



Medicines & Healthcare products  
Regulatory Agency



# PCWP-HCP meeting: COMP update April 2018

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**On behalf of the COMP**



# Recent COMP Activities

## **Strategic review and learning (SRLM) President meeting in Amsterdam in March 2018 (on behalf of Bulgaria)**

- Considering further the impact of the Commission's new Notice and how best to implement the changes into COMP practice
- Discussion on prevalence criteria from the Prevalence Working Group and external experts
  - How the methodology of the COMP has evolved overtime and should be portrayed in an amended guidance
- Feedback from the Conditions Working Group and the use of biomarkers in cancer

# Recent COMP Activities

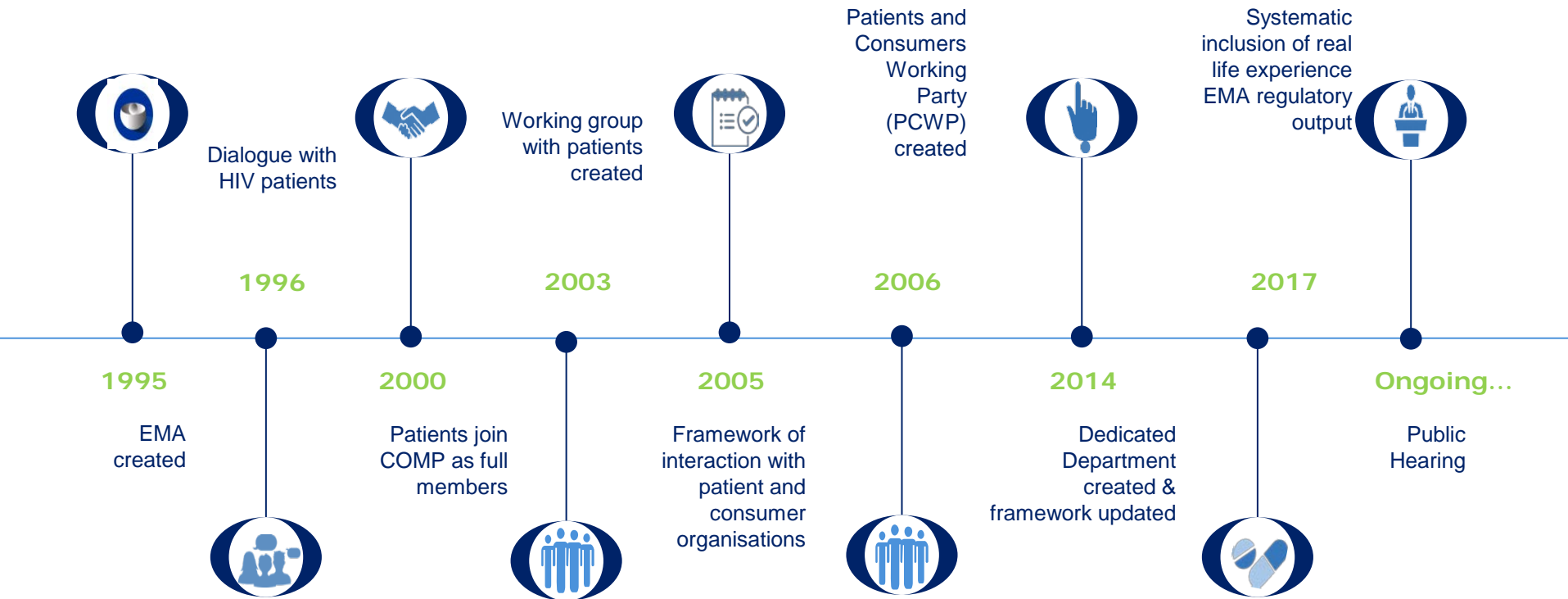
## **Strategic review and learning (SRLM) President meeting in Amsterdam in March 2018 (on behalf of Bulgaria)**

- COMP 'conditions' working group
  - Working group considering some of the challenges in defining a condition
  - Orphan designation starts with the condition – without it COMP cannot evaluate any of the other criteria
  - Contribution to work on a paper for publication considering conditions based on adverse events and treatment modalities, use of mechanism of action to justify breadth of a condition, versus FDA views

