INFARMED - 31st ANNIVERSARY

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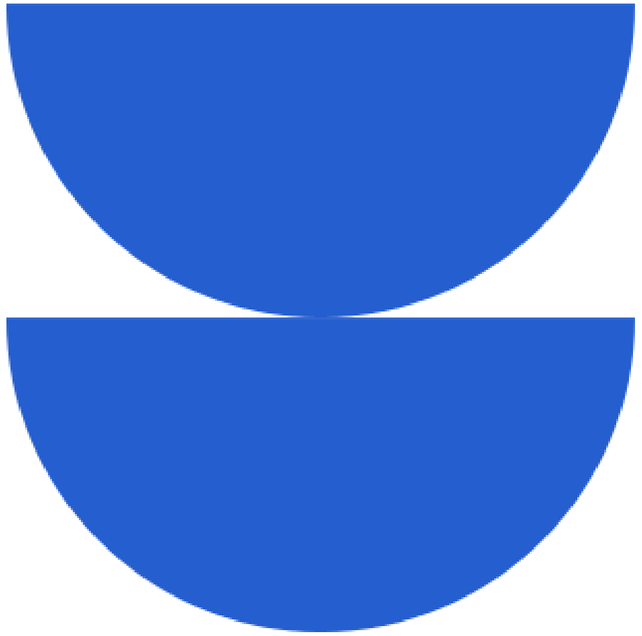
Evolution of EU Medicinal Product Authorisation:

A Journey from Harmonization towards Integration



Introduction

The Journey Begins: 1965 to Present: a stepwise policy

- AUTHORISATION TO MARKET
- QUALITY SAFETY EFFICACY
- NATIONAL IMPLEMENTATION
- EUROPEAN SINGLE MARKET APPROACH INSUFFICIENT
- SUCCESSION OF EUROPEAN PROCEDURES FROM VOLUNTARY TO MANDATORY TO CENTRALISED
- THE EU AGENCY AND ITS NATIONAL COUNTERPARTS

Personal Insights as Head of the Pharmaceuticals Unit (1998) (1)

- NAVIGATING TRANSPARENCY, COMPLEXITY, LEGAL CERTAINTY:
- +/_ 30 APPLICABLE TEXTS
- THREE MA PROCEDURES
- INSTITUTIONAL ADAPTATION AT ALL LEVELS
- BIGGEST EVER ACCESSION PROCESS LOOMING AHEAD
- INNOVATION AND NEW NEEDS
- LEGAL CODIFICATION OF THE “ACQUIS” AND THEN FIRST REVIEW OF SELECTED PARTS IN NEED OF UPDATE AND INTRODUCTION OF NEW PROVISIONS (BIOSOMILAR MP, HERBALS MEDECINES, DATA PROTECTION REVIEW….)

Personal Insights as Head of the Pharmaceuticals Unit (1998) (2) and after

- NEW AREAS COVERED AT EU LEVEL
  - PEDIATRICS
  - ORPHAN DRUGS
  - CLINICAL TRIALS DIRECTIVE (PAVING THE WAY FOR THE 2014 REGULATION)
- LATER (HEAD OF CABINET) :THE CROSS BORDER HEALTHCARE DIRECTIVE AND THE RECOGNITION OF THE NEED FOR APPROXIMATION OF MS PRACTICES (HTA)

Global Impact and EU Leadership

- EU ON THE GLOBAL STAGE: ICH AND CTD THEN E-CTD
- EM(E)A
- ONE EXEMPLE: BIOSIMILAR PRODUCTS AUTHORISATION CRITERIA (US)

Policy Analysis
Achievements and Challenges

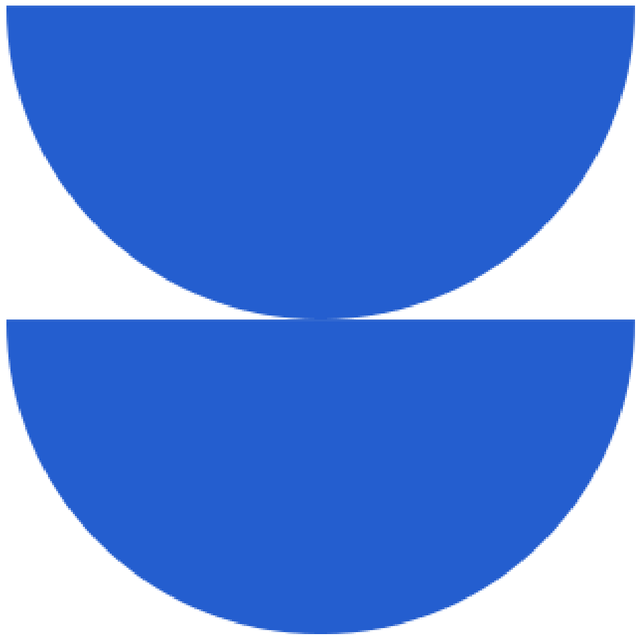
Reflections on Policy: Progress and Pitfalls

- ACHIEVEMENTS IN HARMONIZATION, MORE INTEGRATION AND INTERNATIONAL RECOGNITION.
- CHALLENGES: AUTHORIZATION VS. ACCESSIBILITY, EU PHARMA ECONOMICS DIMENSION ELUDED

Vision for Future Public Health Ecosystem

Towards an Integrated Public Health Ecosystem

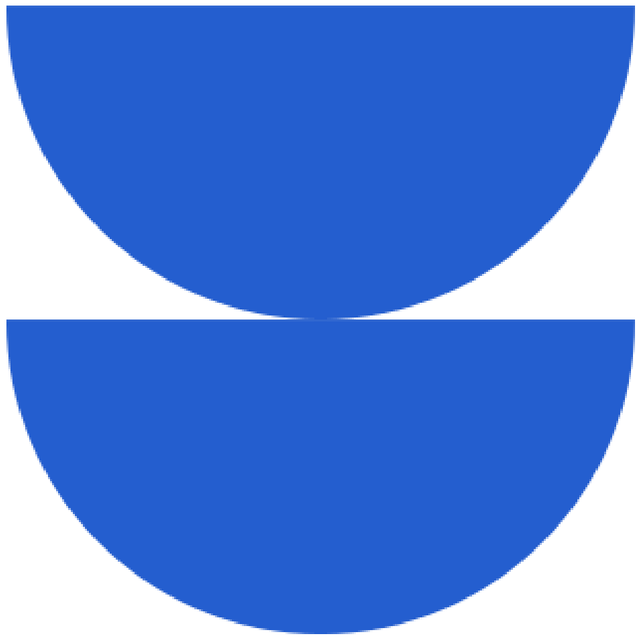
- NEED FOR NEW APPROACH OF THE CONUNDRUM INNOVATION VS ACCESSIBILITY.
- PHARMA POLICY PERTAINS TO HEALTH POLICY AND ECONOMIC / INDUSTRIAL POLICY (SOVEREIGNTY)
- ROLE OF NEW EU R&D APPROACH FOR PHARMACEUTICALS AND ATMPS, AND NEW POLICIES ADDRESSING UNMET MEDICAL NEEDS



Conclusion

Looking Forward

- GREAT ACHIEVEMENTS
- ON GOING PROCESS FOR MS AND EU
- PENDING ISSUES : AMR, RESHORING, EU WIDE CITIZENS ACCESS TO INNOVATION
- EU SOVEREIGNTY CAN BE BUILT NOT DECREED



Thank you

Q&A