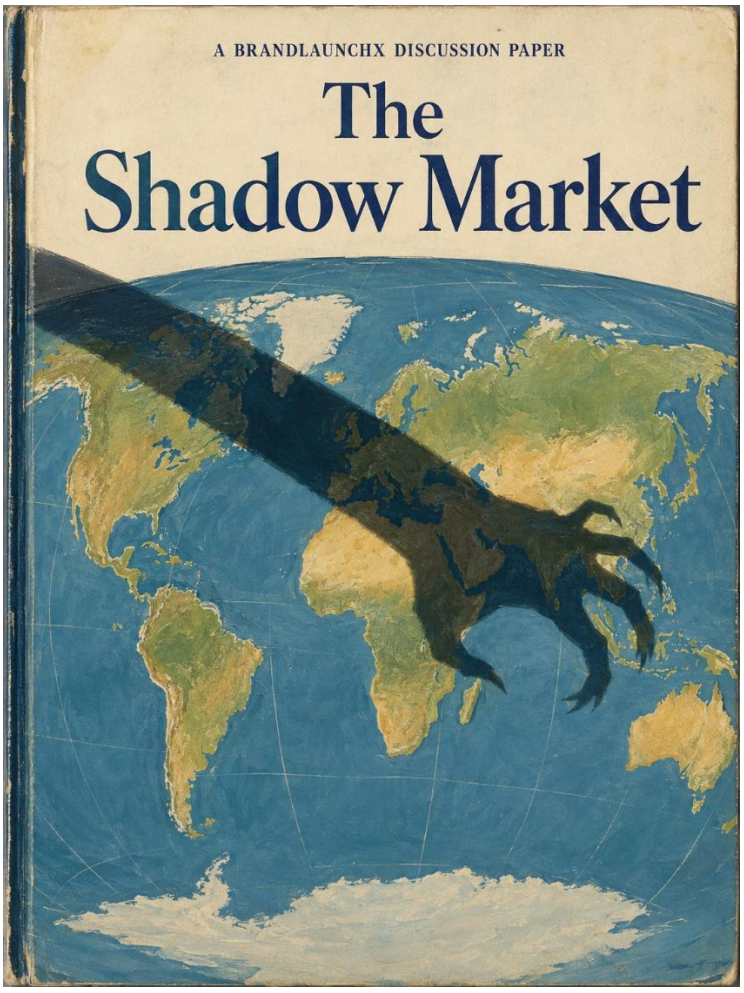
A BRANDLAUNCHX DISCUSSION PAPER

The Shadow Market

Why the gap between approval and dependable access is worth counting, and who pays when it stays open

August 2026

De-Risk. Accelerate. Maximize. Launch Success.



This paper cites only published, verifiable sources. Every material figure is referenced. Where a claim is our own reading of the evidence rather than a sourced fact, we say so. Its purpose is to open a question, not to assign blame or to claim evidence that does not yet exist.

Executive summary

A launch is rarely a one-and-done type affair. Market by market, authorized supply arrives on its own slow schedule, while demand, carried by the same news that announced the approval, arrives everywhere at once. In the space between the two, something else can move in.

We want to be careful about what the evidence shows. Constrained access to affordable, authentic medicines is a recognized driver of falsified medicine risk [1]. It follows that a long gap between the awareness a launch creates and dependable authorized supply *may* open conditions that illicit sellers can exploit. The size of that specific effect has not been quantified, and WHO itself notes the evidence gaps [1,2]. We are not claiming a proven number. We are claiming something more modest and, we think, harder to wave away: the risk is plausible, potentially material, and almost never counted.

The wider problem is not in doubt. At least one in ten medicines in low and middle income countries are substandard or falsified, and roughly **30.5 billion dollars** is spent on such products every year [1,10]. Close to 96 percent of the medicine selling websites one large US review examined were not compliant with the law [7]. And this is not only a problem of distant markets: counterfeit Avastin reached US oncology clinics in 2012, falsified Ozempic was detected in the US and UK supply chains in 2023, and in 2025 WHO flagged nine falsified lots of the breast cancer therapy Ibrance that contained no active ingredient at all [4,5,6].

