Regulatory Update

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Regulatory Priorities
- Examining our drug & medical device review system to determine the best approaches to:
  • better respond to healthcare system needs, and
  • improve timely access to effective products and innovative technologies

Ongoing & Proposed initiatives:
- Working with Health Technology Assessment (HTA) bodies to provide joint advice to industry during product development; better align timing & reduce duplication of HTA review to facilitate faster access to important new drugs;
- Maximizing use of adaptive pathways for drug development and authorization
- Modernizing IM/IT systems infrastructure
- Reforming cost recovery regime to ensure long term funding sustainability

- Simultaneously … work is proceeding to develop regulations that will enhance the power of Health Canada as a regulator, including:
  • ability to require additional tests and studies for authorized drugs;
  • ability to order a reassessment of a drug’s risk/benefit profile; and,
  • ability to attach terms and conditions to market authorizations

Regulatory harmonisation & convergence (& training)

Internationally, Health Canada is taking on a larger role in engaging, promoting and mentoring:
- Full membership status at ICH; participation in most EWGs; guideline adoption
- Work-sharing initiatives within the “ACSS” Consortium (Australia, Canada, Switzerland and Singapore)
- Regular “cluster” t-cons with the FDA, EMA, and Japan to discuss specific issues
- Mentorship and capacity building with other regulators in Latin America and Africa, promoting international convergence and Good Regulatory Practices

Biosimilars
- Increasing interest in potential of biosimilars to serve the health care system in Canada (publicly funded; provinces & territories bear bulk of drug costs)
  • Need for informing/educating Canadian stakeholders – Workshop in March, 2017
- Interest remains high for filing of NDSs for biosimilars (6 authorized; others under review; significant pipeline over the next 3 years)
- Updated Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (biosimilars) released in Dec 2016 to reflect experience gained over the last 5 years and clarify some positions
- Naming conventions, switching, & interchangeability remain contentious issues

Accelerated development of critical medicines
- No equivalent of FDA “breakthrough” designation
- Notice of Compliance with conditions (NOC/c) (efficacy confirmed on market)
- Priority Review (reduced timeframe for evaluation)