Strengthening the checks and balances in the EU pharmaceutical system

Outcome of the Dutch EU Presidency 2016

Maurice Galla – Senior Policy Officer/ EU Presidency Coordinator – Directorate for Pharmaceuticals and Medical Technology – Netherlands Ministry of Health

Priorities Dutch EU Presidency

Key theme: Strengthening checks-and-balances in the pharmaceutical system

- Improve voluntary cooperation and exchange of information on pricing and reimbursement between Member States
- Support timely access to new, essential medicines by clarifying conditions and exit options
- Initiate debate on unintended effects of current incentives in EU pharmalegislation and their impact on innovation and costs
- Strategic debate on cooperation on future challenges and directions for pharmaceutical policy in the EU

Related key priorities: Medical Devices and in-vitro diagnostics and AMR

Meetings during NL Presidency

Political level:

- Informal meeting of Council of Health Ministers and formal EPSCO Council

Policy and technical level:

- Meetings of Directors responsible for pharmaceutical policy in Member States
- Conference on timely access to innovative and affordable medicines
- Competent Authorities for Pricing and Reimbursement (CAPR)
- Meeting of the European Network for Health Technology Assessment (EUnetHTA)

Industry:

- Round Table on pharmaceuticals between EU ministers and CEO's industry

Why was this a priority?

The positives

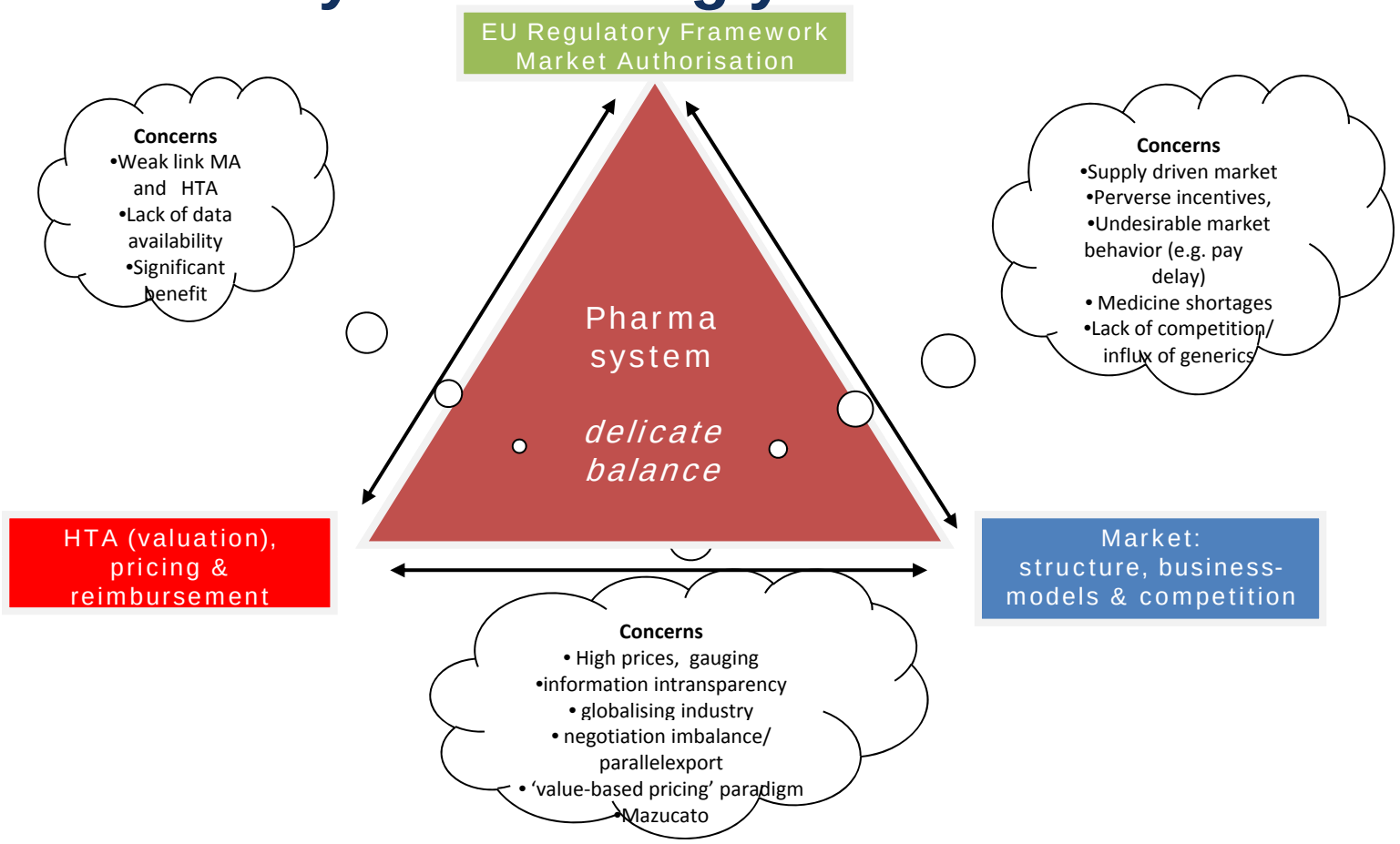
- EU pharmaceutical system (public & private) is innovative; provides safe and effective medicines for the majority of its citizens
- ‘Special’ legislation for rare diseases and paediatrics have generated a variety of new pharmaceuticals that improve and save lives
- EU Member States can decide themselves what pharmaceuticals they wish to pay for, adjusted to national needs
- EU has an important and relatively innovative pharmaceutical industry
- Public investments into R&D stimulates innovative and viable pharmaceutical products

