Highlights of the expert meeting ‘adaptive pathways’/early access schemes

1 & 2 March, Amsterdam

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2016

Innovation for the benefit of the patient: early interaction between market authorization, health technology assessment and 'payer' in order to optimize patient access to innovative medicines

2016


Netherlands Presidency
of the Council of the European Union
2016

Why this meeting?

- EU Presidency Italy (2014): *innovation for the benefit of the patient*
- WPPHSL: better access to innovative and affordable medicines
- One of priorities Dutch EU Presidency: better access to innovative medicines for the benefit of patients at affordable prices

Four subpriorities pharma

- 1. Facilitate voluntary cooperation between EU Member States in the field of Pricing & Reimbursement
- 2. (Joint) analysis of unmeant and unwished incentives in EU market access legislation
- 3. Promote faster ways of (flexible) market access of innovative (essential) medicines, but under the right conditions.
- 4. Stimulate a European debate about the big challenges ahead in the field of pharmaceutical policy.

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Aim of the expert meeting

- Promote timely ways of (flexible) market access of innovative medicines, under the right conditions
- (Further) introduction and interaction between market authorization and HTA organizations, policy makers and payers
- Determine preconditions how adaptive pathways may help to get promising medicines to patients at affordable prices
- Shaping future policy in the field of adaptive pathways/early access schemes

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Three main questions

- For which products are ‘adaptive pathways’ useful and advisable

- Alignment procedures and requirements marketing authorisation and HTA (“how to stimulate cooperation”)

- Necessary conditions to come to acceptable outcome also for payer (“early interaction with payer, managed entry schemes, exit criteria”)

Some highlights

- Positive interaction between different experts and “getting to know” each other’s world
- Demand for better involvement of whole “chain” from beginning
- Upstream: already quite a lot of exchange of information between MA and HTA (more effective?)
- Downstream: complex as different health systems
- Also opportunities: common problems, alignment of patient registries, exit strategies, planning of RWD
- Managing expectations: EU level vis-à-vis patient level
- Followed by kick-off meeting of EUnetHTA (JA-3) and informal SAWP

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Next steps….

- CAPR meeting (23 & 24 March)
- Feed-back to HMA meeting (June 2016)
- Next follow-up meeting to be organized later this year?

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