



European
AIDS Treatment
Group

Innovation in areas of unmet medical need

Innovate, assess, access

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HIV: A lot went well

- ✧ Expanded access / compassionate use (FDA, 1987)
- ✧ Accelerated approval in life threatening indications (FDA, 1992)
- ✧ Use of surrogate markers instead of clinical end points in pivotal trials (EMA, NVP approval 1997)
- ✧ New criteria for conditional approval (Gilead first to apply, access almost 12 months accelerated)
- ✧ Cross-Atlantic lobbying for pivotal trial including 2 NCE, ending exposure to monotherapies and multidrug resistance 2007
- ✧ Single tablet regimens for convenience and adherence, while having single compounds to control toxicities, resistance and adapt drug levels

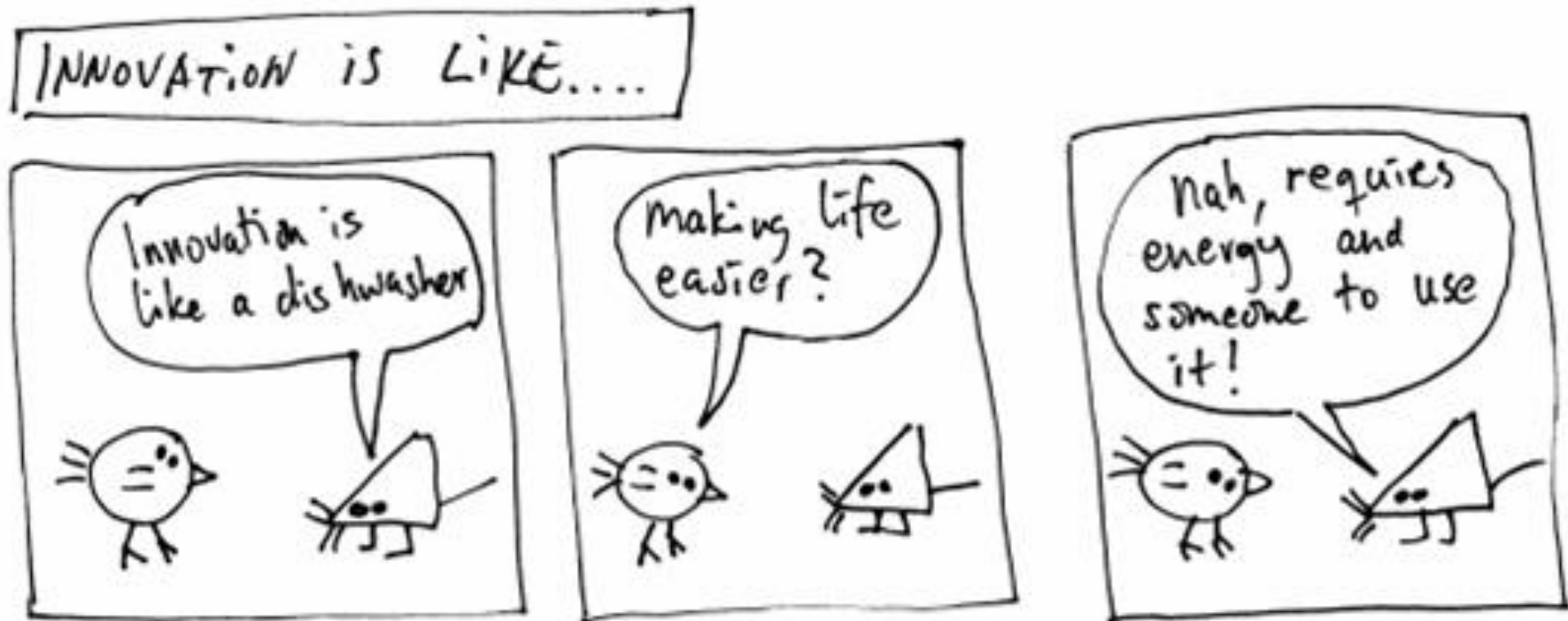
HCV – the silent epidemic

- ✧ DAA and combination treatment: Biggest scientific breakthrough for patients since HAART introduction
- ✧ Much shorter treatment cycles, much less toxicity, a lot more effective & even cheaper
- ✧ Interaction with regulators and industry since 2007
- ✧ Despite all this: bumpy reimbursement at national level while patients continue to die
- ✧ Interesting: HTA bodies assessment in conflict (German IQWiG versus HAS & Scottish Medicines Consortium; Scotland faster than NICE) – apparent methodological discrepancies and challenges
- ✧ Current system aims too much for perfection and cost containment; fails on robustness.
- ✧ Many new drugs STR only – Gilead, Abbvie, MSD – leaving many patients without treatment options and kicking important single compound competitors out of market – HCV treatment is some weeks, not life long!

What do we need

- ✧ Forget about aiming for perfection – focus on clear & agreed priorities:
 - ✧ Develop effective medicines
 - ✧ Assess properly and timely
 - ✧ Get medicines to patients quickly
 - ✧ Have patients use medicines safely
- ✧ Agree on HTA methodology in Europe
- ✧ Establish EARLY & ONGOING dialogue at EMA along product life cycle
- ✧ The secret of true innovation is that it pays out quickly; lack of stability and delaying access is poison for innovation
- ✧ A robust system, strong and trusted to face challenging situations – have the priorities right and muddle through wisely

Simple wisdom



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