

Innovative Payment Models and Structuring Contracts

Marieke Jansen, Head Legal Cell, and Gene Europe, **Novartis**

Adela Williams, Partner, **Arnold & Porter LLP**

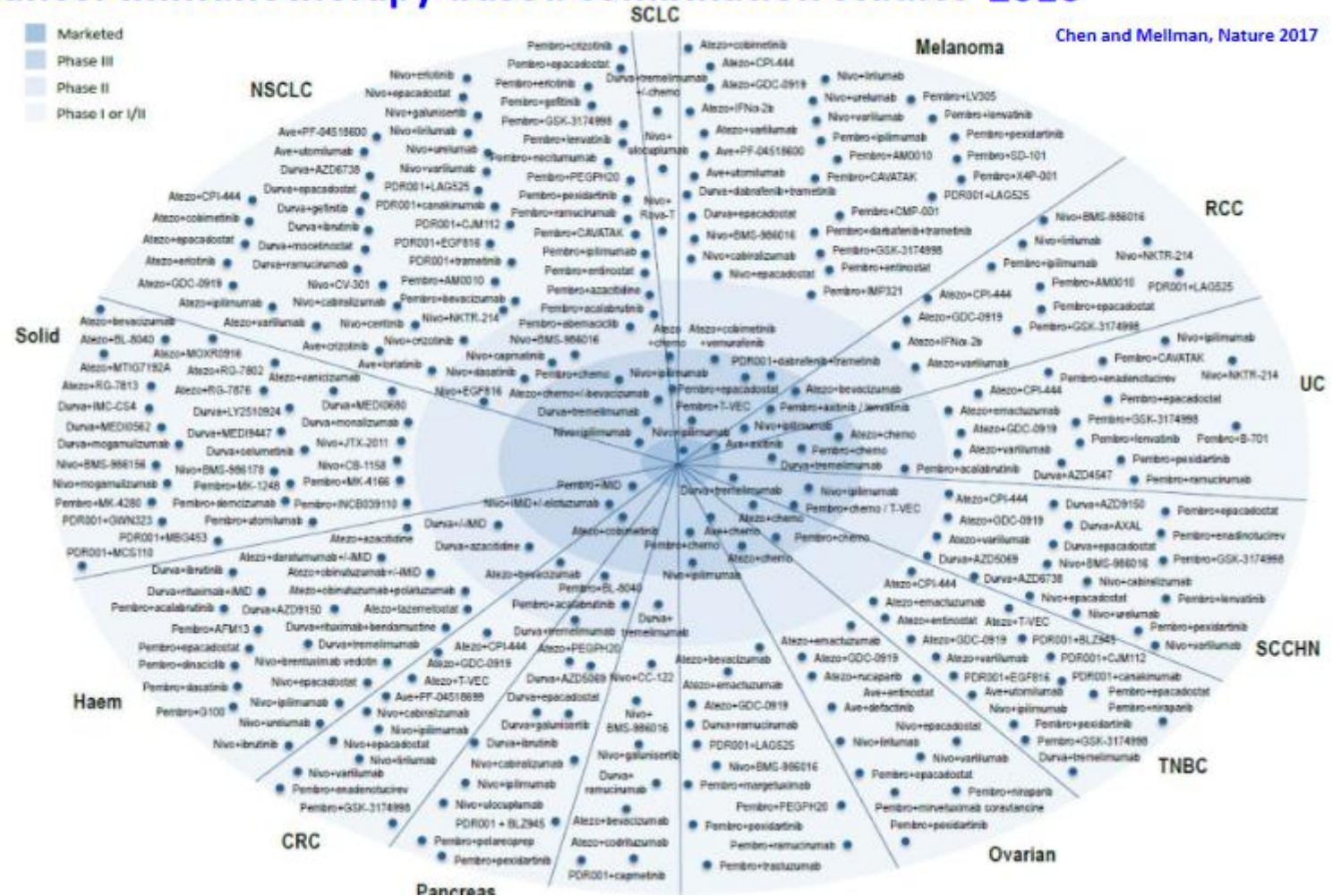
Alexander Roussanov, Partner, **Arnold & Porter LLP**

Jordi Faus, Founding Partner, **Faus & Moliner**

Christian Jervelund, Managing Partner, **Copenhagen Economics**

Cancer immunotherapy-based combination studies 2016

Chen and Mellman, Nature 2017



Sustainability requires changes

Changes imply challenges

What are we talking about? = improve access to drugs in a sustainable manner

- **Legal challenges:**
 - a) Administrative acts of power or agreements inter pares.
 - b) Public procurement issues.
 - c) Access to market after MA but prior to completing P&R.
 - d) Transparency.

- **Structural challenges:**
 - a) Cultural barriers. Investment versus expense.
 - b) The critical question: "Why don't we?"

Some important principles not to be forgotten

- MA decisions are independent from economic considerations (ECJ 1984; Clin Midy).
- Member States are allowed to control public expenditure but obliged to respect Directive 89/105/EEC (ECJ Com. c. Austria, 2001; c. Finlandia, 2003, Menarini et al., 2009, Servier 2015) = Control measures cannot discriminate (ECJ 1983; Roussel) and criteria must be objective and verifiable (ECJ 1984; Duphar).
- Need to ensure equity where payors are diverse even in the same Member State.
- Patients may seek protection under rules that apply to fundamental rights under national law or International treaties (the fundamental right to life and physical integrity versus public health protection as a guiding principle).

Legal Challenge 1: Administrative acts of power or agreements inter pares

- Agreements offer an scenario that acts of power cannot provide.
- A system based on administrative acts of power is dangerous regarding institutional loyalty.
Who does what? The traditional MA approvals and HTA.
- Agreements offer flexibility: sophisticated clauses, monitoring and dispute resolution systems.
- Contesting administrative acts of power tends to be very difficult.

Legal Challenge 2: Public procurement issues

- Public procurement rules offer little flexibility to define the subject matter of the contract.
- Which is the right angle to define the relevant market for innovative products not subject to intra-API competition?
- Do we need public procurement procedures after price & reimbursement rulings?
- Deferred payment schemes are a problem.

Legal Challenge 3: Access to market after MA but prior to completing P&R

- Information to HCP's and HCO's (non-promotional or promotional).
- The need to revise the role of national regulatory agencies on named patient programs for products that have already received an MA (cfr. compassionate use or authorization to use an unapproved product).
- Financial issues. Supply for free or at a price?

Legal Challenge 4: Transparency

- A lot of discussions in Spain:
 - R/079/2019 (Kymriah)
 - R/478/2019 (Hyrimoz)
 - R/888/2019 (Vareniclina)
 - SJCCA 39/2020 on individual hospital consumption including purchase Price.
- Contracting bodies need clearance from transparency authority not to publish full details of contracts.
- Is freedom of information an absolute principle?

Structural challenges

- Need to put aside easy messages, i.e. efficiency (effectivity/cost) and effectivity (real life data) versus efficacy (clinical trials and MA's).
- Risk sharing is something different from total risk transferring. Back to basics and lessons learned from agricultural policies.
- Focusing on short-term expense is easier than focusing on investment. Discounts and caps versus more sophisticated schemes.

Some ideas derived from Spanish recent cases and initiatives

- Restrictions on eligible patients for complex treatments (based on clinical trial inclusion criteria).
- Enrolment of external experts when defining target results.
- Regional payors take the lead on monitorization of results, with MOH having a coordination role.
- Payments conditional on results and total cost also subject to caps based on company forecasts (actual figures are not disclosed).

Thank you!

Jordi Faus

jfaus@faus-moliner.com

www.faus-moliner.com