> *Authorized supply moves market by market. Demand does not. Whatever fills the difference, we did not choose it, and we rarely count it.*

One more point, and it is the one we care about most. Most launch delay is not a pricing decision. It is the accumulated drag of complexity: reporting that looks backward instead of forward, plans that cannot be re-modeled quickly when conditions shift, teams working in silos, and orchestration built for simpler launches than the ones we run now. Pricing strategy is one deliberate contributor, and a relatively controllable one. It is not the whole story. The gap has many authors, and most of them are operational.

1. Two launches, not one

Every therapy can create two launches. The one its maker planned, and the shadow launch it did not. The planned launch is deliberate, sequenced, and traditionally slow, because each market has its own regulator, its own payer, and its own queue. The shadow launch waits for none of that. It needs only three things: awareness, demand, and a gap where authorized supply has not yet arrived.

Figure 1 A gap opens between demand and authorized access

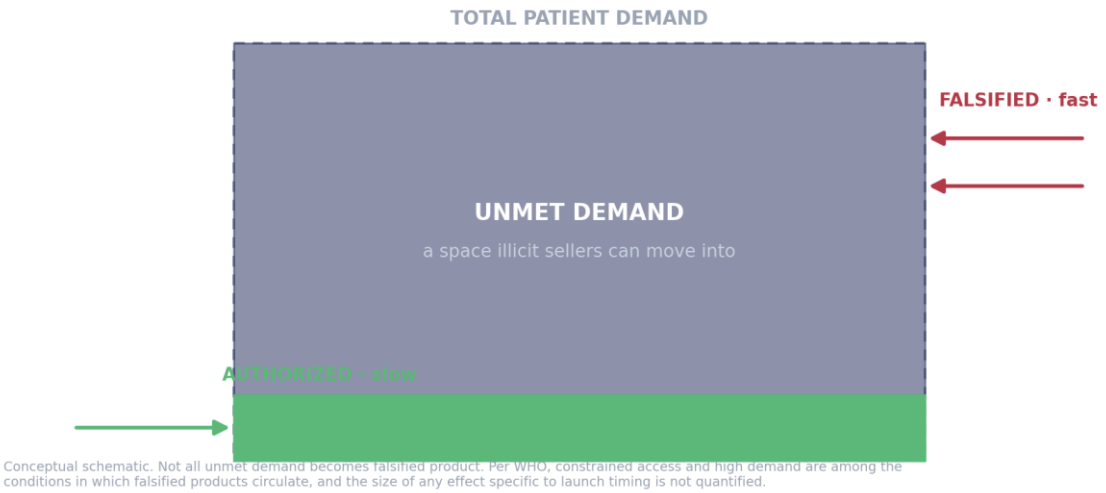


Figure 1. Conceptual schematic. Not all unmet demand becomes falsified product. Mechanism per WHO [1]; the size of any effect specific to launch timing is not quantified [1,2].

The shape is simple. Total patient demand appears quickly and in full. Authorized supply, as it is reimbursed market by market, fills the lower band and rises slowly. The space above is unmet demand. Most of it is simply patients waiting. Some of it, the evidence suggests, is a space that illicit sellers can move into. How much is the open question this paper is trying to raise, not answer.

2. How long the gap stays open, and why

The gap is not brief. On the EFPIA benchmark, compiled by IQVIA for the European biopharmaceutical industry, the median time from marketing authorization to **reimbursed availability** across Europe is 532 days, ranging from 56 days in Germany to 1,201 days in Romania [3]. A caution worth stating plainly: EFPIA measures the date a product is listed for public reimbursement, country by country, which is not the same as the day patients actually use it, and early access schemes are not consistently captured. So treat 532 days as an imperfect proxy for the wait, not a precise one. Even read cautiously, it is well over a year in the middle of the distribution.

Figure 2 How long the gap stays open (EFPIA W.A.I.T. 2025, median)

