



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HCPWP / PCWP meeting: feedback from CHMP

Presented by Harald Enzmann (CHMP)

22 November 2017

An agency of the European Union





Summary

- CHMP opinions on new medicines (October-November)
- Patients' input provided (October-November)



Positive opinions on new medicines Oct – Nov 2017

Cancer

Name	Active S	Indication
Mvasi	Bevacizumab (biosimilar)	Metastatic carcinoma

Rx



EC

EC Authorised

EC EC decision pending



monitored (supervision) HCP



Orphan



Restricted prescription



Positive opinions on new medicines Oct – Nov 2017

Central Nervous System

Name	Active S	Indication
Ocrevus	ocrelizumab	Multiple sclerosis



Infectious diseases

Name	Active S	Indication
Prevymis	letermovir	prophylaxis of cytomegalovirus reactivation and disease





Positive opinions on new medicines Oct – Nov 2017

Gastroenterology

Name	Active S	Indication
Jorveza	budesonide	eosinophilic esophagitis



EC

Haematology

Name	Active S	Indication
Adynovi	rurioctocog alfa pegol	haemophilia A



EC



Positive opinions on new medicines Oct – Nov 2017

Respiratory system

Name	Active S	Indication
Fasenra	benralizumab	Asthma



Gynecology

Name	Active S	Indication
Intrarosa	prasterone	Vulvovaginal Atrophy





Negative opinions on new medicines Oct – Nov 2017

Cancer

Name	Active S	Indication
Onzeald	etirinotecan pegol	Advanced breast cancer whit brain metastasis

Central Nervous System

Name	Active S	Indication
Fanaptum	iloperidone	Treatment of schizophrenia



Interaction between CHMP, HCP and patients: SAG and Ad-Hoc Experts Groups

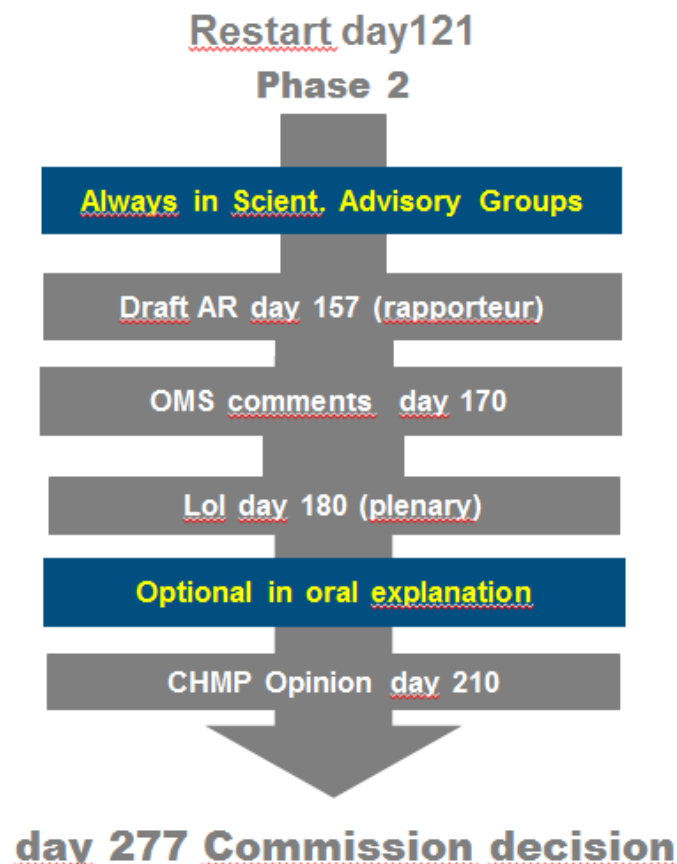
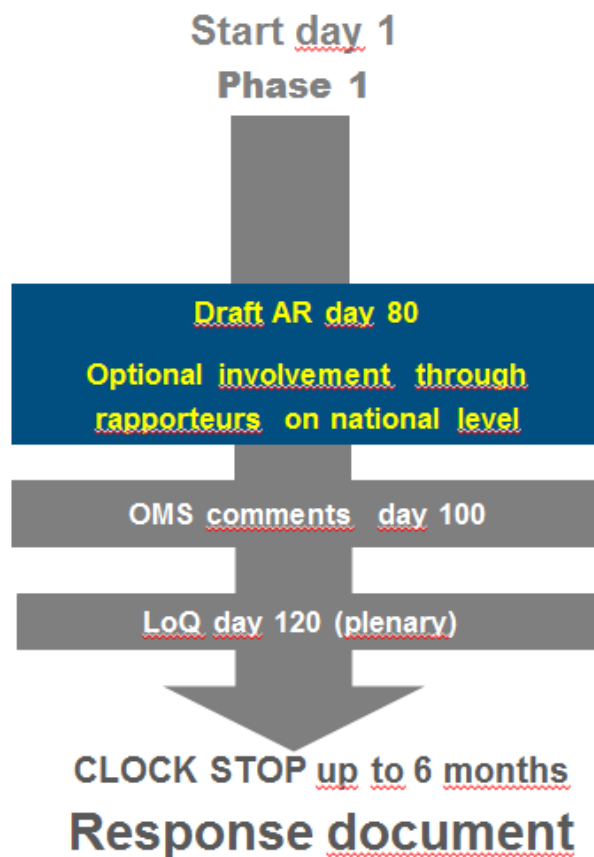
➤ Contributing for decision on recommendations

