. V. and Aspinall, R. (2017) 'A qualitative analysis of the effectiveness of telehealthcare devices (ii) barriers to uptake of telehealthcare devices'. BMC health services research, 17(1): 466.
- 46. Ciani, O., et al. (2015) 'Health technology assessment of medical devices: a survey of non-European union agencies'. International journal of technology assessment in health care, 31(3), 154-165.
- 47. Corbett, M. S., Webster, A., Hawkins, R., and Woolacott, N. (2017). 'Innovative regenerative medicines in the EU: a better future in evidence?' BMC medicine, 15(1): 49.
- 48. Corbett, M. S., Webster, A., Hawkins, R., and Woolacott, N. (2017) 'Innovative regenerative medicines in the EU: a better future in evidence?' BMC medicine, 15(1): 49.
- 49. Frost and Sullivan (11 August 2017) 'Molecular Diagnostics Vendors in Western Europe Leverage Innovation and Need for Point-of-care Testing'.
- 50. Gaff, C. L., Winship, I., Forrest, S., Hansen, D., Clark, J., Waring, P., ... and Sinclair, A. (2017) 'Preparing for genomic medicine: a real world demonstration of health system change'. NPJ genomic medicine, 2(1): 16.
- Hassanalieragh, M., et al (2015) 'Health monitoring and management using Internet-of-Things (IoT) sensing with cloud-based processing: Opportunities and challenges'. In Services Computing (SCC), 2015 IEEE International Conference on (pp. 285–292). IEEE.
- 52. Hubert, M. M., Karellis, A., Sherman, M., Gill, S., Beecroft, R., and Sampalis, J. S. (2016) 'Beyond Budget Silos: Budget impact analysis of transarterial radioembolization with yttrium-90 glass microspheres for hepatocellular carcinoma from a hospital perspective'. Value in Health, 19(3): A308.
- 53. Jiang, F., Jiang, Y., Zhi, H., Dong, Y., Li, H., Ma, S., ... and Wang, Y. (2017) 'Artificial intelligence in healthcare: past, present and future'. Stroke and Vascular Neurology, svn-2017.
- 54. Kutzin, J. (2013) 'Health financing for universal coverage and health system performance: concepts and implications for policy'. Bulletin of the World Health Organization. 91:602-611. http://www.who.int/bulletin/volumes/91/8/12-113985/en.
- 55. Leyens, L., and Brand, A. (2016) 'Early patient access to medicines: health technology assessment bodies need to catch up with new marketing authorization methods'. Public health genomics, 19(3): 187–191.

- 56. Lillie Wenzel, Laura Bennett, Simon Bottery, Richard Murray, Bilal Sahib. 'Approaches to social care funding: Social care funding options'. The King's Fund, https://www.health.org.uk/sites/health/files/Approaches-social-care-funding_1.pdf
- 57. McClellan, M. and A. Thoumi (2015). 'Oncology payment reform to achieve real health care reform'. Journal of oncology practice, 11(3): 22330–230. http://dx.doi.org/10.1200/JOP.2015.004655
- 58. Miquel-Cases, A., Schouten, P. C., Steuten, L. M., Retèl, V. P., Linn, S. C., and van Harten, W. H. (2017) '(Very) Early technology assessment and translation of predictive biomarkers in breast cancer'. Cancer treatment reviews, 52: 117–127.
- 59. Nimmesgern, E., Benediktsson, I., & Norstedt, I. (2017) 'Personalized medicine in Europe'. Clinical and translational science, 10(2), 61-63.
- 60. Ott, P. A., Hodi, F. S., Kaufman, H. L., Wigginton, J. M., & Wolchok, J. D. (2017) 'Combination immunotherapy: a road map'. Journal for immunotherapy of cancer, 5(1), 16.
- 61. Payne, K., & Annemans, L. (2013) 'Reflections on market access for personalized medicine: recommendations for Europe'. Value in Health, 16(6), S32-S38.
- 62. Shih, T., Chen, L. M., and Nallamothu, B. K. (2015) 'Will bundled payments change health care? Examining the evidence thus far in cardiovascular care'. Circulation, 131(24): 2151–2158.
- 63. Spinks, T. et al. (2017) 'Development and Feasibility of Bundled Payments for the Multidisciplinary Treatment of Head and Neck Cancer: A Pilot Program'. http://dx.doi.org/10.1200/JOP.
- 64. Struijs, J. (2015) 'How bundled health care payments are working in the Netherlands'. Harvard Business Review.
- 65. Sutherland, J., and Hellsten, E. (2017) 'Integrated Funding: Connecting the Silos for the Healthcare We Need' and Deloitte (2016) 'The evolution of oncology payment models: What can we learn from early experiments?' https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-evolution-of-oncology-payment-models.pdf.
- 66. Vollebregt, E. (2016) 'The new General Data Protection Regulation impact on medical devices industry, ehealth-law-and-policy'. Volume: 3 Issue: 7 (July 2016).
- 67. Wilson, K. (2016) 'Innovation and sustainability of European healthcare systems'.

Industry position paper and documents

- 68. AmCham EU (2015) 'Implementation of Directive 2014/24/EC on public procurement in the EU healthcare sector AmCham EU calls for a more strategic use of procurement to stimulate innovation uptake'.
- 69. AmCham EU (2015) 'Improving access to medicines in the European Union Value, measured outcomes and innovation crucial to fostering sustainable healthcare systems'.
- 70. AmCham EU (2016) 'AmCham EU's response on the consultation on next phase of EU–US cooperation in eHealth/Health IT Roadmap Work-stream: International Interoperability'.
- 71. AmCham EU (2016) 'AmCham EU's response to the public stakeholder consultation on the next phase of EU-US cooperation in eHealth/Health IT'.
- 72. AmCham EU (2016) Position paper: 'Improving access to medicines in the European Union'. 14 June 2016.
- 73. AmCham EU (2016) 'Revision of the medical devices and in vitro diagnostics regulatory framework designing a safer and more robust system is crucial to safety and innovation'.
- 74. COCIR (2015) 'eHealth toolkit: Integrated Care: Breaking the silos' Fifth Edition May 2015.
- 75. EFPIA (2017) 'The Pharmaceutical Industry in Figures Key Data 2017'.
- 76. GSMA (2016) 'mHealth and the EU regulatory framework for medical devices'. GSMA (Group Special Mobile).
- 77. Medicines for Europe (2017) 'Value added medicines: time to adjust HTA decision frameworks'.

- 78. MedTech Europe (2017) 'MedTech Europe position on future EU cooperation on Health Technology Assessment' March 2017.
- 79. MedTech Europe (2018) 'The European Medical Technology industry in figures 2018'.

Press articles

- 80. MedCity News (15 December 2016) '8 technologies that will transform healthcare in 2017 and beyond'.
- 81. Kubala M (2018) 'How pharma and MedTech collaborations fuel progress prescouter.com', accessible at https://prescouter.com/2018/04/pharma-medtech-collaborations/.
- 82. Daniel B (2018) 'Here's what Google, Apple and Microsoft are up to in healthcare, UK Tech News', accessible at https://www.uktech.news/news/google-microsoft-apple-samsung-tech-giants-healthcare-20170323.

