Payer opinions in context

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EMA Adaptive pathways workshop

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Medicine Evaluation Committee

Payers want

- Control on volume (indication, start-stop, dose)

- Control on data (real life, transparent)
  - Agreement registry, definitions data, when assessed, consequences assessments, NL and EMA experience: dynamics 3-2-1 line therapy, near/off label, combination therapy, transaction costs

- No decline in quality of evidence

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Payers want

- Control on costs (adaptive reimbursement, mutually acceptable prices)
  - Initial prices, future prices (per country?), how to be paid (confidential?)

- Restrict use of MAPPs to special cases
  - Patients who cannot wait for clinical development & benefit/risk evaluation: deteriorate irreversibly or die. Or urgent public health protection. Major improvement expected

- Realistic exit strategy
  - Agreement, patients/doctors aware

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Some ZIN reflexions
(no 100% agreement all payers)

No accelerated uptake without accelerated exit

What defines suitable candidates for experiments?

- Measurable effects and knowing what the measurement result means (registry: include QoL)
- Agreement on degree of clinical relevance
- Right comparator
- Little delay between treatment and emergent results
- Clear alternatives, rapid implementation of decisions

Promote scoping and assuming co-responsibility

- Interested parties discuss before registration what outcomes will be considered (clinically) relevant

- What do you need to know?
- What do you need to measure?
- What constitutes convincing outcome?
- What pricing can we all agree on?
- Set milestones, when wath outcomes?

Collaboration in MAPPs requires guarantees

- Patients (and doctors) should agree in writing and sign in advance that
  - they agree on possible withdrawal medicine
  - they are informed about uncertainties of efficacy/safety

- Reimbursement level can be decreased and increased according to mutual agreed outcomes

- Market authorisation can be suspended or withdrawn

- Population/indication can be restricted

Paying during and after adaptive period

- Money for paying drug cost during adaptive pathways should come from an EU budget, assuring no differential prices in pilot MS
- Then after the full market authorization, all MS can conclude their own pricing negotiations (or do so together)
- A low starting price wil incentivize the industry to complete development a.s.a.p.
- And will give MS a better starting point for negotiations

Payment after performance, no pay back

- If conditions for generous payment *after* performance cannot be agreed upon, pay-back is probably also difficult to implement
- Easier than wrangling over pay-backs
- Strict criteria for performance
- What-if’s must be clear to all concerned

Thank you for your cooperation

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