Industry Perspective

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How it all started?
Realization of competing objectives

- Allow timely access for patients to address urgent medical need
- Enable precision medicine, ‘difficult’ indications
- Ensure sustainability of the innovation engine

- Allow only well-studied drugs on the market
- Rely on robust study methodology and end points
- Ensure sustainability of health care systems

Source: Eichler H. EMA - Medicines Adaptive Pathways to Patients (MAPPs).
**EMA Evolution of thinking**

Licensing is necessary but not sufficient

Adaptive Licensing

Adaptive Pathways to Patients

“MAPPs seeks to foster access to beneficial treatments for the right patient groups at the earliest appropriate time in the product life-span in a sustainable fashion”.

from the mission statement for Accelerated Development of Appropriate Patient Therapies a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes

Source: Eichler H. EMA - Medicines Adaptive Pathways to Patients (MAPPs).

**MAPPs what does it mean?**

“Flexible development and access pathways within the current regulatory framework that balance early patient access, public health and societal benefits”.

How is MAPPs different from Current Pathways?

• An early authorization of a product in a well-defined and targeted patient population with a clear safety and efficacy profile
• The target population is adjusted as additional evidence becomes available
• MAPPs relate to the entire life cycle from development, through licensing to patient access

Source: EFPIA - Medicines Adaptive Pathways to Patients (MAPPs): Saving Time, Saving Lives
Who stands to benefit?

Industry
- Continuous reduction of uncertainty throughout product lifecycle
- New risk management paradigms that may restore public confidence
- Earlier revenue stream & staggered development costs
- Decrease risks of (costly) late stage failures and post-market withdrawals

Payers
- Adaptive reimbursement to align value with price and utilization
- Continuous risk/benefit information flow to better support coverage decisions
- Earlier access to promising new medicinal products
- Lower realized harm

Patients
- Earlier access to promising new medicinal products
- Lower realized harm

Regulators

Source: Eichler H. EMA - Medicines Adaptive Pathways to Patients (MAPPs).

"Think different"

- from a “silver bullet” to a life-span management
- from RCTs only to a toolkit for evidence generation
- from big populations to small populations
- from focus on licensing to focus on patient access
- from open utilization to managed utilization

Source: Eichler H. EMA. Medicines Adaptive Pathways to Patients (MAPPs).
From Industry, Regulators, Payers...

Evolution of the MAPPs “Ecosystem”

...To Industry, Patients, Payers, Providers, Regulators

EMA - Medicines Adaptive Pathways to Patients (MAPPs)
The Drug Innovation Paradox
Likelihood of drug approval and R&D reward

Yet, with major contributions to health
The Checkpoint Immunotherapy Revolution

Check point antibody inhibitors have over 1,000 trials underway. These checkpoint blockers are rapidly becoming a highly promising cancer therapy that yields remarkable antitumor responses with limited side effects.

Survival in 2L-CT MCC patients is poor (mOS: ≤5.7m and 12m OS: 0%) with low and short lived response rates (ORR: 9-23% and DDR ≥6m: 0%). In experienced patients, more than half who received Avelumab are still alive at 1-yr with ORR of 33% and DDR ≥6m: 31%

But is about halfway through... US, EU and LATAM Regulator timelines


And there are some caveats in LATAM CPP, μ approval time, ODD, Parallel submission

Temporary options “the lesser of two evils”

Access to cancer medicines
The case of Colombia – Market Authorization

Obtaining registration for a new product takes on average 22 months

Cancer drugs take the longest time (26 months) because of the pharmacological evaluation

Source: IMS Consulting Group - Colombia’s access to medicines within the OECD countries’ context (2016)
Access to cancer medicines
The case of Colombia – Patient Access

Only 6% of the launched products obtained POS (Mandatory Health Plan) listing

Few NMEs in OECD countries require ≥18 months for inclusion – in Colombia the average is 2.7 years

Source: IMS Consulting Group - Colombia’s access to medicines within the OECD countries’ context (2016)

Opportunities to expedite the regulatory and reimbursement process during the lifecycle of a medicine in LATAM

Pre-submission
- LATAM agencies should continue to provide the opportunity for these meetings on a case-by-case basis.
- Clarity in requirements: LATAM regulators should clarify chemistry, manufacturing, and controls (CMC) requirements as they are issued, especially as they apply to the CTD.
- Authority-industry workshops: Industry and agencies should continue to conduct workshops as a vehicle for the communication of requirements and expectations of both stakeholders.

Review process
- Priority/accelerated review pathways: LATAM agencies should start developing these pathways, as their capacity and experience increases.
- Risk-based review: Authorities should continue providing the opportunity for acceleration for certain products.
- Specialised review by product/country: Clinical/technical review approach.
- Convergence in international standards:

Approval
- Better collaboration across agencies.
- Post approval commitments: Similarly to priority pathways, post-approval commitments may play a role in the reduction of review time in the future.

Post-Approval

**EMA - Medicines Adaptive Pathways to Patients (MAPPs)**

**Process map model – Step 1**

Step 1: This model indicates the construction of the first step of the process maps. The Sponsor is shown in red and the connections with the agencies are numbered to indicate the typical order in which these contacts occur. The Agencies are shown in blue with external connections in white and external connections in blue. The light blue shading indicates those agencies that are within the national level government.

**Process map model – Step 2**

Step 2: Seven functions that represented significant measurable key components of the system were defined and then mapped onto the agencies that conducted those functions in order to show where in the system such functions occurred and how they related to one another.
Step 3 - For the HTA function, a "task bar" of key activities was developed in order to characterise a selection of defining elements of the HTA process. Each activity was given an identifying icon that was shown in the HTA task bar if it was a normal part of that agency's actions.