Name	Active S	Therapeutic area
Alcover	sodium oxybate	CNS
Fanaptum	iloperidone	CNS
Valproate		CNS
Zinbryta	daclizumab	CNS
Prolia	denosumab	Musculo-Skeletal
Blincyto	blinatumomab	Oncology
Opdivo	nivolumab	Oncology



End of 2017 - Where are we?

Patients' involvement in the regulatory assessment



AR: assessment report; OMS: other member states; LoQ: list of questions; LoI: list of outstanding issues



End of 2017 - Where do we want to go?

Patients' perspective and regulatory perspective

Regulatory decisions are for
medicines in defined indication



Evidence for positive benefit risk balance:
Scientifically sound and statistically
significant data demonstrating “net”
benefit of the medicine

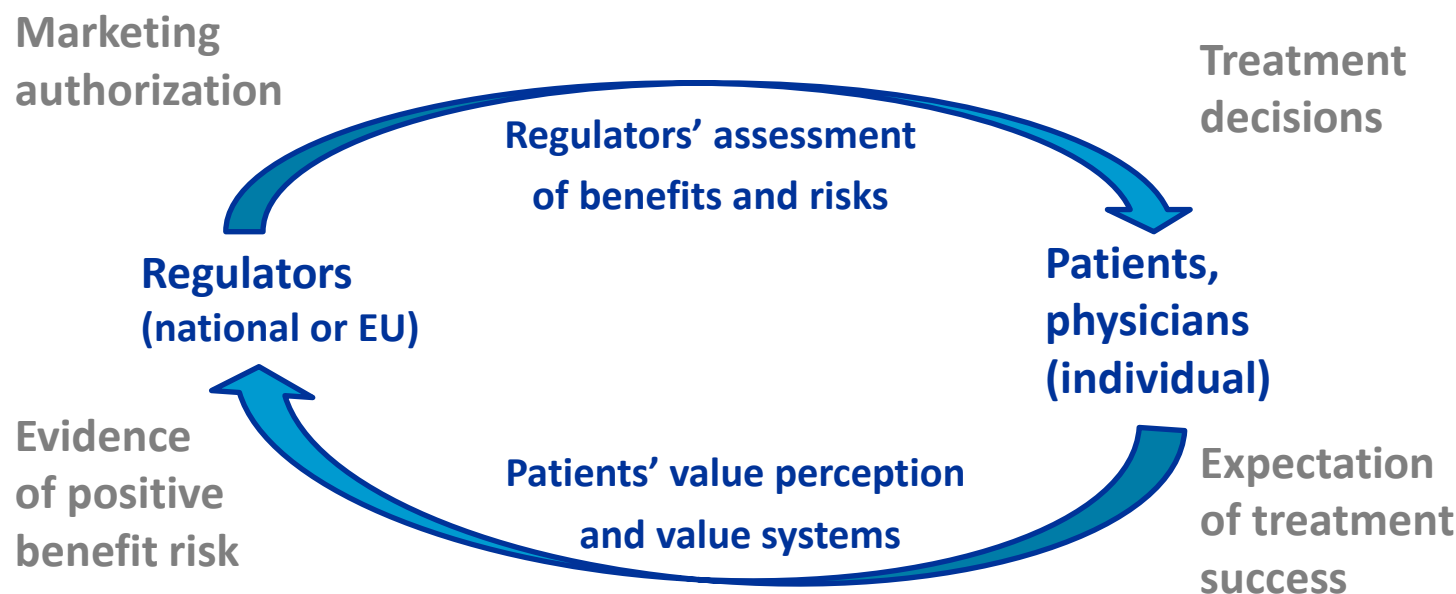
Treatment decisions are for
individual patients



