



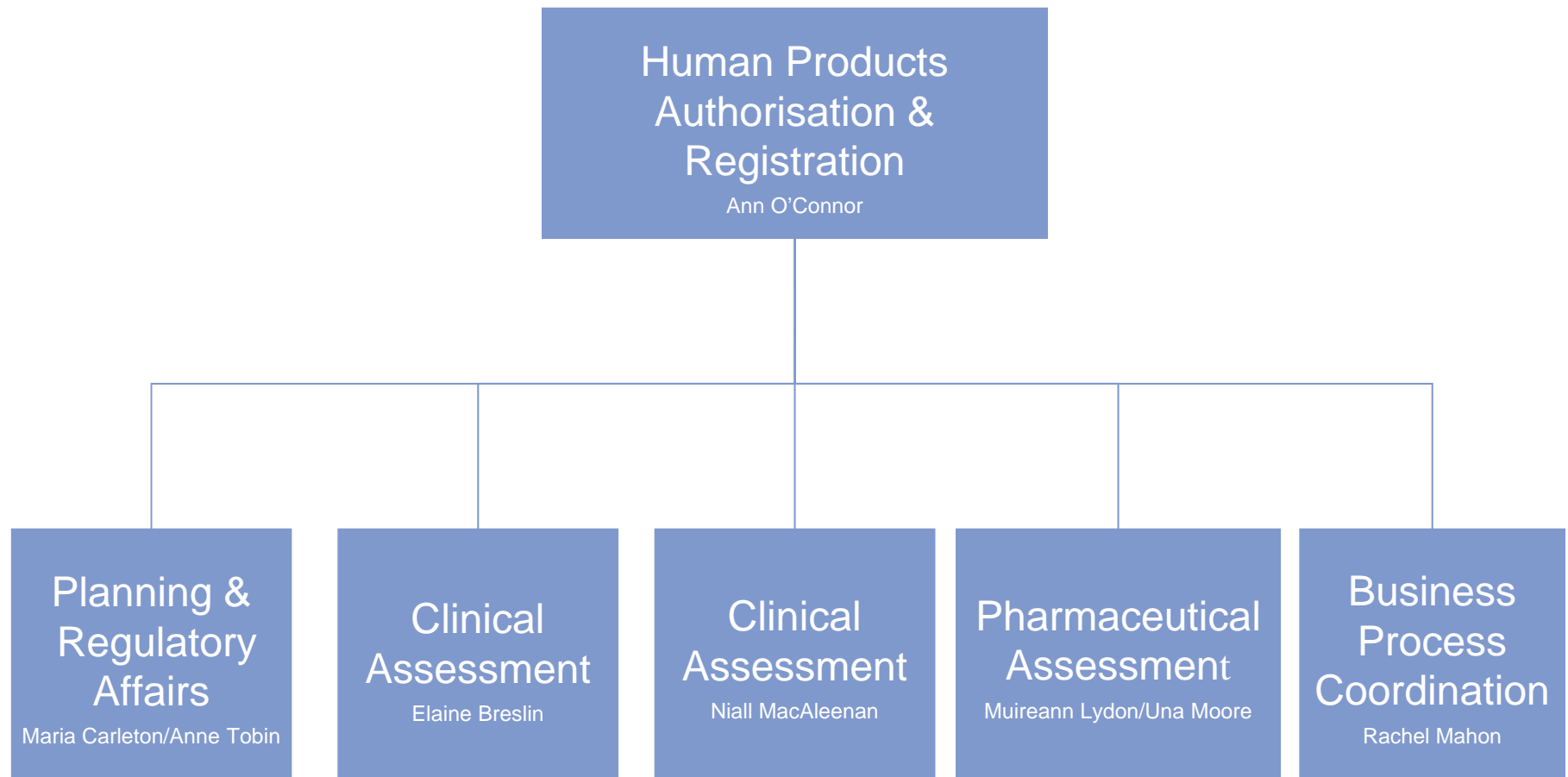
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Information Day - New Variations Regulations General Introduction

