2.1. Vaccine manufacturing

channels. Border clearance conditions for ancillary immunization products (e.g. syringes, refrigerators) needed for administering vaccines can be quite different. As the number of doses of COVID-19 vaccine delivered worldwide grows, it is unclear whether these expedited border clearance processes will remain in place.

2.4. Therapeutics and pharmaceuticals

- Different technical requirements on the same product between countries (e.g. the more common fill volume of 3.5 ml versus 3.51 ml in some countries; the sterilization of injectable products

- A rolling review of vaccine and therapeutics dossiers can shorten approval time.
- Agile inspections could be conducted or alternatives found (e.g. through remote means).
- Building transparency by design – for all parties, including regulators and manufacturers – could enable agile and informed regulatory decision-making during a pandemic and strengthen collaboration for more efficient vaccine development.
- NRAs can enhance transparency and openness (e.g. sharing data nationally with experts and explaining the process and findings at public briefings) and gather independent expert advice in real time to mitigate any potential risks of expedited processes.
- The pharmaceutical industry could improve transparency and data integrity by providing better access to clinical data for all new medicines and vaccines (including to the approximately 50% of clinical trials that go unreported because the results are negative[8]).
- Sharing data between regulators in real time can facilitate multi-country approvals.
- Regulatory systems in developing countries can be strengthened

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