Institution: The Open University

Unit of Assessment: C24 Anthropology and Development Studies

Title of case study: Creating and implementing appropriate governance of the life sciences

1. Summary of the impact

The ESRC Innogen Centre brought together a multiplicity of disciplines for a large 12-year research programme (2002-14) on the impact of regulation on innovation dynamics in the life sciences. Research design promoted interactions between stakeholders to achieve policy impact. Innogen developed a range of tools to disseminate research findings and influence policy in Europe, the African Union (AU), Kenya, Qatar and at the OECD. We used secondments and temporary placements to achieve impact, as well as more traditional activities and outputs, resulting in major policy impacts in Europe, Africa and the Middle East.

2. Underpinning research

The ESRC Innogen Centre

Innogen (ESRC Centre for Social and Economic Research on Innovation in Genomics) research has crossed geographic and disciplinary boundaries to find solutions to real-world challenges in global health, food and energy security, the environment and the economy.

Appropriate Governance of the Life Sciences

In 2002, Professors Joanna **Chataway** and David **Wield** (OU during the whole research period), Professor Joyce Tait (Visiting Professor, OU since 1993), with Drs Julius **Mugwagwa** (2004-), Anne Kingiri (2004-09) and Adele Langlois (2004-08), developed a research programme entitled, 'Appropriate Governance of the Life Sciences' (AGLS). The OU programme has a global perspective with major empirical research results from Europe, North and South America, Africa and Asia (**1-3**).

AGLS focuses on the question: *'Can the life sciences be better regulated globally?'* The research programme investigates regulation and governance broadly – within a framework of stakeholder interaction, rather than as barriers to simple linear progression – as key drivers of innovation. Using a 'triangle' model to structure our pathway to impact, our work links three broad groups of stakeholders: **innovators** (scientists, medics, farmers, firms); **government and regulators** (multilaterals, OECD, EU); and **public advocacy groups** (patient advocacy groups, NGOs). Our research demonstrates that inappropriate and overly complex regulation can prevent the development of innovative and potentially beneficial technologies in the life sciences (**4**). Work in more than 20 countries across four continents shows that regulation strongly influences which products are developed and which companies take the lead in their development, and that poor regulation decreases sectoral dynamism and plays into the dearth of innovation in new medicines and agricultural products (**5-9**).

Through analysing pharmaceutical sector changes, Innogen has investigated new actors and institutions that are changing regulation and governance structures (**4, 10**), finding that advances have occurred in stratified medicine, rare and neglected disease innovation, stem cells, and synthetic biology, but regulatory systems are lagging behind. In agriculture, Innogen's findings show that US/European systems are driving biosafety, but differences between the US and Europe have stifled development and application of agro-biotechnologies in the South (**5, 6, 9**). These governance systems limit the opportunities for new entrant firms from developing countries.

The significance of the research is evidenced by the successful review and consequent four-fold increase in funding from the ESRC to the OU Innogen Centre from 2007-14, by further competitive funds obtained (**2-3**), and by the independent evaluation that found that Innogen had the strongest density of UK interdisciplinary linkages between the social, health and biosciences as measured through Web of Science citations (see Rafols and Costa http://innogen.ac.uk/reports.php?id703). Their bibliographic maps evidence the 'remarkable breath of Innogen and its exceptional degree of

cross-citation'. The reach of the OU research can be evidenced, for example, by the 27 invited international conference presentations given since 2003 in 11 countries across 4 continents.

3. References to the research

3.1 Relevant Grants

1) ESRC Innogen grant, 2002-14 (£7.5m). (PI Wield, Chataway as Co-Director)
2) Julius Mugwagwa, 'Cross-national technology regulation in Africa' grant, Leverhulme, £80K, 2009-11 (PI Mugwagwa)
3) Chataway et al, 'Institutional impacts of N-S partnerships in Agro-biotechnology' and 'Regulatory practices and challenges of the African crop biotechnology sector', ESRC, £90K, 2003-07 (PI Chataway)

3.2 Relevant Publications

4) Chataway, J., Tait, J. and Wield, D. (2006) The governance of agro- and pharmaceutical biotechnology: public policy and industrial strategy, *Technology Analysis and Strategic Management*, 18, 169-185.
5) Chataway, J., Tait, J. and Wield, D. (2004) Company R&D strategies in agrobiotechnology: trajectories and blindspots, *Research Policy*, 33, 1041-1057.
6) Ayele, S., Chataway, J. and Wield, D. (2006) Partnerships in African crop biotechnology and the MDGs', *Nature Biotechnology,* 24, 619-621.
7) Mugwagwa, J. (2011) To harmonise or not to harmonise? The case of cross-national biotechnology governance in Africa, *I.J. Technology Management and Innovation*, 6, 31-47.
8) Kingiri, A. (2011) Conflicting advocacy coalitions in an evolving modern regulatory sub-system, *Science and Public Policy*, 38, 199-211.
9) Wield, D., Chataway, J. and Bolo, M. (2010) Issues in the political economy of agricultural biotechnology, *Journal of Agrarian Change*, 10, 342-366.

