NEWS DIGEST

- The S2 Hurdle: How the current funding pathway is restricting cross-border access for rare disease treatments
- What is the role of commercial arrangements in ensuring patients have timely access to new medicines?
- Cochrane's collaborative agreement with NICE
- Big Pharma double-digit price hikes





THE S2 HURDLE: HOW THE CURRENT FUNDING PATHWAY IS RESTRICTING CROSS-BORDER ACCESS FOR RARE DISEASE TREATMENTS

THE NEWS

Innovative therapies for rare diseases may only be available in a select number of countries in Europe.

However, the cross-border funding pathway currently in place to facilitate cross-border treatment of rare diseases (the S2 pathway) severely limits the ability of patients to access these cutting-edge treatments, exaggerating the disparity in access faced by patients.

THE IMPACT

In our article, we break down the consequences of having an inadequate funding system which impacts both patients and manufacturers.

From the patient's perspective, being denied the opportunity to access rare disease treatment that is available in neighbouring countries is very unfair and against the principles of the European idea.

For the manufacturer, an obstructive and overly bureaucratic system limits uptake and overall commercial success of the product, damaging the prospect of developing future treatments for rare diseases.





WHAT IS THE ROLE OF COMMERCIAL ARRANGEMENTS IN ENSURING PATIENTS HAVE TIMELY ACCESS TO NEW MEDICINES?

THE NEWS

The introduction of new medicines in England requires the cooperation of industry and the NHS. Industry has long been familiar with the need to prove that new treatments are both clinically-effective and cost-effective; and for the majority of new treatments, the standard NICE procedure is viewed as a fair procedure for assessing their value.

THE PATIENT ACCESS SCHEMES

There are currently three main options open to manufacturers:

- Complex Patient Access Schemes (PAS)
- Commercial Access Agreements (CAAs)
- Managed Access Arrangements (MAAs)

THE IMPACT

Until recently, complex PASs were the only option available to companies wishing to offer the NHS a discount other than a simple percentage reduction on the list price.

However, the fact that NHS England have included CAAs and MAAs in their Commercial Framework suggests that their use may become more frequent in future





COCHRANE'S COLLABORATIVE AGREEMENT WITH NICE

THE NEWS

In Early September, Cochrane and NICE signed a collaborative agreement which creates a formal process for people who are preparing reviews for the Cochrane Library to share their findings with NICE.

THE IMPACT

While it can be hard to coordinate timely production of reviews with the guideline development process, sharing the results of Cochrane reviews before their publication has produced more effective ways of working and helps to benefit NICE, people working in the NHS and ultimately people using the health service.

Actively supporting the process of delivering reviews for NICE guidelines in this way means the findings of our reviews can help to develop evidence based recommendations for the NHS.

Sharing evidence with NICE is part of a broader approach to help Cochrane to identify priority reviews, and to identify them early.





BIG PHARMA DOUBLE-DIGIT PRICE HIKES

THE NEWS

For years, top pharma companies responded to pricing criticism by pledging to limit their increases. But now it appears some big players are starting to test the limits of pharma's social contract.

For one, California-based Amgen recently raised the list price for its Celgene-acquired psoriasis med Otezla by 2.4% in August, bringing its total increase to 10% over the last year.

The company said the price increases across its entire U.S. portfolio "accurately reflects our continued clinical trial spend and key pricing indices."

SO, WHAT'S NEXT?

Pharma companies have faced years of pricing scrutiny and at times have responded by reining back their price hikes.

Now, it appears the pressure from Washington, D.C., is set to ramp back up, with proposals ranging from Medicare negotiations to importation being floated in Congress.





GET IN TOUCH

"We always welcome your thoughts and opinions on the topics raised here.

If you'd like to share anything or hear how we can support you in getting your product to market email Paul and Graham, managing directors, today at: **contact@remapconsulting.com**"



Paul Craddy Managing Director & Founder



Graham Foxon Managing Director & Founder

