The process of registration with SAHPRA and prices

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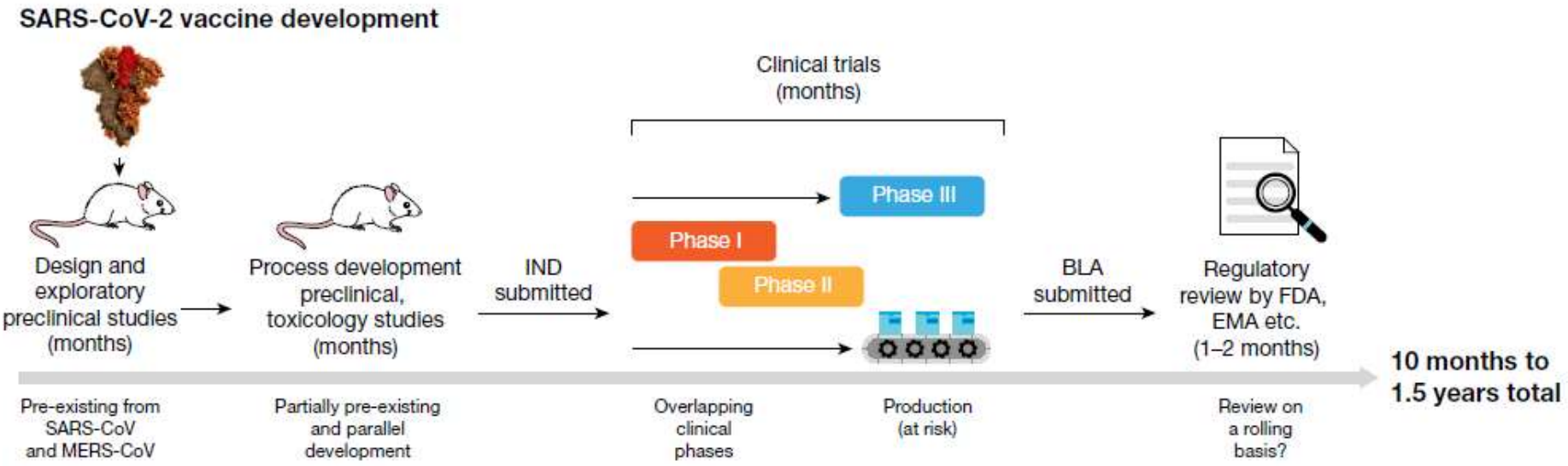
VACCINE LITERACY WORKSHOP

Organised by SECTION27 and The Treatment Action Campaign

Linking to the previous input ….



SAHPRA

- An independent, national medicines regulatory authority (now located outside of the NDOH)
- Decision-making is vested in the STAFF (not the BOARD)
- CEO is enabled to appoint ADVISORY COMMITTEES, which may make recommendation to the staff
- Responsible for medicines (human and animal), medical devices, *in vitro* diagnostics, (radionuclides)

Medicines and Related Substances Act (Act 101 of 1965)

- **14. Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered.**—
  (1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.
- (2) (a) The Authority may from time to time determine that a medicine, medical device or IVD, or class or category of medicine, medical device or IVD or part of any class or category of medicine, medical devices or IVDs mentioned in the declaration, shall be subject to registration in terms of this Act.

Implications

- **All** category A medicines (human use, apart from complementary medicines; including biological medicines) have been the subject of a "call-up notice", so have to be registered before they can be sold.
- **Section 21** allows for access to unregistered medicines for individual patients or in clinical trials. Some provisions for "bulk" approvals (e.g. out of stock).

Assessment focuses on:

- **Quality**
  - How is the medicine made and how will quality be assured during production and distribution?
- **Safety**
  - Are the expected adverse effects proportional to the proposed use? Pregnancy/lactation?
  - How will further data on safety be gathered? Adverse events following immunisation (AEFI)? Risk management plan?
  - How will access be controlled (scheduling)?
- **Efficacy**
  - Does the medicine achieve its proposed purpose (in preventing or treating a disease or symptom)?
  - Are there important differences in effect between patient groups (age/sex/co-morbidities/other medicines)

Who does the assessment and who makes the decision?

- Internal screening
- External evaluator/advisory committee member review (primary)
- Peer review, with the possibility of committee discussion
- Recommendation to the Authority
- Final decision is taken by the Authority (CEO + staff)

- Certificate of registration + conditions + PI/PIL
- Single exit price (if sold to the private sector) set by the manufacturer/importer

The possibility of a reliance model

- **2B. Functions of Authority.**—
  (2) The Authority may—

  (*a*) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of—

  (i) matters of common interest; or

  (ii) a specific investigation; and

  (*b*) enter into agreements to cooperate with any regulatory authority in order to achieve the objects of this Act.

Specific biological medicine issues

- Batch-by-batch testing at the National Control Laboratory for Biological Products (UFS)
  - Applied to all current vaccines
  - Possibility of reliance options
- Genetically Modified Organisms Act (Act 15 of 1997), in the case of adenovirus-vectored vaccines

Pricing – not a formal "4th hurdle"

22G. Pricing committee.—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a);

(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

(3) (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances **to any person other than the State**.

(b) No pharmacist or person licensed in terms of section 22C (1) (a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

Exceptions

- Schedule 0 medicines (sold through any retail outlet)
- Medical devices and IVDs

Time-limited exceptions?

Opportunities to intervene

- Annual maximum single exit price adjustment (SEPA)
  - On the advice of the Pricing Committee
- International benchmarking (external reference pricing)
  - Proposed, but never implemented
- Pharmacoeconomic evaluation
  - Voluntary
  - Uncertain implications (NDP 1996)

http://www.icmra.info/drupal/en/covid-19/vaccines_confidence_statement_for_hcps

ICMRA

International Coalition of Medicines Regulatory Authorities

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