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Ad Schuurman, Zorginstituut Nederland (ZIN)

Bridging the regulator and the payer world, how far are we?

Payer & EMA collaboration

- Horizon scanning
- Information sharing
- Indication and labelling
- Early dialogue
- (high) Unmet medical need

Horizon scanning

- EUnetHTA uses this information for prioritisation of activities
- Payers can prepare collaboration (Beneluxai, Valletta,…) on coming assessments and price negotiations. Monopoly? Upcoming competitors?
- Prepare for new methodology if technology is new (e.g. Gen-therapy)
- Increasing predictability extension of indications
- Planning treatments and budgets in hospitals

Indication and labelling (1)

Awareness at EMA

- Compare new treatments with existing ones
- Pressure on off-label use
- Possible impact of EMA decisions

Indication and labelling (2)

- Transparency on approved populations
- Usefulness of considerations on non-approved indications
- Choosing a suitable comparator in late-stage clinical trials
- More clarity on the meaning of references within an SPC

Real adaptive future

- Need an approach with default reimbursement levels
- For poorly proven but promising products
- That obviates the necessity for industry to take patient hostages
- Everybody can have access to products at registration
- At low default reimbursement levels
- That may go up provided solid pre-agreed outcomes are achieved

Important for EMA and HTA/Payer

- Early: agreement on common registry, data needed for each stakeholder
- During authorisation: pre-agreed outcomes, EMA conditions, payer reimbursement levels
- Post: full commitment on data for pharmacovigilance. Possible withdrawal of license and/or reimbursement

Thank you

Aschuurman@zinl.nl

Adrianus.schuurman@ema.europa.eu