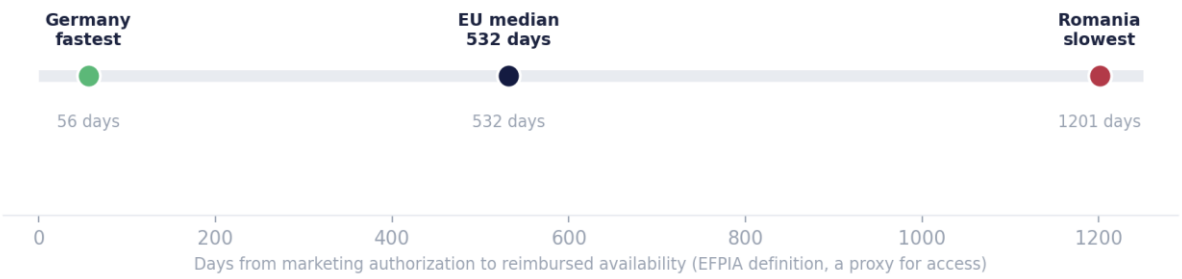


Figure 2. Days from marketing authorization to reimbursed availability, EFPIA definition. Source: EFPIA W.A.I.T. Indicator 2025, prepared by IQVIA [3].

Why does the gap stay open so long? Mostly because launching a modern therapy across many markets is genuinely hard, and the tools have not kept pace. Reporting tends to describe what already happened rather than model what is about to. Plans are difficult to re-run at speed when a payer moves the goalposts or a market slips. Commercial, medical, and market access teams often work

from separate versions of the truth. The result is avoidable delay that nobody decided on and everybody inherits.

Pricing is the exception that proves the rule, because it is the one delay that is often chosen on purpose. A historic analysis by Danzon and colleagues, using data from 1994 to 1998, found evidence consistent with the idea that when a low price in one country spills over to others through external referencing and parallel trade, a company may rationally prefer to delay a launch, or skip a market, rather than accept a low headline price [8]. A later review reached a similar directional conclusion, while cautioning that the evidence base remains weak [9]. We flag this not to single pricing out, but to make the opposite point: pricing is the *controllable* facet. The larger, less controllable driver is execution. Both leave the same gap, and the shadow market does not ask which one caused it.

3. The scale of the problem

It is tempting to treat falsified medicines as a fringe concern. The evidence says otherwise, though it pays to be precise about what the numbers count. WHO estimates that at least one in ten medicines in low and middle income countries is substandard or falsified, and that roughly 30.5 billion dollars is spent on such products each year [1,10].

Figure 3 The scale of the problem

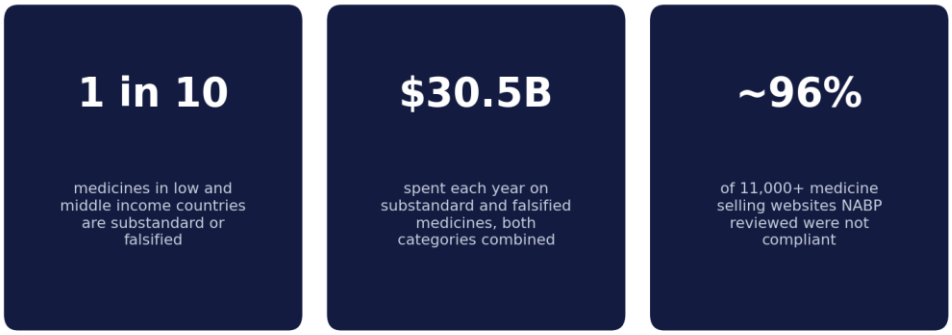


Figure 3. Sources: WHO [1,10]; NABP [7].

Two clarifications the numbers deserve. First, these figures combine two different things: *substandard* products, which usually reflect manufacturing or quality failures, and *falsified* products, which are deliberately misrepresented to deceive. Only the second is the intentional shadow market this paper is about, so the 30.5 billion is context for the wider problem, not a measure of criminal trade alone. Second, the channel has changed the math. In repeated reviews, the National Association of Boards of Pharmacy found roughly 96 percent of the medicine selling websites it examined operating outside US law, and its 2024 work on GLP-1 medicines showed exactly how high demand, cost, shortages and thin insurance coverage push patients toward illegal online sellers [7]. When the front door is slow, the side door is one search away, and market borders are easily blurred in cyberspace..

4. It reaches regulated markets too

The comfortable assumption is that this happens elsewhere, in places with weaker systems. It reaches closer to home than that, and it reaches the kind of high value therapies a modern launch is built around.

Figure 4 It reaches regulated markets too

Sources: FDA, 2012, and Mackey et al., Nature Reviews Clinical Oncology, 2015 (Avastin); WHO Alerts N°2/2024 (Ozempic), N°7/2025 (Ibrance).

