Exploring the effects of the European Union (EU) joint health technology assessment (HTA) on the launch sequencing of new drugs and identifying opportunities to improve the availability of reimbursed medicines in Europe

HTA87

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SUMMARY

OBJECTIVES

- Launch delay refers to the time between the first international launch of a pharmaceutical and its availability in a specific country.
- This could be time to reimbursement and a factor of commercial launch sequencing.
- The study aimed to assess whether European Union (EU) joint Health Technology Assessment (HTA) regulation could lead to reductions in delay to market.

METHODS

- Targeted literature search: Focused search on joint HTA policy.
- Data sources: Used data from Initiate Reimbursement Radar.
- Launch sequencing tool: Tested optimisation opportunities based on market factors.
- Reference pricing: Investigated the role of reference pricing in launch waves.

FINDINGS

- The EU joint HTA regulation has the potential to significantly improve and speed up the availability of medicines across Europe.
- Overall, the research underscores the importance of optimising launch sequences and regulatory processes to improve access to new medicines and enhance healthcare quality across the continent.

BACKGROUND & AIMS

- This research seeks to establish the traditional launch sequencing pattern of new drugs in Europe and to explore potential opportunities to optimise launch sequencing in the light of EU HTA regulation, which will apply from January 2025. If, within 2 years of marketing authorisation, a product is launched and continuously supplied in all EU member states, an additional 2 years of data protection can be obtained. In the case of small and medium-sized enterprises, not-for-profit entities, or companies with limited experience in the EU system, the period for launch extends to 3 years.
- Based on new product launch data in Europe, it has long been suspected that clear patterns exist in launch sequencing. Patterns can often be found in products launched by smaller and mid-sized companies, less for larger companies that have greater resources.
- The order of launch across the EU4+UK has changed over time. Germany now dominates first-in-row, rising over the last three decades from average to first or second in more than half of all launched products. Meanwhile, the rate of simultaneous launches in multiple markets increased drastically over time, implying a change in strategy by grouping launches. [1]

METHODS

- A targeted literature search of joint HTA policy was conducted and supplemented with data from GPI-Pulse® and the Initiate Reimbursement Radar. A launch sequencing tool was employed to test opportunities to optimise the sequence based on factors including time to market, population, and price maintenance.

RESULTS

- A generalised pattern of launch was established, with three waves: Wave 1 comprising the EU4 and UK, Wave 2 the Nordics, Benelux, and central markets; and Wave 3 in Eastern European markets.
- This traditional launch sequence typically lasts for 24-36 months. Launch sequencing varied for drugs for rare and ultra-rare diseases.
- The average delay in drugs getting to market, defined as being reimbursed, has reduced over time. This could partly be due to changing reimbursement assessment and commercial drivers to launch, such as pricing. [2]
- On average, in the period 2009-2017, the launch delay was 9.4 months in Germany, with the UK following closely (10 months). Sweden and Netherlands show smallest delay of 6.1 months. [2]
- Germany remained quickest of the EU4+UK for drugs for ultra-rare diseases, there was a disconnect in launch sequencing records due to differences between national and local funding.[2]
- If pharmaceutical companies can optimise this sequence and meet the 2-year target defined by EU HTA, they can potentially achieve higher pricing and greater revenue in a shorter time.
- There are reported disparities in drug availability, with patients in Eastern and Southern Europe experiencing longer wait times compared to Western Europe. Economic factors, regulatory processes, and market size influenced launch speeds, highlighting a need for regulatory alignment and policy reform to improve access across Europe. The study underscores how delayed access affects healthcare quality, especially in lower-income regions. [2]

