International Pharmaceutical Aerosol Consortium

Timeline and Considerations For Introducing New Propellants

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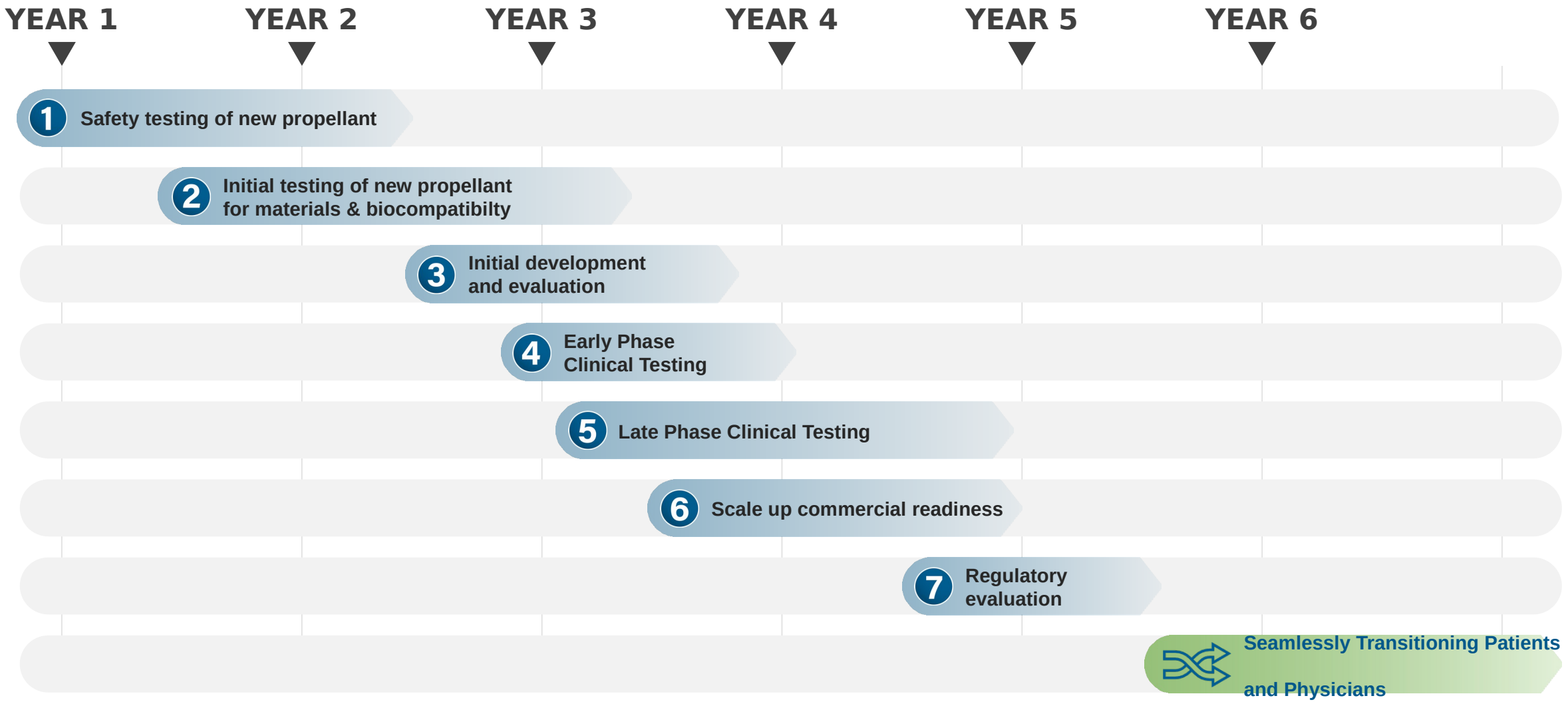
Timeline for Introducing Next Generation Lower GWP MDIs

IPAC
International Pharmaceutical Aerosol Consortium



1 Safety testing of new propellant

APPROX. 36-60 MONTHS

- A series of toxicological studies to confirm that the propellant would not cause undue harm to health. These may include both short-term and long-term dosing studies that range in time from days, to several weeks, to over a year.
- For the new propellants under discussion, this step is currently ongoing. Some studies have been completed, others are still open.

