SUPPLY CHAIN POST-APPROVAL CHANGE:

Global Complexity Contributing to Delayed Patient Benefit

International Federation of Pharmaceutical Manufacturers & Associations

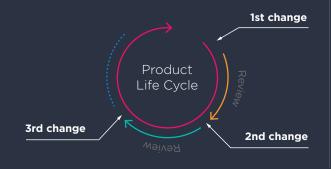


When it comes to licensing a **Medicinal Product** at country level, it will be subject to changes



Hard to step up to the challenge as:

- 1 change could trigger 0.5-2 year delay
- 2 changes could trigger 1-4 year delay
- **5** changes could trigger 1.5-6 year delay



Country A					
None		2nd change review	3rd change review		
Country B					
More Stability Data					
Country C					
More Clinical Data					
Country D					
Reference Country Approva Prior to Submission	al Required)			
0 6 months	12 months 18 m	onths 24 months	30 months 36	months 42 months	48 months

0-18 Months 12-24 Months 6-24 Months

License approval

Data development time

Variation approval time

CHALLENGES:

Unsustainable inventory fragmentation



18m => Fastest timeline for licensure +1 post-approval change

5.5y => Longest timeline for licensure + 1 post approval change +years => Multiple changes will lead to different product versions

SOLUTIONS:

Important for countries to reach convergence on:

1. Data license2. Timelines forrequirementsreview

r **3.** Inspection requirements

 4. Product testing requirements