The Institute for Regulatory Science (IRS)

Presentation: 3rd Annual Regulatory Workshop

Dr Desmond Johns, Project Manager:
Institute for Regulatory Science

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Background

- Multiple preceding enquiries (circa 1998 onwards) into structure and functioning of Medicines Control Council, → South African Health Products Regulatory Authority (SAHPRA) Bill

- Recognizing the need to develop national regulatory capacity, including anticipating and servicing SAHPRA's needs –

  - Intention to establish IRS announced Feb 2014,
  - Feasibility study by EU Task Team (Mar 2014)

- IRS project team constituted March 2015 to prepare for establishment of IRS and tasks now almost complete.

Key Guiding Principles

a) Additional regulatory capacity urgently required across the sector (beyond just the regulator).

b) The capacity to deliver regulatory training in South Africa is both limited and fragmented.

c) An increased skills base, efficient regulatory processes underpinned by a unifying regulatory philosophy, are all required to achieve the step change that will bring South Africa on par with International Peers.

What will the IRS do ?

- Provide flexible access to quality assured, basic and advanced courses in regulatory science. **[Value Proposition #1]**

- Support the development and deployment of structured Work Integrated Learning / Mentorship programs. **[Value Proposition #2]**

- Provide a strategic / think-tank function in order to monitor / engage global policy developments and mobilize the appropriate constituencies and responses **[Value Proposition #3]**

How will IRS accomplish this ?

1. Coordinate development of curriculum for web based accredited post graduate programs (NQF 8) yielding the National Occupational qualification as Regulatory Officer: Pharmaceuticals (or Medical Devices etc).

   - Theoretical knowledge : 60%
   - Experiential learning: 20%
   - Work Integrated Learning: 20 %

2. Broker partnership with academia, industry and other institutions to develop, quality assure and deliver components of these programs, based on <u>Institutional Expertise and Capacity.</u>

How will IRS accomplish this ?

3. Consistency, Coherence and Cross learning for corresponding functions in National Regulator and Industry

4. Regulatory Officer program to offer articulation points to Masters / Specialization programs

5. Initial focus on medicines regulation = replicable system for regulation of medical devices, in vitro diagnostics and complementary medicines.

How will IRS accomplish this ?

6. Initial focus on needs of SAHPRA and SA Industry, but project is scalable with established coherence with regional (SADC) and continental (African Medicine Regulatory Harmonization) endeavors.

7. Strategic / think tank function will be institutionalized within the IRS, affording a multilevel platform for stakeholder engagement:

   a) IRS Committees
   b) High Level Roundtables
   c) Seminars and Workshops

What will the IRS look like ?

Proposed

Legal identity = A non profit Public Benefit Trust

Governance = Board of Trustees comprising, Regulator, Industry, Academia & Higher Education, Science and Technology.
Led by Chair appointed by Minister of Health.

Executive functions delivered by secretariat headed by a CEO / Executive Director, appointed by Minister of Health on the recommendation of the Board.

How will the IRS be funded ?

1. **Ideally the IRS will be funded through lump sum contributions or multi-year pledges to the IRS Trust Fund**

2. Establishment phase Sep 2015 – Mar 2016, (NDOH + Donors + ?)

3. Long term funding model

    a. SAHPRA
    b. Industry
    c. Donors
    d. Revenue generation – Fees, seminars etc.

What are the next steps? (Sep 15 – Mar 2016)

- ✓Establish the IRS as Public Benefit Trust
- ✓Recruit IRS senior management team
- ✓Formalize key partnership arrangements
- ✓Complete course development and accreditation
- ✓Establish e-learning platform and
- ✓Complete conversion to online format.

First strategic seminar / roundtable hosted (Q1 / 2016)

First accredited online courses offered (Jul 2016)