- Over the past two decades, launch delays across Europe have seen a noticeable reduction. For example, the average launch delay decreased from 37.2 months in 2000 to 11.8 months in 2017. [2]
- The availability of new pharmaceuticals also varies significantly across European countries. Germany, the UK, and Norway have some of the highest availability rates. [2]
- To achieve efficiencies, the EU HTA regulation and Joint Clinical Assessment will need to provide efficiencies in the timeline for assessment, and pharmaceutical companies will need to accelerate their launch activities.
- Drug launches tend to be planned in a wave approach based upon pricing potential and protection of reference prices. Earlier wave markets have higher populations and can be thought to command higher pricing.
- Reference pricing plays into the dynamic of drug price launches and is often a driver in launch waves. [3] So called 'free price' markets, such as Germany and UK often lead the price setting mechanism in Europe, and hence the launch sequence.
- Figure 2 demonstrates a **theoretical launch sequence** to achieve a reimbursed product launch in Europe to satisfy the EU HTA regulation for extended patent protection. This timeline launch sequence would require further refinement for optimisation of international reference pricing but provides a suggestion of 4 launch waves to manage pricing and workload.

Figure 1. Delay to market [2]

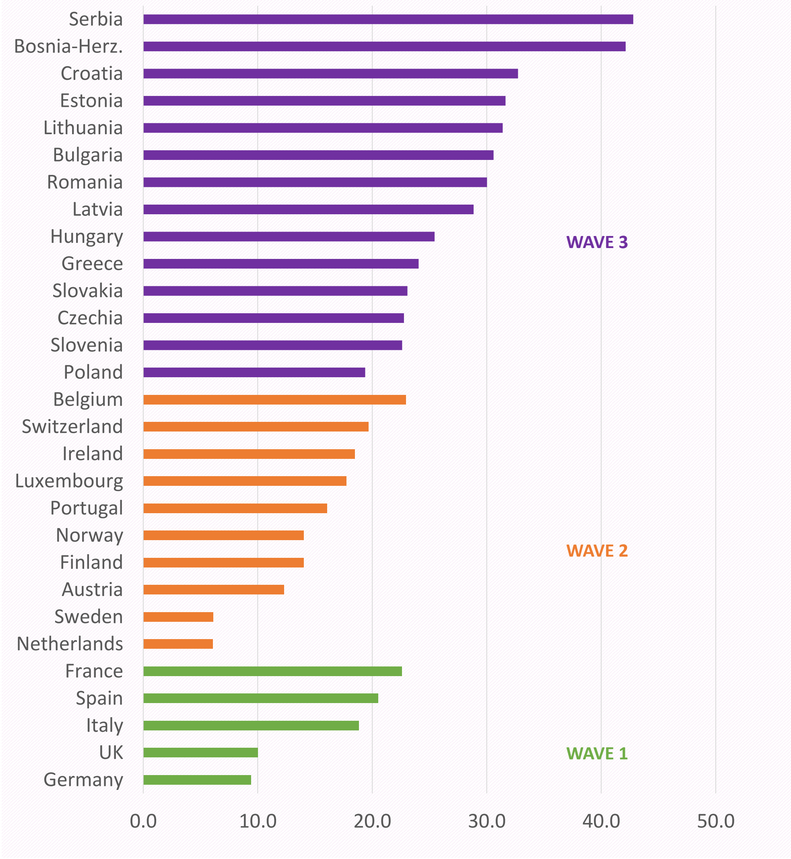

Figure 2. Possible 2-year launch wave model

DISCUSSION

- Our analysis suggests that changes could be made to the traditional launch sequence to accelerate patient access in line with the goal of the EU HTA regulation.
- Our theoretical launch sequence comprises 4 waves. Compared with the traditional launch sequence, the EU4+UK remain wave 1, whereas there are differences in the following waves. For example, our model suggests that Portugal, Luxembourg and some Eastern European markets be launched later.
- It should be remembered that each products launch sequence should be tailored to individual circumstances.
- Further research and testing is required to validate this approach.

CONCLUSIONS

- This research suggests that the objective of the EU HTA regulation to improve and accelerate the availability of medicines could be fulfilled. It should be noted that the regulation does not require reimbursement to be secured, only the medicine to be made available, although this research does suggest opportunities do exist to achieve reimbursement in the 2-year time horizon.

References

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