# NEWS DIGEST

- Can Orphan Status Pave the Way for Higher Prices in the UK?
- Italy: AIFA reports on manufacturer paybacks
- UK: DHSC launches consultation on proposal to revise payment percentage paid by companies under statutory scheme for branded medicine pricing
- Europe: PRIME scheme has positive impact on the authorisation of new medicines - report

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# CAN ORPHAN STATUS PAVE THE WAY FOR HIGHER PRICES IN THE UK?

## THE ORPHAN DISEASE ISSUE...

It has long been recognised by the healthcare world that the treatment of rare, or orphan, diseases is a challenge. It was the year 2000 when the European Medicine's Agency launched its Orphan Designation Programme, to encourage pharmaceutical companies to research and develop medicines for such conditions. The scheme offers incentives such as specialised scientific advice, fee reductions and ten years of market exclusivity for products granted orphan status.

Beyond the regulatory level, a well-recognised challenge for companies launching drugs in orphan disease areas is return on investment. Although the estimated R&D costs for orphan diseases are 27% lower than non-orphan therapy areas, the potential market revenue is limited by the far smaller target population. To counteract this, manufacturers often seek elevated annual per patient prices for drugs with orphan status, following a loose rule that the smaller the prevalence of the disease, the higher the price potential for the drug.

The outcome of this is clear in the US market, where the average annual cost for drugs with orphan status is $32,000 per patient per year, and over one third have price tags of more than $100,000 per patient per year. But is this happening in markets such as the UK, where cost-effectiveness is both the major driver, and major restraint, of price?

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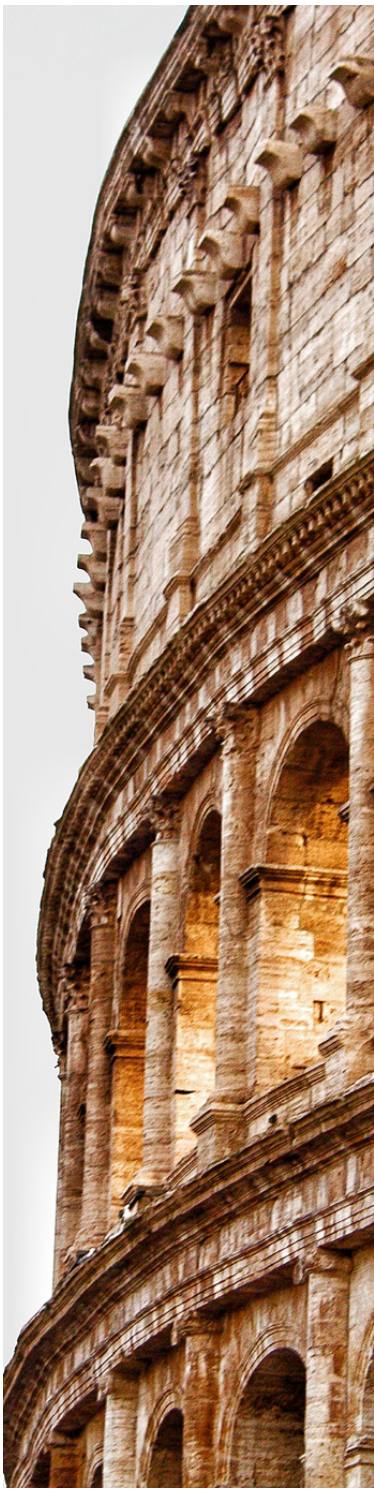
# ITALY: AIFA REPORTS ON MANUFACTURER PAYBACKS

## THE NEWS

The Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) reports that collectively manufacturers have now paid 87% of the amount due for exceeding the pharmaceutical spending cap for direct purchases in 2019 and 2020.

For the year 2019, 156 companies liable for repayments have collectively paid 92% of the total amount due while for the year 2020, 134 companies have paid 81% of the amount due. Collectively, companies still owe AIFA €370 million of the €2.8 billion that industry has to repay for exceeding the pharmaceutical spending cap for direct purchases in 2019 and 2020.

Source: https://remapconsulting.com/portfolio-items/italy-aifa-manufacturer-paybacks/



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# UK: DHSC LAUNCHES CONSULTATION ON PROPOSAL TO REVISE PAYMENT PERCENTAGE PAID BY COMPANIES UNDER STATUTORY SCHEME FOR BRANDED MEDICINE PRICING

## THE NEWS

The Department of Health and Social Care (DHSC) has announced the launch of a consultation on its proposal to revise upwards the payment percentage paid by pharmaceutical companies who are members of the statutory scheme for branded medicine pricing in 2022 and 2023.

The statutory scheme is one of two schemes, alongside the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), that control the prices of branded medicines to the national health service (NHS).

The DHSC is proposing to increase the statutory scheme payment percentage for 2022 from 10.9% to 14.3%. As the amendment will not take effect until 1 July 2022, companies who made payments under the statutory scheme in the first half of 2022 at the lower rate of 10.9% will instead pay a rate of 17.7% from 1 July 2022.

For 2023, the DHSC proposes to increase the payment percentage from 10.9% to 24.4%.

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# EUROPE: PRIME SCHEME HAS POSITIVE IMPACT ON THE AUTHORISATION OF NEW MEDICINES - REPORT

## SUMMARY


- 95 PRIME requests granted between March 2016 and June 2021
- ATMPs account for 46% of successful PRIME applications
- PRIME medicines granted MA have a consistent reduction of the clock-stop duration
- PRIME products more likely to be granted accelerated assessment



## INTRODUCTION

According to the European Medicines Agency (EMA) its PRIority Medicines (PRIME) scheme "has had a positive impact on the authorisation of new medicines that address patients' unmet medical needs", reducing the time to marketing authorisation. The EMA launched the PRIME scheme in March 2016 to provide early and enhanced scientific and regulatory support to medicines that are expected to benefit patients with no current treatment options, or which offer a major therapeutic advantage over existing treatments. PRIME medicines include CAR T-cell therapies, one-time potentially curative gene therapies, rare cancer treatments and a vaccine for the Ebola virus.

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