Crowne Plaza Hotel, Santry, 22nd January 2010

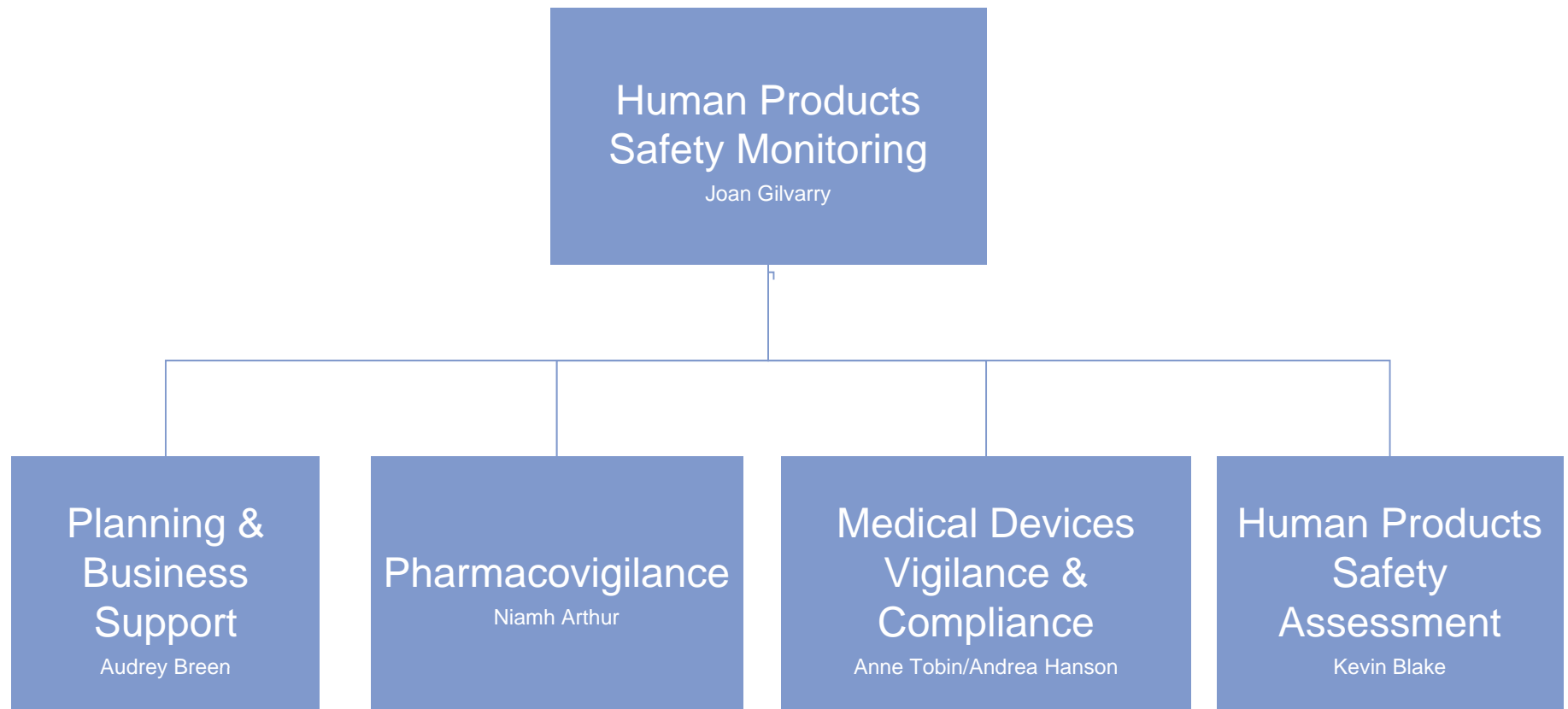
Ann O'Connor,
Director
Human Products Authorisation and
Registration

Human Products Authorisation & Registration Department



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Human Products Safety Monitoring Department



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Activities in 2009

- Impact of the H1N1 Pandemic
 - Input into the licensing of vaccines
 - Input into the licensing of antivirals
 - Dealing with post market issues e.g. ADRs, queries, National Committees
- 24,100 applications issued
- Move to electronic/on line submission of applications



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Activities in 2009

- Preparation for implementation of variations regulations
- Dual Pack Registration scheme revised
- Consultation on national rules scheme for homeopathics
- Updating of the method of sale and supply for medicinal products on the website
- Benchmarking of the Agency under Heads of Agencies initiative



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Strategy for Year 2010

- Effective risk management and improving consumer safety.
- Effective regulation through the ongoing development of our work force and non-staff resources.
- Effective communication with all stakeholders.



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Activities planned for 2010

- Implementation of the variations Regulations
- Workforce and capacity planning
- Enhanced focus on national applications and DCPs
- Document management
- Improve technology systems incl updates to RIO and the internal workflow system (NIMBUS)



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Activities planned for 2010 cont'd

- Drug consultations for medical devices
- Implementation of the sunset clause
- Review of PPA process
- Policy on and procedure for changing the legal status of medicines
- Project to publish SPCs to the website to be completed
- Progress on publication of method of sale and supply



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Challenges

- Current economic situation
- Government moratorium on staff recruitment
- Implementation of variations regulation
- Handling of herbals products – very few applications



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