BEUC The European Consumer Organisation

The Consumer Voice in Europe

Adaptive pathways:the consumers' perspective

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BEUC MAIN OBJECTIVES

- Ensure consumers benefit from **high quality** healthcare in all EU Member States
- Guarantee consumers have **timely access to safe and innovative** treatments
- Allow consumers to make **informed choices** regarding their health

ADAPTIVE PATHWAYS: MANY UNANSWERED QUESTIONS

1. What is the **scope** of the project?

- Unclear definition of "unmet medical need"
- "[…] *in the context of adaptive pathways, a broader acceptation of the term unmet medical need is considered*". (*EMA, final report, August 2016)*
- Faster approval procedures should be the exception, not the rule

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ADAPTIVE PATHWAYS: MANY UNANSWERED QUESTIONS

2. **How** will medicines **safety and efficacy be monitored**?

- Poor compliance with post-marketing studies by pharmaceutical companies *(Council Conclusions, June 2016)*
- Obligations imposed by EMA fulfilled with delays and discrepancies *(Adamski J. et al, 2010; Ferrario A, Kanavos P., 2015;Banzi, 2015; Hoekman, 2016)*
- "[..] *the challenge remains to identify sound strategies of real-world evidence collection to support assessment of both efficacy and effectiveness*." *(EMA, final report, August 2016)*
- Patients registries not fully operational yet

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ADAPTIVE PATHWAYS: MANY UNANSWERED QUESTIONS

3. How will **patients and doctors** be **informed**?

- The majority of patients overestimate the treatments benefits and underestimate their potential harm
- Patients affected by serious diseases revealed important decision-making deficiencies when compared with healthier patients
- Generally difficult to increase patients‘ awareness of higher risk associated to some medicines (ex. Black triangle)
- Excessive responsibility over prescriber physicians
- "[..] *For some of the proposals controlled prescription was feasible, while others were difficult to implement and manage*"
  (EMA, final report, August 2016)
- Difficult to withdraw unsafe and ineffective medicines

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ADAPTIVE PATHWAYS: MANY UNANSWERED QUESTIONS

4. How will patients be protected **in case of harm**?
   - Through Adaptive Pathways, risks are comparable to those in clinical trials but without similar guarantees (e.g. damage compensation)

5. How will these medicines be **financed**?
   - "*Clear challenge to the tools currently in use to assess a drug's value*" *(Luca Pani, Director General AIFA, August 2015)*
   - Critical positions from payers & HTA bodies
   - "[..]*The submission of plans on value proposition and reimbursement strategies has been limited in most cases. In some cases (..) the involved HTAs were not in a position to provide an answer.* *(EMA, final report, August 2016)*

ADAPTIVE PATHWAYS: MANY UNANSWERED QUESTIONS

6. What is the **ADDED VALUE** with regard to existing options?

- Accelerated assessment
- Conditional marketing authorisation
- Compassionate use

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Thank you for your attention!

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