WHY DONE:

Required by regional medicines regulatory agencies. Reduces risk of human safety hazards.

2 Initial testing of new propellant for materials compatibility & biocompatibility

APPROX. 12-24 MONTHS

- A series of tests to investigate whether the new propellant is physically and chemically compatible with the delivery device and to confirm that it is not harmful when in contact with humans.
- If any concerns are uncovered, the materials used in and/or design of the device need to be re-considered and re-developed.
- Supply chain delays may increase the development time.
- In some cases of a delivery device materials change, new and/or additional suppliers must be identified and qualified.

WHY DONE:

Required by regional medicines regulatory agencies. Supports quality and efficacy of final drug product; reduces risk of human safety hazards.

3 Initial development and evaluation

APPROX. 24-36 MONTHS

- The combination of the new propellant, active therapeutic ingredient, and the device needs to be studied from multiple perspectives to ensure that the combined product performs as intended, i.e., that it can deliver therapeutic dose of the aerosol consistently, that it is stable upon storage, that the aerosol particles are sufficiently small to be inhalable, that patients can interact with the products appropriately, that there are no harmful impurities over the life of the product.

WHY DONE:

Required by regional medicines regulatory agencies to ensure the quality, safety and efficacy of the clinical stage and final drug products.

4 Early phase clinical testing

APPROX. 12-24 MONTHS

- The product is studied in a clinical setting in human volunteers to confirm safety of the product. Study protocols are developed and reviewed by regulators. Subjects for the study must be recruited and followed for a period of time. Data must be collected and analyzed. Any unintended health impacts must be discussed with regulators, and development programs may need to be halted until all issues are resolved.

WHY DONE:

Required by regional medicines regulatory agencies as a critical part of product development, to demonstrate the safety of the product in humans.

5 Late phase clinical testing

APPROX. 24-36 MONTHS

- Further clinical studies in large numbers of patients, to demonstrate that the new product is safe to use, is efficacious, and that it can be manufactured consistently and with high quality.

WHY DONE:

Required by regional medicines regulatory agencies as a critical part of product development, to further demonstrate the safety and efficacy of the product in humans.

6 Scale up commercial readiness

APPROX. 6-18 MONTHS

- Manufacturing controls and processes are developed and established, which must produce the new drug products using the new propellants in large numbers with consistent high quality.
- New propellants differ in their pressure, density, boiling point, flammability and other characteristics from all previously used propellants. Therefore new manufacturing facilities are needed.
- Supply chains for the equipment and construction materials will need to be identified and qualified. Any supply chain delays will increase the overall timeline.
- To ensure that patients have an uninterrupted supply of existing inhalers, manufacturers would need to maintain commercial manufacturing facilities for the current pMDIs in parallel.

WHY DONE:

Scale-up and adherence to rigorous Good Manufacturing Practices to produce consistent high quality commercial product is required by regional medicines regulatory agencies; critical part of ensuring availability, accessibility, safety and efficacy of product for patients.

7 Regulatory Evaluation

APPROX. 6-24 MONTHS

- The government agency responsible for review and approval of new medicinal products will review data about safety, efficacy, manufacturing controls (including manufacturing site inspections), labeling, and other aspects of the new product.
- The timelines for regulatory assessment are fixed. If regulators raise questions about the new products that cannot be addressed with available data, the sponsor may need to repeat some of the previous steps, or conduct additional studies/evaluations to develop further data.
- Each country has its own process, timeline and specific requirements for approving new products. The sponsor would need to prepare data packages for each of the countries in turn. Those review times will add up due to multiplicity of regions.

WHY DONE:

Required by law of each country.

Seamless transition for patients

- We expect this phase to be fairly smooth and the patient instructions and experience should be quite similar to the existing products. Clinicians and health care providers will facilitate and educate on the transition.
- Each company will transition its portfolio as new products are approved.
- Depending on national health care system structure there may be some time and process needed for adoption of new products.

WHY DONE:

This is the natural process of introducing new products and ensuring smooth and seamless for patients as possible.

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