ERNs and Research: state of play from the European Commission perspective

‘Snapshot’
ERNs and Medicinal Product Point of View

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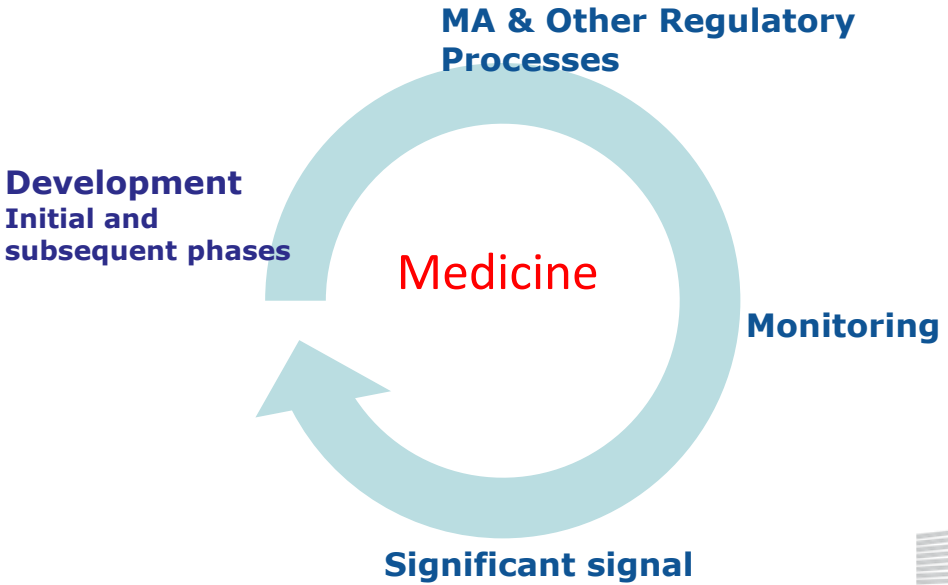
Pharmaceutical System in the EU:

Marketing Authorisation (MA) and monitoring of the medicinal products

- ERNs and the whole life cycle of the Medicinal Product



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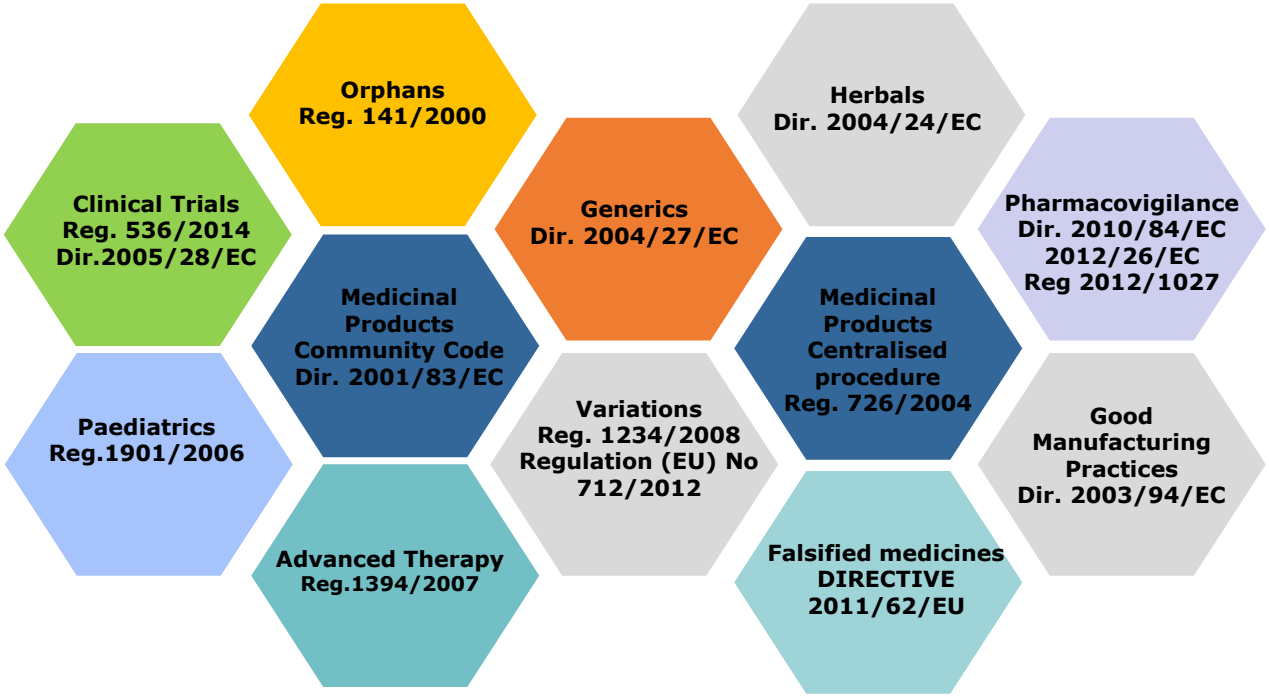
Pharmaceutical legislation in the EU