4. Details of the impact

Innogen's AGLS research on life science regulation has had significant impact on legislative and policy formulation and implementation at national and international levels, has contributed to the formulation and strengthening of networks at national, international and supra-national levels, and has impacted public and policy discourse. Practical activities and outputs included producing: policy-oriented outputs (**10, 11**); publications read by practitioners, such as *Nature Biotechnology* (**12**); and policy and press briefings. In the REF period, the named researchers gave 39 talks in 11 countries to industry/government/international agency audiences; 21 workshops and public events; 3 select committee briefings. The *Financial Times* Pharmaceuticals Correspondent confirmed that the FT invited **Chataway** and Tait to prepare a session for their high-level Global Pharma conference (2009), because of the 'significant policy relevance of their research' (**19**). Chataway maintained regular industry contact, leading to several research projects with pharma companies and the international Pharma Futures working group that began work in 2013. Additionally, Innogen supports the movement of researchers into policy environments as a way of maximising impact, and its staff are involved in numerous decision-making fora. **Mugwagwa** undertook placements at New Partnership for Africa's Development (NEPAD) and the AU (2007 and 2012), Langlois worked in the Parliamentary Office for Science and Technology (POST) (2007) and Chataway held a part-time placement at RAND Europe (2010-13) and is currently vice-president of Globelics where she promotes policy-relevant research.

Impact on European and global life science legislation, policy formulation and implementation

Given the global nature of governance of life science products, such as pharmaceuticals and GM crops, European and global legislation and policy implementation has a direct effect on policy and legislation in developing countries. The OECD International Futures Project invited us to develop scenarios based on our research on the global healthcare sector trajectory. This work investigated possible trends in the development of health technologies and the bioeconomy, focusing on the period 2015-2030. Three scenarios were developed and published in an influential report, which concluded that wide-ranging governance reforms were necessary to ensuring best outcomes from

biotechnology advances (**10**). 1985 copies were distributed, with 4851 downloads. The report constituted the basis of the work of the OECD Working Party on Biotechnology, comprising 33 member states, in formulating the influential new OECD policy on harmonisation in biotechnology, which subsequently led to its industrial biotechnology policy. The Director of the OECD International Futures Programme confirmed (**14**) the report was discussed and presented in 60 OECD working groups, to member state governments (including Japan, US, UK and Germany), and to 14 large-scale stakeholder events. He also confirmed that the work was 'a crucial contribution' to the OECD's involvement and influence in biotechnology.

The work of Adele Langlois has impacted public and policy discourse. As part of her doctoral studies, she secured a competitive scholarship from the Wellcome Trust to undertake a fellowship at POST (2008) to develop a policy briefing (**13**), widely distributed among peers and MPs. POST's Scientific Advisor for Biology and Health stressed the timeliness and policy relevance of the work, *'which had been the reason for selecting Langlois's project for the fellowship in the first place'* (**20**). The POSTnote received an average of 161 downloads a month during the latest data period, and a total of 1935 downloads by 2012.

Impact on African legislation and policy formulation and implementation

AGLS research has been used to frame and establish new African policy and regulation on drugs and agro-biotechnology. Innogen's relationship with the AU began in 2006 with advice that led to policy initiatives that improved and harmonised regulation of medicines and biosafety. **Chataway**, **Mugwagwa** *et al* wrote an invited report on building the case for health systems innovation in Africa, which the Science and Technology Advisor of NEPAD/AU confirmed formed the background document for the 8th Summit of the AU (2007). He confirmed also that the work informed ministerial-level discussions that led to the inter-ministerial agreement on the science and technology programme of NEPAD/AU, an example of international policy impact (**15**). Later, it was published as a book by the AU and made widely available in paper and online (**11**). 15,000 copies were distributed, and the book is now widely used by Ministries of Health throughout Africa in developing health policy.