Is pharmaceutical system out-of-balance?

The concerns

- Increasing mismatch between marketing authorisation topped up by incentives supporting innovation versus affordability of and access to final product
- Increasing focus of industry on development of (new) pharmaceuticals for smaller patient groups with high earning potential, not necessarily for unmet medical needs
- Essential medicines not available to increasing number of EU patients due to unaffordable high prices, withdrawals due to low revenues or (too) small markets
- Governments act individually, while counterparts act globally; information asymmetry
- Examples of socially undesirable or irresponsible behaviour
- Public investment R&D often does not benefit public interest (tax payer pays twice)

Pharma system strongly interconnected



Informal Meeting of Health Ministers

- Several Member States agreed with analysis that imbalances exist in the pharmaceutical system and that action is needed
- Support for voluntary cooperation on pricing and reimbursement, e.g. between economically similar countries
- Support for assessment of the (un)intended effects of intellectual protection and additional incentives in the pharmasystem

But:

- Voluntary cooperation should have clear added value; decisions on pricing & reimbursement remain MS prerogative
- Tackling of unintended effects incentives should not discourage innovation
- There should be a dialogue with industry

Council Conclusions

Strengthening the balance in the pharmaceutical systems in the EU and its Member States

Main aims council conclusions

- Political statement – recognition that imbalances exist in pharmaceutical system
- Address pharmaceutical system as a whole, with interlinkages and cross-silo/ pillar (spill over) effects
- Aiming at ‘rebalancing’ the system to make it work as intended – legislation, innovation, incentives and national policies
- Initiate longer-term strategic cooperation to ensure consistency and continuity, ownership by all Member States

Actions for Member States

- Invest in voluntary and Member State driven cooperation on pricing and reimbursement
- This through joint activities, information sharing, joint negotiations with selected countries and cooperation on HTA, including through EUnetHTA
- Strategic policy reflection and exchange between Member States
- Development list of shared challenges and actions for 2017-2020, targeting the pharma system as a whole and its interrelations
- Collaboration accross the system to ensure follow up actions

Actions for Member States & Commission

- Cooperate together and set clear and enforceable (pre-)conditions regarding the use of early access tools
- Further develop cooperation on Health Technology Assessment at EU level
- Improve and strengthen dialogue and cooperation in existing fora in the field of pharmaceuticals, while also assessing their relevance, functioning and added value
- Invest in essential R&D to address unmet medical needs and registries
- Also promote open access to data and ensure fair return on investment of successful publicly funded research

Actions for the Commission

- Streamline implementation orphan regulation; ascertain proper application rules, incentives and rewards; revise if necessary
- Create overview of EU pharma legislation in relation to IP related incentives and their intended purpose
- Analyse effects of these incentives on innovation, accessibility, availability and affordability of medicines, as well as price strategies of industry
- Analyse functioning of the EU pharma market in terms of transparency, market behaviour and competition and strengthen market oversight
- Recommend possible remedies in context of agenda 2017-2020

Thank you!

ms.galla@minvws.nl