

GLOBAL LANDSCAPE ON PERSONALIZED MEDICINE POLICY: KEY ELEMENTS AND CHALLENGES

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The Concept

- * Before 1990: sociological, educational, and psychological bases for alternative approaches to patient management
- * After 1990: more common usage of the term reflected genetic understanding for differences in pharmacotherapy. Market entry of several molecularly targeted therapies in oncology and application of novel therapeutic agents



Main Key Aspects and Benefits

ATTRIBUTES

- * Personalized
- * Predictive
- * Preventive
- * Participatory

BENEFITS

- Early detection of disease
- Selection of optimal therapies
- Reducing risk for adverse reactions
- Reducing risk and costs of clinical trials

Practical and Policy implications (I)

- * For patients
- * For healthcare providers
- * For biopharma companies
- * For diagnostic companies
- * For researchers
- * For IT companies
- * Advocacy groups
- * Payers



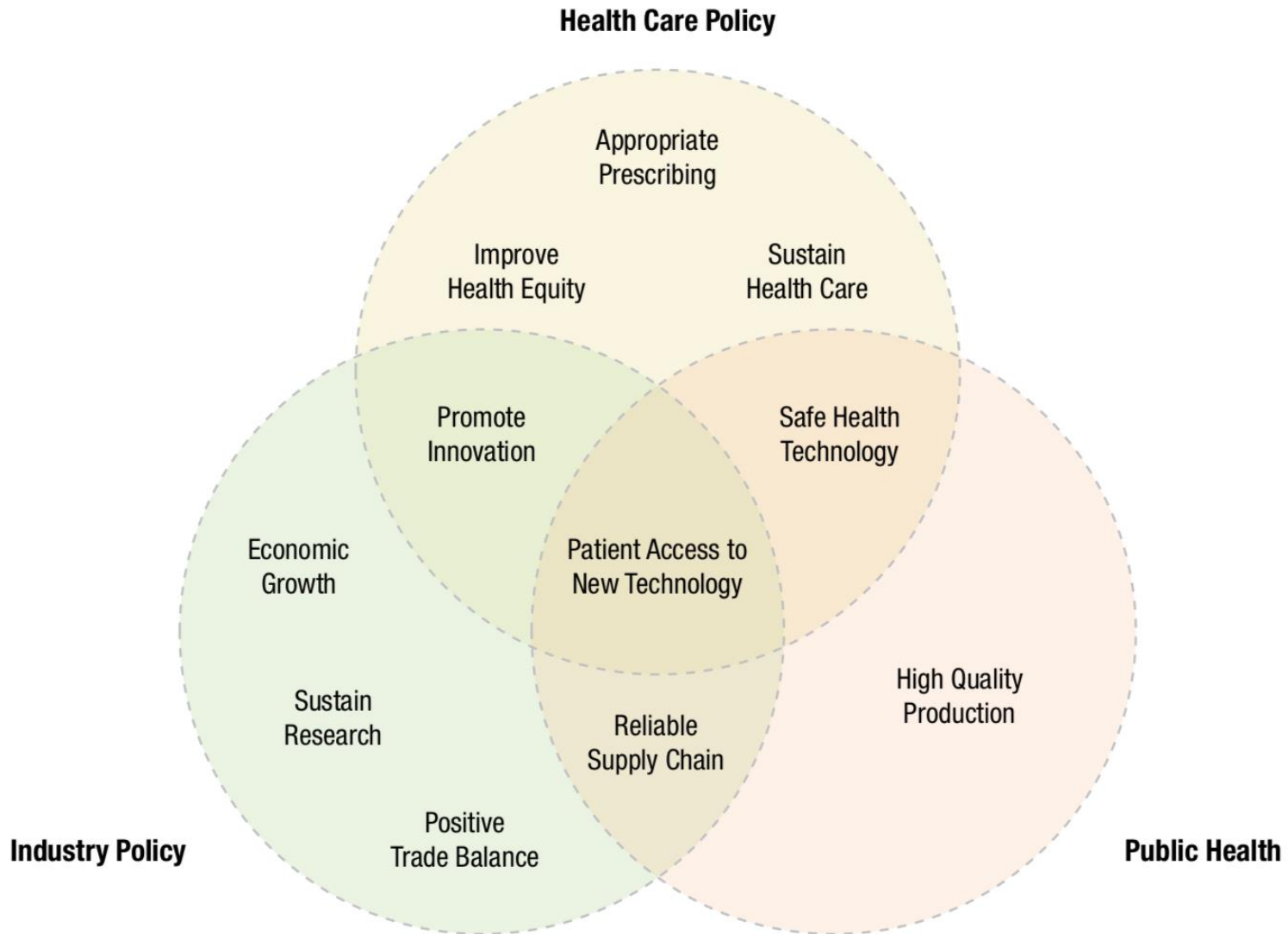
Practical and Policy implications (II)



Globally, the adoption of personalized medicine has been creating several implications from a policy standpoint in key issues:

1. Intellectual property
2. Regulatory oversight
3. Coverage and payment
4. Privacy and confidentiality
5. Healthcare system infrastructure
6. R&D incentives

Health Technology Policy Goals (CPS, 2014)



¿International views on PM?



Final remarks

- * PM: new paradigm for the development of drugs and the practice of medicine.
- * Obstacles in public policy include uncertain regulatory requirements, insufficient insurance reimbursement for diagnostic tests linked to pre-emptive care, incomplete legal protections to prevent genetic discrimination, the lack of a comprehensive healthcare information technology system