How the legislative review might affect the regulatory environment in Ireland

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- The views presented in this presentation are those of the author and should not be understood or quoted as being made on behalf of the IMB, the HMA or the CVMP

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Possible national ramifications

- Effects on climate for innovation
- Effects on existing products
- Distribution of veterinary medicines
- Other issues

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Historical perspective

- The 2001/4 Review

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Goals of 2001 review

- To guarantee a high level of public health
- To address the availability problem
- To complete the single market
- To increase transparency
- To favour competitiveness of the industry
- To prepare for EU enlargement

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2001 -Guarantee of Public Health

- Changes to scientific structures and procedures at EMEA level and at Commission level

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2001 - Availability initiatives

- Harmonisation of data protection period to 8+2 years
- Incentives for protection for data for minor species (to a max of 13 years)
- Incentives for products for use in bees and fish

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2001 - Completion of single market

- Harmonisation of protection period
- Obligatory binding arbitration procedure where countries have divergent views on same product
- Reinforcement of Committee dealing with products subject to mutual recognition procedure
- Structural changes to the regulatory framework

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2001 - Improvement of transparency

- Assessment reports and opinion of the competent authority to be available to any interested party
- Structural changes to Management Board and other committees at the EMEA

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2001 - Competitiveness of the animal health industry

- Removal of 5-yearly renewal of authorisations
- Simplified registration system for homeopathics
- Reduced timelimits for evaluation of applications

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2001 - Other important changes

- Established the cascade principle (off-label use conditions) in food-producing animals
- Adequate records necessary for 5 years
- Products not marketed within 3 years of authorisation to have authorisations invalidated (Sunset clause)
- Lists of products to be submitted to EU Commission for obligatory harmonisation

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The pending review

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Possible effects on climate for innovation

- Change in data protection period
- ? Improved system for conditional authorisations
- ? Protection for other developments
- ? New EMA/decentralised authorisation model
- ? Simplification of requirements for generics
- (Reduction in administrative requirements should translate into reduced overall costs for industry)

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Other effects on the regulatory climate for innovation

- ? Regulation of new technologies
  - *In vitro* diagnostics
  - Medical devices
  - Tissues and advanced therapies
- ? Antimicrobial bias by European Parliament

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Effects on existing products 1

- ? Two tiered system (legacy products *versus* pan-European products)
- ? Further harmonisation initiatives for withdrawal periods and other SPC details
- ? Changes to system for referrals – possibility of different EMA committee
- Streamlining of pharmacovigilance requirements

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Effects on existing products

- ? Simplification of language requirements on product labelling
- ? Dossier content may be changed
- ? Better controls on active substance manufacture and trade
- ? Anti-counterfeit controls
- No change expected on homeopathics
- Improved tools for product monitoring and pharmacovigilance compliance

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Distribution of Veterinary Medicines

- ? Further controls on distribution
- ? Further restrictions on use of antimicrobials
- ? Re-work of the ‘Cascade’ provisions

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Other issues

- Improved transparency
- Improved procedures
- Improved cooperation between agencies
- ? Surprises during the review process

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Conclusions

All of us might wish at times that we lived in a more tranquil world, but we don't. And if our times are difficult and perplexing, so are they challenging and filled with opportunity.

Robert Kennedy

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