Workshop Session

„Regulation, Reimbursement, Market Access“

CSA PerMed Workshop 1, Berlin 27./28.03.2014

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„Regulation, Reimbursement, Market Access“

What is different ?

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„Regulation, Reimbursement, Market Access“ (2/3)

regulatory need: safety, risk ...

1. Systematic early dialogue for informed policy-making

1.1 Decision Maker (DSM) – HTA
1.2. Manufacturer – HTA
1.3. Manufacturer – HTA – DSM
1.4. Manufacturer - Manufacturer

„Regulation, Reimbursement, Market Access“ (1/3)

regulatory need: safety, risk ...

2. Data („big data“)
- Ownership (citizen owned and controlled), handling, access, open source field, silos
- different purposes/users (beyond health), HiAP
- algorithm user‘s responsibility (validation, regulation, different policies)
- „bottom-up“ policy-making

„Regulation, Reimbursement, Market access“ (3/3)

3. Assumption of non-linearity/dynamics of information - complexity

„momentum“: no prediction of risk/phenotype possible, no indication, no validation possible – regulatory need??

4. product/diagnostics versus process/tools (medical device) – no regulatory need...

5. Outcome data: feedback from market back to DSM (conditional approvals, adaptive licensing and conditional reimbursement

„Regulation, Reimbursement, Market Access“ (3/3)

Research on the adequacy of current regulatory pathways and development of new regulatory and legal frameworks for personalised medicine/healthcare

Systematic early dialogue between all key stakeholders and across sectors