ERNs and the special interests

Orphan Regulation (EC) No 141/2000	Paediatrics Regulation (EC) No 1901/2006	Advanced therapy products (ATMP) Regulation (EC) No 1394/2007
Rare disease (not more than 5 in 10,000 persons in the EU) or not sufficient return on investment Seriousness: life-threatening or chronically debilitating No satisfactory method of treatment or if existing significant benefit has to be demonstrated	· Ensure high-quality research into developments of medicines for children · Ensure that over time majority of medicines used for children are authorised for such use · Ensure availability of high-quality information about medicines used by children	The medical products based on gene therapy, cell therapy and tissue engineering Considerable research activities, with several hundred registered clinical trials on ATMPs in the EU over the last ten years Demonstrates that research in ATMPs is significant; the majority is carried out by SMEs, hospitals or academia

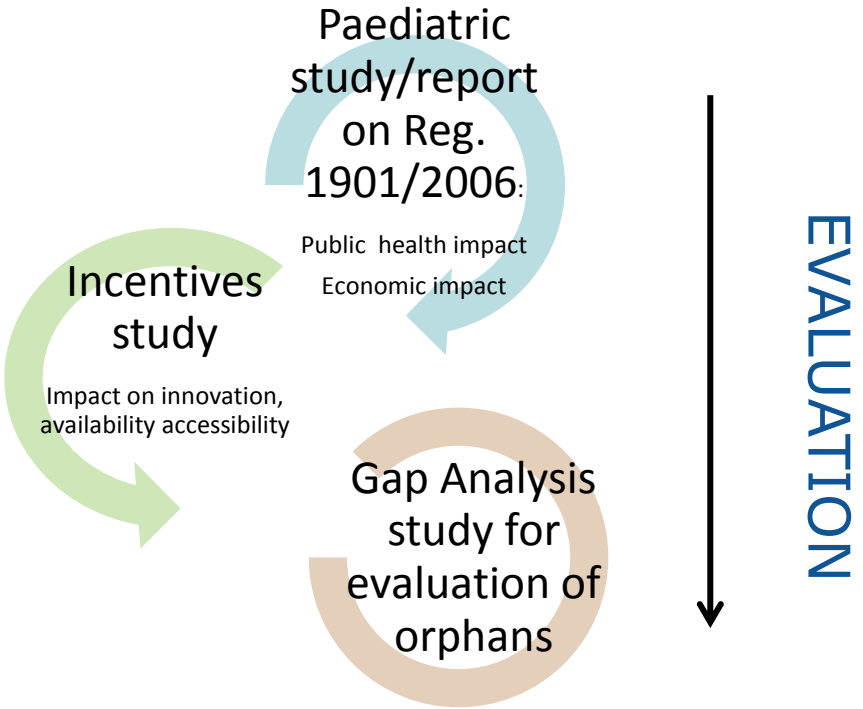
Recent up- date ATMPs

- Supporting the development of ATMPs through an optimised application of current legal framework
- EC-EMA joint action plan on ATMPs (2017-2019)

- Specific GMP framework adopted
- GCP for ATMPs in preparation
- Increased harmonisation / best practices
- Increased clarity of regulatory expectations/ requirements

In sight/ Joint Evaluation of paediatric and orphan legislations

- Background three studies



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Thank you for your Attention

https://ec.europa.eu/health/human-use_en