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THE VALLETTA DECLARATION

# *The Valletta Declaration*

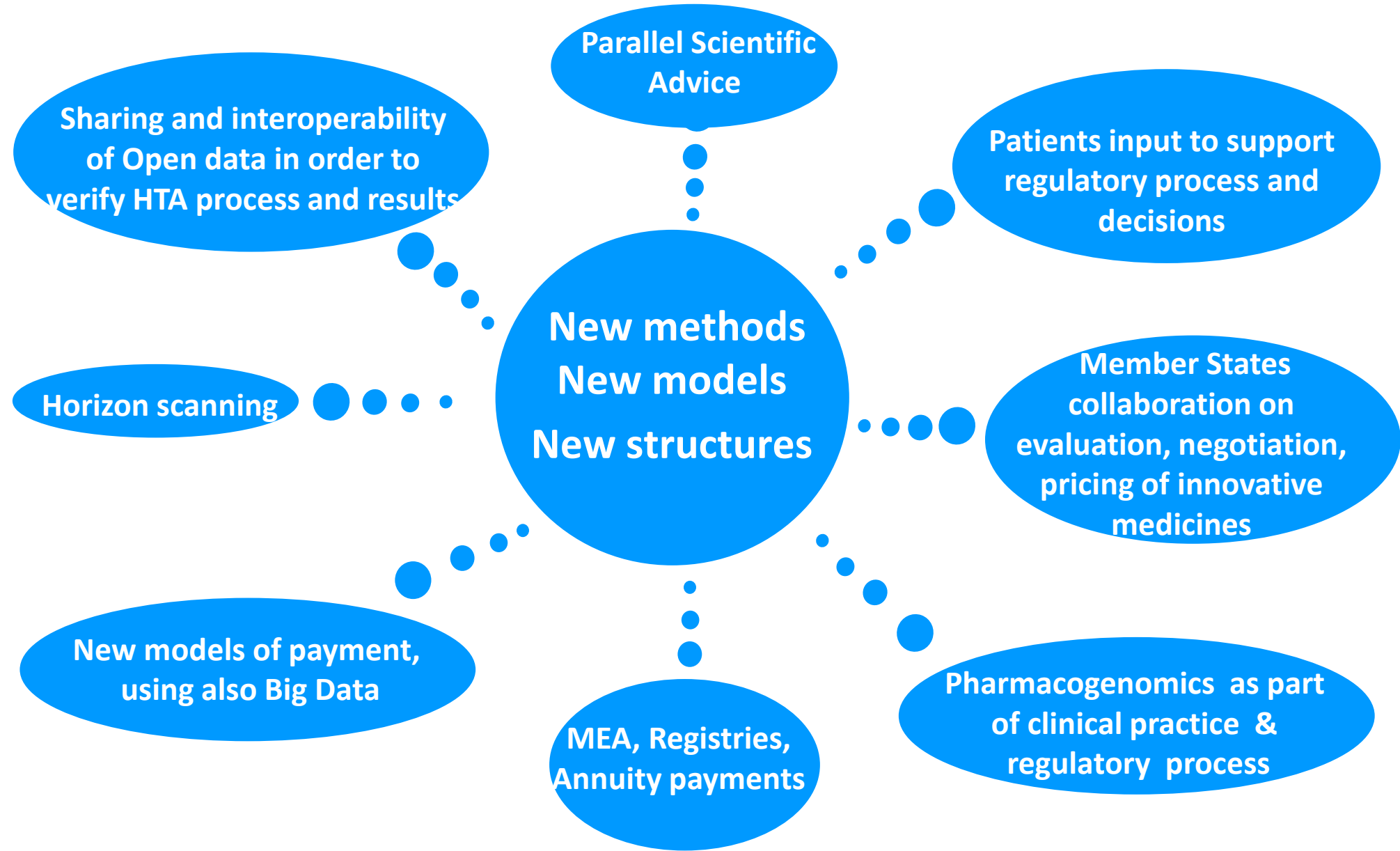
*Facing the challenges: Equity, Sustainability and Access*

*Lisbon 29-30 November 2018*

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# How to deal with the ever-increasing spending on pharmaceuticals ?



# The Valletta Declaration

Member States expressed their political will to cooperate in full trust, loyalty, solidarity and transparency for better access to medicines, 8 May 2017 in La Valletta

## ***Objectives***

- Guaranteeing patients' access to new and innovative medicines and therapies
  - Ensuring sustainability of national health systems
  - Achieving collaboration between the Member States leading to synergy between these countries
- Permanent Technical Committee (**Valletta Technical Committee**):
- IT Chair and PT Vice-Chair, Secretariat in La Valletta, Malta
- Meetings of the Valletta Technical Committee held, on a rotation basis, in the participating countries, some of which with a joint Ministerial session
- Confidentiality agreement signed by VTC Members

# The Valletta Declaration



- Croatia
- Cyprus
- Greece
- Ireland
- Italy
- Malta
- Portugal
- Romania
- Slovenia
- Spain

**over 160 million citizens**

**31,5% of EU population**

as one aggregated joint market

open to other EU Member States



# The Valletta Declaration: focus and activities (1)

- ❑ Performing joint clinical assessment and economic evaluation
- ❑ Running joint price negotiations
  - Choice of medicines
    - *Medicines without MA or at early phase of MA*
    - *Innovative medicines, including orphans*
  - Criteria for prioritization of products
    - *Interest of the therapeutic indications*
    - *Unmet medical need*
    - *Cost of therapies*
    - *Expected volume of use and prevalence of the disease*
    - *Alternative treatments already approved for these indications*
    - *Level of cooperation with the marketing authorization holder*
- ❑ Six products prioritized and work started



# The Valletta Declaration: focus and activities (2)

- ❑ Sharing of information on specific medicines or categories of medicines with significant therapeutic value and high financial impact, in view of:
  - *Input in the negotiation phase*
  - *Renegotiation of contractual arrangements*
- ❑ Exchange of information and good practices on policies and pricing & reimbursement of biosimilars
- ❑ Sharing of pharmaco-therapeutical/effectiveness assessments of medicines
- ❑ Horizon scanning of innovative therapies

# The Valletta Declaration: crucial issues

- It is a political and administrative agreement between governments of Member States
- Different procedures and timing of assessment and negotiation at national level
- The joint assessments should be harmonized and rapid in order not to introduce delays in the access to medicines, and must start at an early stage so as to ensure that no reimbursement dossier is submitted in any country
- Any joint outcome has to be implemented in each country in accordance with its respective legal framework.
- Which price has to be jointly negotiated ? Fixed price? Maximum price? Range of prices?
- Industry is concerned about possible uncertainty in the implementation of joint outcomes at national level
- Need to guarantee confidentiality during the whole process and in the final agreed prices



# The Valletta Declaration: benefits

- Regional cooperation is an effective way to facilitate the access to medicines and address the challenge of high pricing of medicines
- Establishment of strategic collaboration on pricing & reimbursement of medicines amongst national authorities
- Exchange of policy solutions on key issues relating to the access of medicines
- Sharing of information and best practices relating to the access of medicines of relevant therapeutical value and/or high financial impact

