ANALYSIS OF EXCUSES - ACHIEVING ACCESS ON DAY 1 FOLLOWING EUROPEAN COMMISSION AUTHORISATION

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OBJECTIVES

To identify barriers to patient access in Europe and ways in which access could be achieved on day 1 of European Commission (EC) authorisation.

METHODS

Analysis of EFPIA Patient W.A.I.T. Survey and the European Access Hurdles Portal. Hypothesising and evaluating alternatives that would allow access as soon as a drug received authorisation by the European Commission. Exploratory Monte-Carlo simulation of pricing, access, and uptake from national and pan-EU perspectives under various "day 1" access algorithms.

RESULTS

The Patients WAIT Indicator Survey[1] and analysis of the European Access Hurdles Portal[2] indicate declining availability and increasing access delays for new drugs in Europe. The root causes are identified as process delays (**assessment and appraisal**), delays due to health system readiness (**affordability and willingness**), and the **commercial decisions** of pharmaceutical companies.

"Day 1" access solutions could involve algorithmic approaches to setting an initial price. These do not need to be complicated.
Given the **P (population), I (intervention), C (comparator), O (outcomes)** focus of Joint Clinical Assessment **(JCA)** it would be relatively simple to set a cost neutral initial price, with subsequent later adjustment for value, using "**Lower bound PICO model(s)**". These would assume non-inferiority to standard(s) of care and factor in budget impact neutrality and include other specific predetermined variables within the algorithms:

Disease Severity / Burden	Unmet Need / Degree of Innovation	Uncertainty in outcomes	Relative Clinical Value (RCV)	Competitive Intensity
•High •Medium •Low	•High •Medium •Low	•High •Medium •Low	•High •Medium •Low	•High •Medium •Low

At the end of a time limited negotiation process an adjustment would address the difference between the price applied and the negotiated price. Failure to achieve a negotiated price would be addressed through a pre-agreed industry arbitration process that trades off the benefits of early access with affordability considerations.

Exploratory Monte-Carlo simulation of pricing, access, and uptake, comparing the current national level pricing and access systems with various alternative access scenarios, indicated that day 1 access algorithms based on "lower bound PICO model(s)" have a high probability (>80%) of a win-win-win for all parties defined as overcoming the challenge of short-term affordability **(a payer win),** delivering higher NPV of national level revenues **(a pharma company win**) and achieving better cumulative health outcomes **(a patient population win).**

Access prior to Regulatory Authorisation	Access on day 1 following EC authorisation	Access on day 1 following JCA publication	Access delayed until completion of National pricing and reimbursement processes
• Not Applicable	• Best for 20% of products • High Severity, High Unmet Need, Low Uncertainty, High RCV, Low Competitive Intensity	• Best for 50% of products • High/Medium Severity, High/Medium Unmet Need, High-Low Uncertainty, High/Medium RCV, Low/Medium Competitive Intensity	• Best for 30% of products • Medium/Low Severity, Medium/Low Unmet Need, High-Low Uncertainty, Medium/Low RCV, High/Medium Competitive Intensity

The simulations assumed the existence of a simple rapid high level **Joint Access Appraisal (JAA)** running in parallel with, and complementary to, JCA. JAA would establish an early consensus on burden/severity of disease, level of unmet need/degree of innovation of the technology, and competitive intensity (with outcomes uncertainty and RCV coming from JCA) and would allocate 1 of 4 access routes for a product:

1. Access prior to Regulatory Authorisation	2. Access on day 1 following EC authorisation	3. Access on day 1 following JCA publication	4. Access delayed until completion of National pricing and reimbursement processes
• Existing regulations • Named patient • Emergency situations (eg Pandemics)	• Priced under "lower bound PICO" assessment	• Maximum 40 days after European Commission approval • Priced under "lower bound PICO" assessment	• This is the current situation for the majority of new drugs • Current average delay across EU = 531 days[1]

To achieve a "win-win-win" at both national and pan-EU levels, the issues of **differences in affordability between member states, International Price Referencing (IPR), and parallel trade** need to be addressed. **Equity Based Tiered Pricing (EBTP)**[3] is one potential option for addressing this.

CONCLUSIONS:

Politicians, Policy Makers, Payers, and Pharmaceutical Companies appear to be **covertly guilty of delaying patient access** to new drugs whilst **overtly claiming they seek faster access**.

The published root causes of delay and non-availability[2] are mainly "excuses". The overarching cause of delayed access is the intricate dance between Payers and Pharmaceutical Companies. This standoff often leads to a lose-lose situation where the true victims are the patients. If we shift our perspective from a zero-sum finite game to an infinite game[4] a healthcare system can be built where collaboration replaces conflict, and where the ultimate winners are the patients and their health outcomes.

JCA will bring efficiency benefits but will not be sufficient to reduce time to access. A simple complementary high level **Joint Access Appraisal (JAA) is needed to facilitate this goal**. With JCA, JAA, and the willingness and desire of all parties in place, "day1" access should be achievable. **Where there is a will there is a way**.

References:

1. https://www.efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf
2. https://www.efpia.eu/media/0m4pswzd/european-access-hurdles-portal-2024-cra-report.pdf
3. https://www.efpia.eu/media/676587/ebtp-efpia-discussion-document-slides-final-170722.pdf
4. Prisoners Dilemma and Nash Equilibrium. https://www.investopedia.com/terms/n/nash-equilibrium.asp

TealeHealth is a B2B healthcare consultancy providing access to more than 40 years of experience and expertise in pharmaceutical market access and management science across industry, consultancy, and healthcare systems. Contact: Chris@TealeHealth.com +44 7308 681 727

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