Policy changes impact development plans

Linda Pullan in Pullan's Pieces #221, January 2026

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At Sachs Oncology, I listened to a presentation by Aditya Nataran of LEK.

He spoke about multiple policy changes impacting choice of indication and country. I'm summarizing his messages with a biotech and BD perspective on changes in indication choices and development countries and likely deal changes too.

1. **Accelerated Approval in US more rigorous**, now requiring early dose optimization, novel endpoint validation (greater scrutiny of surrogate endpoints), and confirmatory trials being underway at approval.

For smaller biotechs, this may mean

- **partnering earlier** to avoid increased costs and longer times
- prioritizing indications with **established surrogate endpoints**
- avoiding accelerated approval if the **confirmatory trial risk** is too high.

2. **Orphan Designation is expanded** in the US One Big Beautiful Bill, such that the clock for price negotiations for Medicare only take place when a non-orphan indication is approved.

- High-priced **orphan drugs can stay high-priced** indefinitely.
- A strong incentive to **pursue orphan indications first**.
- Desire for products with **multiple orphan indications**

3. **Most Favored Nation (MFN) can pull the US price down** toward lowest peer-country price. Today peer countries (with per capita GDP>=60% of US) are Germany, France, UK, Italy, Spain, Canada and Japan.

- **One low-price country** can reset global pricing.
- Companies may focus on **US-centric indications.**
- Companies may focus on indications with **strong clinical differentiation** and aim to be **first-to-market** to withstand pricing pressures.
- Companies may **push for higher prices in peer countries**.
- Companies may **skip countries** expected to lower US prices (such as Japan and Canada).
- **Out-licensing in Europe** would mean pricing impact in the US out of the control of the US company.
- Pharma companies are now **stress testing their models** for potential price drops under MFN.

4. **EU-level Joint Clinical Assessments begin with oncology and cell, gene and tissue product (ATMP)**, with orphan drugs to follow in 2028. The EU HTA (Health Technology Assessment) is introducing an

EU-level Joint Clinical Assessment on clinical effectiveness (and safety) versus comparators.

- This sets up a **shared baseline** for evidence used in pricing and reimbursement decisions at the national level.
- A negative assessment **could quickly ripple** across all countries.
- The Joint Clinical Assessment may enable **earlier launch in smaller markets** historically with lower prices.
- The shift toward centralized clinical evidence may encourage companies to prioritize markets where **clinical differentiation** is the primary driver of value, while delaying entries where economic or "non-clinical" hurdles remain high.
- **Variations in standard of care** will also figure into country planning.
- It is expected the Joint Clinical Assessment will be **a referenced document for Japan, China, US etc.**

5. One more not covered by the LEK talk is **Direct-to-Consumer Sales**.

- **Lilly, Novo and Pfizer are selling drugs directly** to the consumer and/or employer, bypassing PBMs.
- This fits obesity and other **chronic high demand indications**.
- The channel change **provides pharma more information** faster and may benefit uninsured.
- DTC sales may **mean a reduction in Net Sales and lower royalties** in contracts as the list price changes and the costs of the sales platform can be deducted from sales before royalties are applied.
- Contracts need to **address the definition of Net Sales, intracompany transfer of sales, DTC reporting.**

What does it mean for deals?

We in BD are likely to see **deal terms and contract language shifting** to reflect the changing risks and benefits of these policy changes. Biotech companies will need to think about their early clinical development plans to **persuade partners that a good path exists**. **Orphan drugs up**, **Europe development first less likely**!