Expectation of benefit:
Chance of benefit justifying risk of
harm (probabilities)

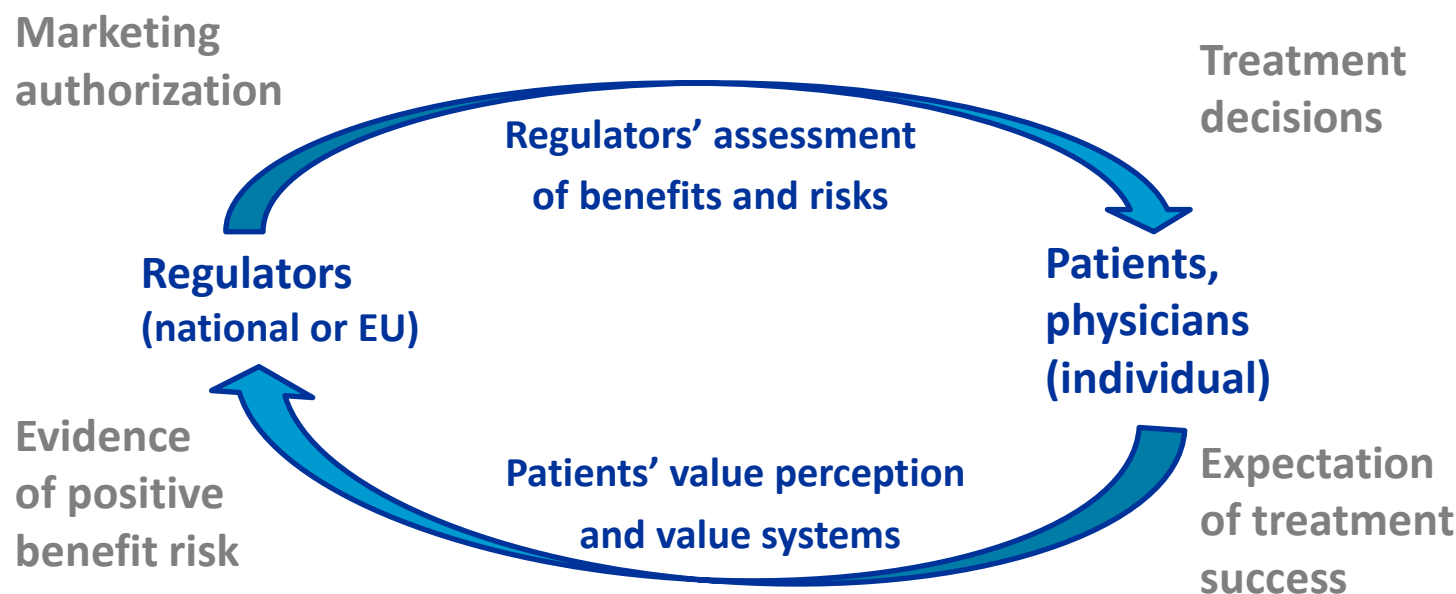


Patients' and regulators' two way communication





How to promote role of patients' perspective and advance beyond individual opinions?





Thank you!