Figure 4. Sources: FDA, 2012, and Mackey et al., Nature Reviews Clinical Oncology, 2015 (Avastin) [6]; WHO Medical Product Alert N°2/2024 (Ozempic) [4]; WHO Medical Product Alert N°7/2025 (Ibrance) [5].

We should be careful not to force one clean pattern onto three different events. They are not identical. The Avastin case, to be clear, was not a drug shortage: the FDA compared the products involved against its shortage list and found approved supply was adequate, so it illustrates unauthorized sourcing and supply chain vulnerability rather than an access gap [6]. What the three cases *do* show, together, is simpler and harder to dismiss: falsified versions of high value medicines can penetrate both informal channels and regulated supply chains, and in two of the three the product contained no active ingredient at all [5,6]. Ozempic goes one step further, showing how exceptional demand and supply strain can create a particularly exploitable environment [4]. The patient, in each case, pays full price for something that cannot work, and loses the time the real medicine would have bought.

5. Three of the people who pay

A shadow market is not a victimless inefficiency. It transfers value and risk onto real people, and there are more of them than we can cover here. We choose to look at three, because each one sits inside the launch you are running. They are not the only three.

Figure 5 Three of the people who pay (not the only three)

Figure 5. Three of the people who carry the cost of the gap. Others, from payers to prescribers to regulators, carry it too.

For the launch leader, the demand you spent years and a fortune creating can be met, in markets you have not yet reached, by product you did not make. And when a falsified version fails or harms, the name on the box is yours. For the investor, value can migrate quietly from the asset toward whatever fills the gap, and a single safety incident can reprice the story overnight, well before it shows up in a quarterly number. For the patient, the one the launch exists to serve, the gap is measured in days but the harm is not. A wrong dose, no active ingredient, or a contaminated injection is not a commercial footnote. It is the outcome the therapy was meant to prevent.

6. The cost of delay nobody prices

Put the two halves together and the discomfort is useful. Launching across many markets is hard, and some delay is unavoidable. Some is a deliberate, defensible commercial choice. None of that is wrong, and we are not arguing that companies should launch everywhere at once at any price.

Our argument is narrower. Whatever its cause, a longer gap is not neutral. It is a window, and there is an industry that has shown it will climb through one. That exposure is plausible and potentially material, it has not been quantified, and it is almost never priced into the sequencing decision alongside revenue, margin and reimbursement. The point of naming it is not to frighten anyone. It is to move a real risk from the footnotes onto the same page as the numbers it sits next to.

> *A slow launch is not only a commercial risk. Left open long enough, the gap it leaves can become a patient safety risk.*

7. A better question to carry into the next launch

If the gap is where the cost hides, then the gap is the thing to watch. Most launch measurement is a commercial post mortem, precise about revenue and quiet about time. A team can tell you market share to the decimal, and rarely how many days stand between approval and the first patient reliably treated through an authorized route.

There is, in truth, not one number here but two. There is the gap a team plans for, the days it expects between authorization and dependable access in each market. And there is the gap it actually delivers. Plan against reality. Most launches never write either number down, so they cannot see the distance between them until it has already cost something. We are not going to define these measures formally here (that is work we want to tackle with your input and insights) but the shape of the idea is worth carrying into your next launch. A team that watched both the forecast and the realized version of that wait, from day one, would be managing the gap on purpose, instead of discovering it after the shadow market already has.

A note on method and caveats

We have deliberately drawn a firm evidential line. Constrained access and affordability are recognized drivers of falsified medicine risk [1]; WHO itself notes that the relationship between formal market availability and informal market activity is not yet fully quantified [2]. We therefore present launch delay as a plausible and potentially material contributor to that risk, not as a proven or measured one. The prevalence and spending figures combine substandard and falsified products and are weighted toward low and middle income countries [1,10]; only deliberate falsification is the shadow market proper. The EFPIA figure measures reimbursed availability, defined country by country, which is a proxy for access rather than a record of use; EFPIA is the European industry association and the survey is compiled by IQVIA [3]. The three cases are illustrations, not a frequency, and none is individually linked to launch timing; the Avastin products were not on the FDA shortage list [6]. The Danzon dataset is historical, from 1994 to 1998, and the external reference pricing evidence base is described by its own authors as weak [8,9]. Figure 1 is a conceptual schematic and its proportions are indicative only. Where we have offered our own interpretation rather than a sourced fact, we have said so.

References

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