# Other COMP / EMA activities

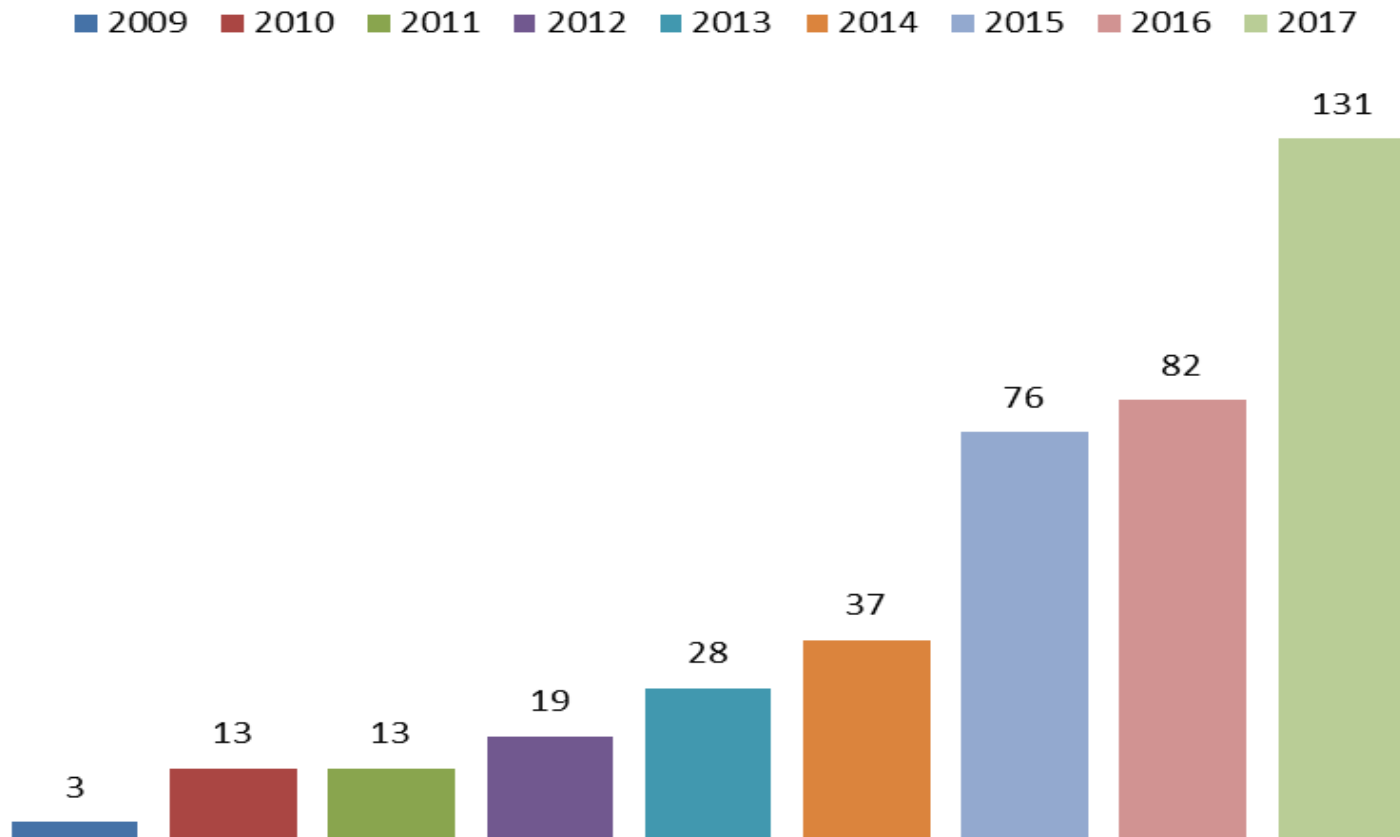
- Patients' organisations, national competent authorities, HTA bodies and payers have requested more information on the grounds for maintenance
  - Orphan Maintenance Assessment Report (OMAR) now being published
    - [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2018/01/news\\_detail\\_002885.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002885.jsp&mid=WC0b01ac058004d5c1)
    - Example Jorveza (budesonide) Treatment of eosinophilic oesophagitis
    - [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Assessment\\_report\\_on\\_maintenance\\_of\\_orphan\\_designation/human/004655/WC500241897.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_report_on_maintenance_of_orphan_designation/human/004655/WC500241897.pdf)
- Rare diseases, orphan medicines –
  - Getting the facts straight
    - Misunderstandings often arise about orphan medicines and how orphan designation is given. New questions & answers address some common ones
    - [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2018/02/WC500244578.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/02/WC500244578.pdf)

# Collaboration with patients: the EMA journey... so far



# Increasing the patient voice in SA/PA activities

Patients' involvement in scientific and advice and protocol assistance is increasing year by year. Collaboration with committees, and patient groups and support by the **Public Engagement Department Stakeholders and Communication Division** has played a pivotal role in this positive development





**COMP Raises Hands for Rare Disease Day!  
THANK YOU!  
DAN & LESLEY**