MEDICINE EVALUATION PROCESSES ENVISAGED FOR SAHPRA

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SAPRAA meeting: 13 April 2018, Midrand

Requested topics

- New submissions (NCE/clone/generic)
- Post-registration amendments
- Pre-Registration responses to Committee recommendations
- Pre-registration amendments

Pre-registration amendments

- 9.40_Changes_during_registration_process_Jun11_v1.pdf
  - Write an official request (not an e-mail) to obtain permission for the change;
  - Clearly indicate this as an additional change in the letter of application and in the Amendment Schedule;
  - All the relevant documents and data as for a post-registration amendment have to be submitted;
  - Arrange with Santhani for a set to be delivered to her, in order to have this for the inspectorate report and to amend the database in Siamed;
  - This is not evaluated and approved separately by the inspectorate, but is done as part of the registration process;
  - Final approval will therefore only be given when the registration certificate is issued.

Need for change

- Delays in evaluation attributable to —
  - increasing number of generic applications;
  - registration without intent to market/distribute;
  - historical procedures for fast-track;
  - large number of post-registration variations/amendments;
  - IT systems and infrastructure;
  - absence of project management and logistical support;
  - limited abbreviated procedures and application of reliance models;
  - availability of skilled technical reviewers.

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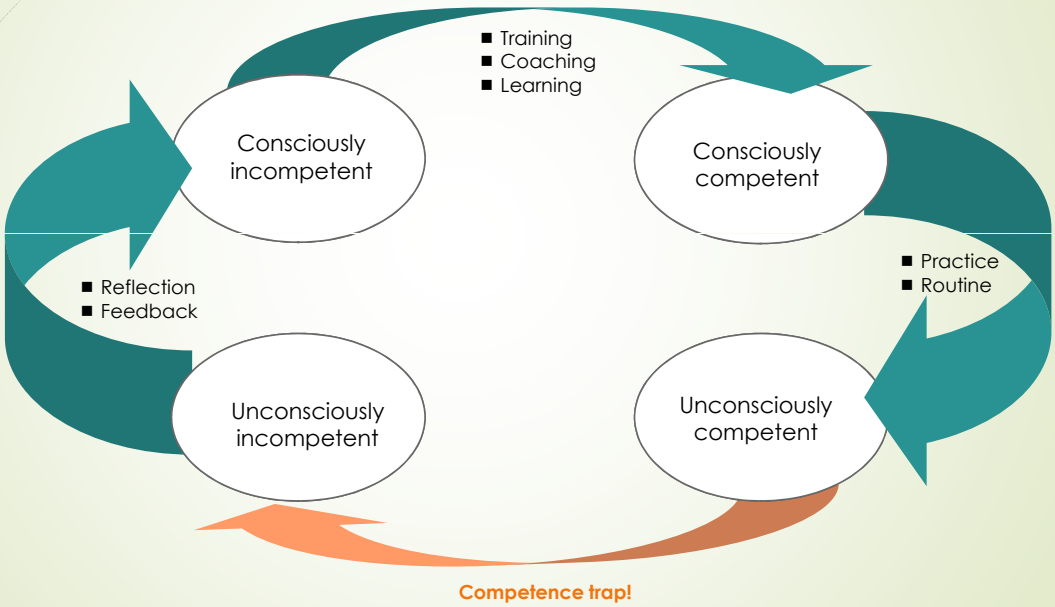
Competence & efficiency cycle



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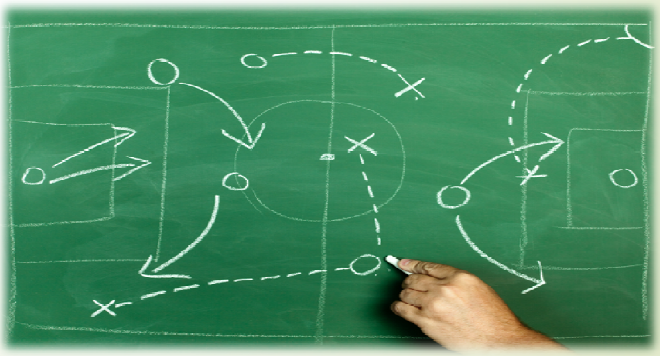
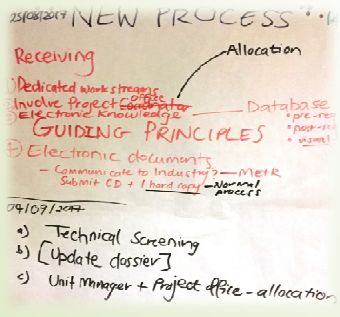
"The" question

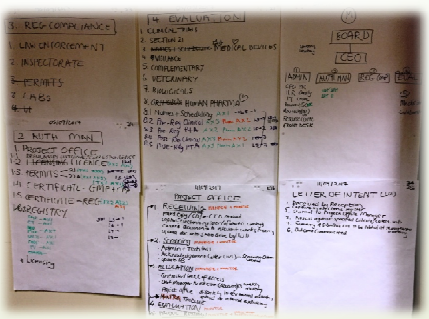
- How do we optimise the regulatory decision-making process, within the framework of the Act, to improve efficiency?