While attached to the NEPAD Office of Science and Technology (2007), **Mugwagwa** used the AGLS approach to develop a framework on medicine control harmonisation. The Director of the African Biosafety Network of Expertise (ABNE) and the Scientific Affairs Officer of the Economic Commission for Africa confirmed that this work constituted a core dimension of the policy to harmonise drug regulation within the AU (**16**). In particular, it determined the agreed approach of cluster-based harmonisation, as opposed to horizontal harmonisation across all countries.

In Kenya, Innogen research impacted agro-biotechnology legislation and policy, as a result of Kingiri's work with government agencies. During her OU doctorate (2004-08), she worked on the implementation of the Kenyan National Biosafety Act using Innogen approaches. Following completion in 2009, she joined the African Centre for Technology Studies in Kenya and was invited to join the team drafting regulations later appended to the Biosafety Act. She contributed to four draft regulations (environmental release; import, export and transit; contained use; labelling) approved in 2011 and 2012. The Biosafety Director of the Kenyan Biosafety Authority (KBA) confirmed the importance of her work and involvement from the initial stages of the development of the policy in 2008 (**17**). In addition, he stated that Kingiri and her Innogen experience were instrumental in the development of Kenya's first guidelines for inspection and monitoring of genetically modified (GM) field trials, a clear example of policy impact. Kingiri is also a registered member of the Kenyan Roster of Experts on Biosafety and the KBA confirmed Kingiri's Innogen experience as important for her major role advising on new applications for GMO field trials in Kenya.

Impact on Qatar national research strategy

In Qatar, working with RAND researchers, **Chataway** used Innogen research on research governance and as PI, led a project that resulted in the Qatar National Research Strategy 2012 with its strong focus on responsible and participative development of life sciences, health and environment. The Executive Director of the Research Division of the Qatar National Research

Foundation stated that Chataway's expertise and leadership was fundamental in formulating the strategy, which has been formally adopted as national policy. Implementation is underway (**18**).

In summary, Innogen's research question, *'Can the life sciences be better regulated globally?'* has led to significant influence and impact, which suggests not only that regulation (and related governance frameworks) can be improved, but also that Innogen has played a significant role in its improvement.

5. Sources to corroborate the impact

5.1 Examples of publications produced with policy makers

10.) Tait, J. with Wield, D., Chataway, J. and Bruce. A. (2008) *Health Biotechnology to 2030*. Report to OECD International Futures Project. "The Bio-Economy to 2030: Designing a Policy Agenda', OECD, Paris; http://www.oecd.org/dataoecd/12/10/40922867.pdf.
11.) Chataway, J., Chaturvedi, K., Hanlin, R., Mugwagwa, J., Smith, J. and Wield, D. (2009) Building the case for systems of health innovation in Africa, in *Science, technology and innovation for public health in Africa*, 7-94, African Union/NEPAD, Pretoria.

5.2 Examples of publications in outlets read by policy makers

12.) Chataway, J., Tait, J. and Wield, D. (2008) Off the rails or on the mark? *Nature Biotechnology*, 26, 500-501.
13.) Langlois, A. (2008) Research governance in developing countries, POSTnote 304. http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-304

5.3 Evidence from users

5.3.1 Available to be contacted by HEFCE

14.) Director, OECD International Futures Programme.
This contact will be able to speak to the impact of Wield and Chataway's work on OECD policy on biotech regulatory harmonization, especially in regard to bringing about an eco-efficient bioeconomy.
15.) Science and Technology Advisor, NEPAD/African Union.
This contact can corroborate the role of Chataway and Mugwagwa's research on the shaping of an inter-ministerial agreement on the science and technology programme of NEPAD/African Union,
16.) Director, African Biosafety Network of Excellence (ABNE) and Scientific Affairs Officer, United Nations Economic Commission for Africa.
This contact can discuss the role of Mugwagwa's research in the development of the policy of drug regulation harmonization within the African Union.
17.) Biosafety Director, Kenya Biosafety Authority.
This contact can speak to the importance of Kingiri's work in the development of Kenya's biosafety policy (2008), her role in drafting the Kenyan Biosafety Act, and Kenya's first guidelines for inspection and monitoring of GM field trials.
18.) Executive Director, Research Division, Qatar Foundation for Education and Science.
This contact can discuss the role of Chataway's work in shaping the Qatar National Research Strategy 2012, and policies of the Qatar National Research Foundation.

5.3.2 Testimonials available upon request

19.) Financial Times Pharmaceutical Correspondent.
20.) Scientific Advisor (Biology and Health), Parliamentary Office for Science and Technology.