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European Confederation of Pharmaceutical Entrepreneurs AISBL

13 February 2019

EURORDIS SYMPOSIUM

***Breakout session 3*, 14 February 2019: "a transparent EU cooperation framework between national healthcare systems for the determination of fair prices and of sustainable healthcare impacts"**

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Question a) "Can a collaborative framework for negotiation be put in place?"	
What we understand (or reasonably assume) the expectations and "endgames" of EURORDIS are • Pushing for greater collaboration and partnership. • Short-term: to the industry for a **strong political signal that, to some extent, it is embracing the concept of a EU-wide negotiation process** to later on gain support from the national and European decision-makers. To do so, EURORDIS is willing to cut down on their expectations and apply a staggered approach, by focusing on very rare diseases.	
Aspects with which we can reasonably agree	• A collaborative framework can certainly be put in place, as long as the purpose is to accelerate and expand patient access (faster / broader). • Already much collaboration happening: National level: P&R negotiation = an effort by payers and developers to collaborate and compromise towards a successful outcome – patient access Regional initiatives: BeneluxAI, FINOSE, Valetta…MoCA, etc.
Aspects with which we could potentially agree under well-defined conditions	• Main question: **what is the greater purpose of that collaboration is** ≠ a means to an end, i.e. lower prices = value determination and patient access • A true and genuine collaboration requires full, unquestioned agreement on basic pillars. ⇨ Before launching a grand scheme -> pilot! (voluntary, not lead to additional negotiations which are locally-led) **Backup: principles include** • risk-taking and transformative innovation deserve to be rewarded. • EU table of negotiations should facilitate value-based pricing discussions, recognise that the value may precisely differ across countries (differences in economic powers, willingness to pay, health priorities, value criteria) • ORPH-VAL principles
Aspects with which we must disagree	• **joint purchasing**, with which EURORDIS is flirting in their White Paper 2018. • Cost-plus pricing or margin regulations, which would drive innovation in the wrong direction and ultimately further hamper patient unmet needs • EU table of negotiation difficult to swallow for MS (cf HTA proposal). Suggestion to reframe and propose an EU table of cooperation (on research, cross border HC implementation, ERN stabilization within the national HC systems, paid access mechanism whilst in negotiation processes, evidence generation)

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Question b) "How do we negotiate a fair price at EU level, based for example on experience such as MoCA?"	
What we understand (or reasonably assume) the expectations and "endgames" of EURORDIS are EURORDIS critical of the fact that value assessments and price negotiations for OMPs are firmly kept at the national (or sometimes even sub-national) level, which lead **to widely discrepant assessments on the value or benefit of a same product**, but also to wide variations in the willingness to pay and in the reimbursement status of the product in questions.	
Aspects with which we can reasonably agree	• EU cooperation is feasible. Cf MoCA: proof that joint discussions between developers and various payers can take place to evaluate the value of a new product. • Cluster of countries with the same value framework, health priorities and similar GDP/capita. •

Aspects with which we could potentially agree under well-defined conditions	• Fair price definition. fair ≠ low. Even the WHO Director General Dr Tedros said it last year!!!
	• Need to agree on common principles, priorities and criteria for fairness. Methodology to define fair price.
	• Use of the ORPH-VAL principles to guide value determination and P&R of the OMP
	• MoCA+ on valuation (mechanism to assess value) rather on price -> changing the scope and name of the roundtable setting.
	• After definition work on fairness, cross-country collaboration to follow criteria, such as:
	  ○ Demonstrated faster & broader patient access through a fact-based comparison of patient access benefits following the CCI process v. national process
	  ○ Net price confidentiality guaranteed
	  ○ Collective agreement should not impose additional access barriers or limit patient numbers
	  ○ Cluster (see above)

Aspects with which we must disagree	• A single European fair price. technically impossible. And maybe Member States will not be receptive to the idea. • Even if agreement on model for value determination of an OMP, possible further disagreements on the quantification of this or that criterion in the mix – e.g. patient experience or quality of life, societal burden, etc. **Moving to one table of negotiation only does not fundamentally solve that problem.** • Question of initiative overload: avoiding duplicating already-existing initiatives. Rather replace existing (inefficient?) mechanisms and initiatives which would anyways become redundant at national level -> avoiding duplication, additional costs. • One question would also be, how do we negotiate for products with evidential uncertainty? Although we could see some positive signs of having, e.g. registries at a EU level rather than national level, what would it mean for renegotiations?

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Question c) "Can collaborative and voluntary experiences such as BeNELuxA be scaled up and made sustainable?"	
What we understand (or reasonably assume) the expectations and "endgames" of EURORDIS are Please expand…	
Aspects with which we can reasonably agree	• pooling up of countries that are reasonably comparable in socio economic terms, but also that have reasonably similar (and similarly structured and functioning) healthcare systems.
Aspects with which we could potentially agree under well-defined conditions	• Observation: existing platforms are run by decision-makers employed by each of the participating national authorities and groups like Beneluxai come as another time and resource commitment on top of their own day jobs, on top of the work already done by INAMI-RIZIV, ZIN, etc. • "scaling up" = need for more resources, more staff, etc. ⇨ Just like the EMA with scientific advice: **participative model whereby a company would pay fees to the said platforms whenever one of its products is being reviewed by it?** • need for basic rules of conduct / guiding principles.
Aspects with which we must disagree	• bottleneck could well be the national payers more than the industry. • "scaled up" meaning? - Horizontally: extending a platform to more countries. Danger if no longer a balanced cluster of countries (economic, health priorities, HC systems organisation) - Vertically: deepened existing collaboration & more united decision-making on more aspects of drug reimbursement and purchasing? • Scaling up in the remit and competence of governments to decide and act upon. no industry say except for **the need to pool together countries that are reasonably comparable in socio economic terms**, but also that have reasonably similar (and similarly structured and functioning) healthcare systems. • If scaling up would turn out to mean slower and more complicated decision frameworks, with the only consequence of further delaying patient access, then no, scaling up is not such a desirable proposition.