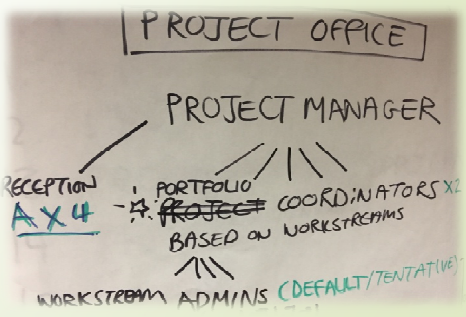


High priority task team

- SAHPRA Board Committee: "Technical Operations & Regulatory Strategy" in collaboration with SAHPRA middle and senior managers
  - Section 2B(2) of the amended Medicines Act allows for information exchange, cooperation agreements, work-sharing and recognition of work done by other regulatory authorities → no longer a question of 'if', but when and how...
  - procedures, processes & requirements under development.
- Board resolution: imminent engagement with Industry groupings







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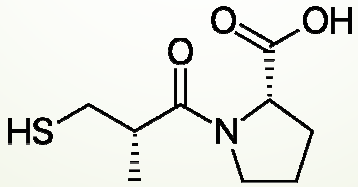
Pharmacopoeial (older) molecules

- Compliance with monographs;
- Rapid assessment of essential information on the quality, safety and efficacy of the product;
- Focus on critical quality attributes.



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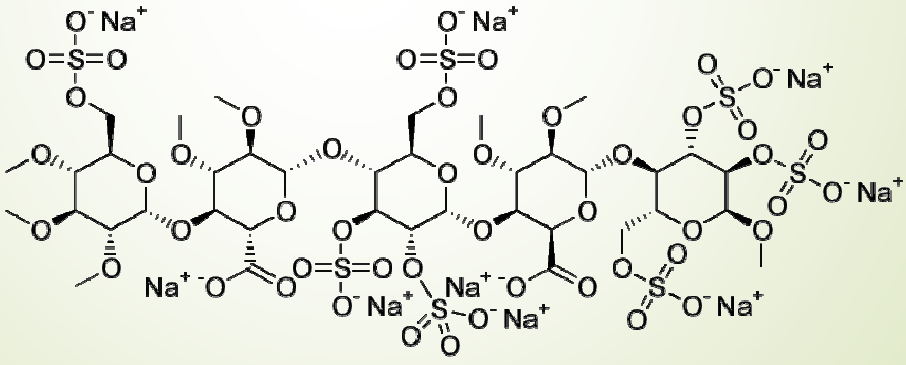
Non-pharmacopoeial (newer) molecules

- Registration status with recognised NRAs, with access to the evaluation reports;
- Abridged evaluation process, focusing on country-specific requirements.



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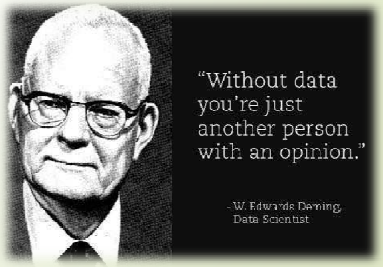
What about abbreviated evaluation?

- Example: quality review
  - Module 2 → good overview and start to the evaluation;
  - But the main review is based on module 3;
  - However, a well written module 2 could allow the Regulator to base parts of the actual review on Module 2 (rather than Module 3), and only referring to module 3 for critical topics;
  - Could therefore potentially ask for submission of only specific parts of Module 3…



