



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The next 10 years

A regulatory view

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An agency of the European Union





Some headlines... I hope I never see
(and I am not playing with fear politics)

EU bureaucrats kill patient's hope

***Greedy industry push health system
to the limit***

National budgets insensitive to rarity

Patient's Icarus flight



The future

- It is on us, depends on our actions today
- Individual responsibility
 - Aim shared by different stakeholders
 - Even though we have different short term objectives

Responsibility to build on something that already works

Different stakeholders to play different roles

- keep pushing, but safely



Regulator's responsibilities / opportunities (I)

- a. Keep balance between development chances and data required (at designation and authorisation)
- b. Wise management of challenges
 - Sub setting policy (consistency and communication)
 - Biological advances and application for designation
- c. Transparency
 - Better communication on designation and SB
 - collaboration with Member states and HTA bodies



Regulator's responsibilities / opportunities (II)

d. Further assistance / incentives

- Pre designation assistance (?)

e. Advice to EC : full implementation of the COMP role (research and policy)

f. Monitoring orphan drugs:

- Development

- After marketing: registers, shortages of supply



The future as I see it (I)

- Debate about regulation (not future anymore)
- Need for in depth assessment
 - Legal advice (amendment?; to open all or part of text?)
 - What needs change
 - Risk assessment
- Increased transparency
 - Procedural / outcome
 - Development (clinical trials)



The future as I see it (II)

- Increased international collaboration
 - Development
 - Post marketing issues
- Consolidation of EU structure on rare diseases
 - Will strengthen rare diseases position
 - Opportunity to fight back misconceptions



The people / resources

We will need dedicated people (like you)

Ideas and challenges

Continuous support to Agency and fee reduction policy

Collaboration, discussion and more collaboration



And a big thanks to all those at the Agency
that made this possible....

Cinzia

Agnieszka

Patrick

Stiina

Eric

Agnes

Marco

Francesco

Melanie

Spiros Federica

Teresa

Florence

Bo

Channa

Marisa

Sandra

Monica

Johanna

Sarah

Frida

Thomas

Paolo

and
more ...

Cathrin

Juan

Stelios

Driss