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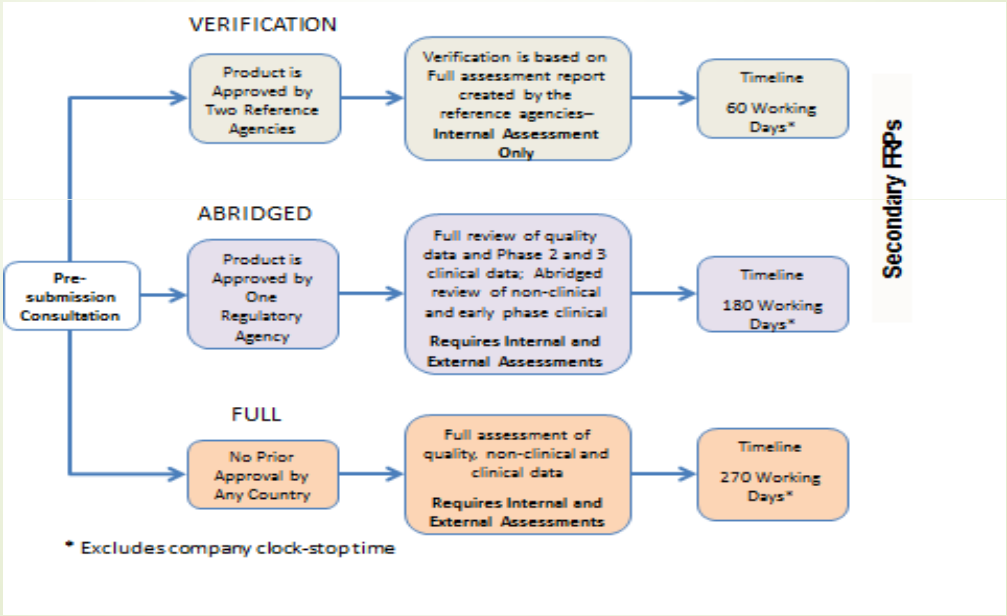
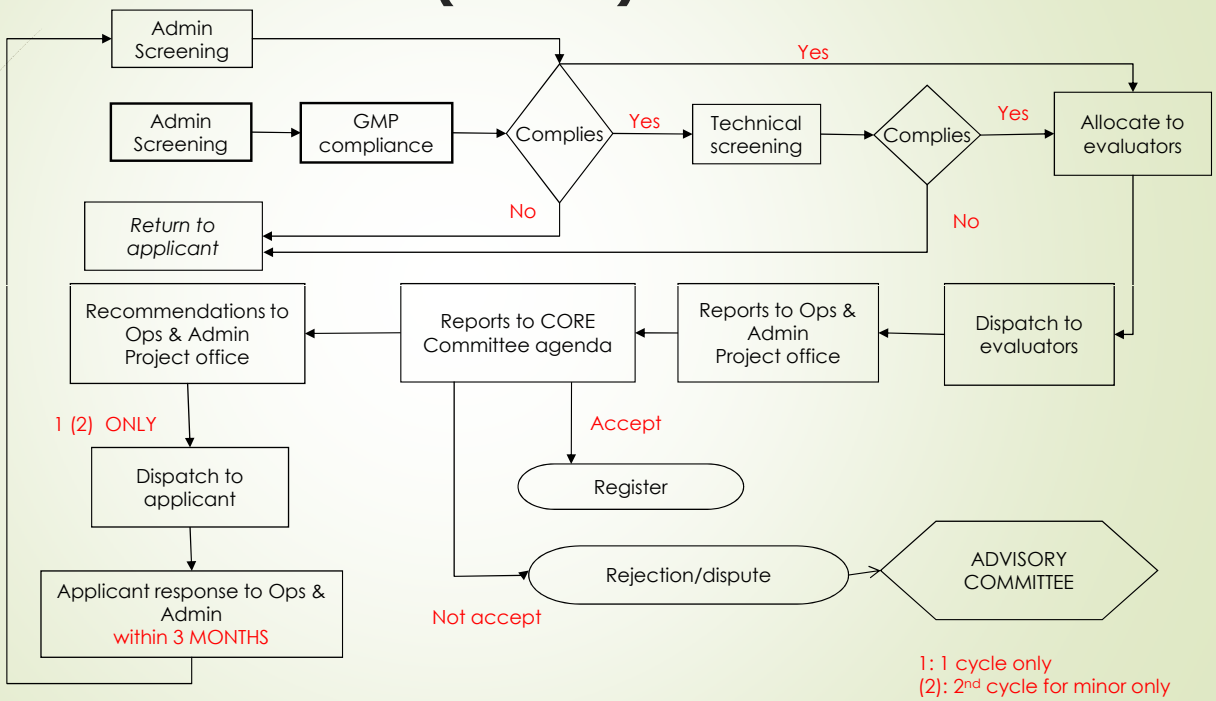
Example: risk-based stratification (Singapore model)



NEW PROCESS (DRAFT)



QUESTIONS?