

NEWS DIGEST



News:

- Kidney Research UK deems NICE process “not appropriate for a rapidly evolving virus
- Sharp criticism is received for the increased VPAS clawback rate of 26.5% in 2023
- Health benefits paid by supplementary bodies jumped by 11.6% last year

Our Latest Articles:

- EU HTA - looking back on 2022
- Effective P & R Processes to Ensure the Future of Gene Therapies in the EU - a 2022 review
- Reflecting on the pricing and market access trends that shaped 2022



UK: Kidney Research UK deems NICE process “not appropriate for a rapidly evolving virus”

Kidney Research UK has responded to the National Institute for Health and Care Excellence (NICE) draft guidance on therapeutics for patients with COVID-19. The protests arose following the regulatory body’s draft decision to dramatically reduce the number of available treatments. Organisation believes the guidance would leave renal patients with no effective treatment outside the hospital.

Currently, kidney disease patients are only being offered Paxlovid by NICE, which is not suitable and could be harmful. The charity pointed to the evidence that failed to consider the impact on high-risk patients and strongly supported the case for fast-tracking of potential COVID-19 treatments. Moreover, charity emphasized the flaws in the evidence cited in the initial guidance, stating that the studies used did not accurately reflect the population who would benefit from treatment, with recommendations based on evidence from a general hospitalised group, rather than a population of immunosuppressed individuals. In addition, other studies focusing on higher-risk communities saw higher hospitalisation risks than in NICE’s analysis. In response, the charity has called on NICE to conduct more sub-group analysis into at-risk groups before concluding their final recommendation.

They also urge the Government to provide COVID-19 treatments in a similar manner to the original introduction of vaccines by incorporating them into wider clinical practice. In its formal response, the charity emphasised that the structures of NICE approval generally lack the flexibility to deal with an ever-changing situation.

Source

1.NICE process “not appropriate for a rapidly evolving virus” <https://www.kidneyresearchuk.org/2022/12/12/nice-process-not-appropriate-for-a-rapidly-evolving-virus/>. Accessed 16th December 2022



UK – Sharp criticism is received for the increased VPAS clawback rate of 26.5% in 2023

The government has recently announced that 2023 payment percentage for the voluntary scheme for branded medicines pricing and access (VPAS) agreement has been calculated to be 26.5%. Prior to this increase, payment percentages were 5.9%, 5.1%, and 15%, in 2020, 2021, and 2022, respectively. This increase in payment percentage is due in part to the impact of the amendment agreed in January 2022 to defer part of the payment calculated to be owed in 2022, to the following year. Without this amendment, the payment percentage in 2023 would have been 22.6%.

The raised payment percentage of 26.5%, however, has received backlash from the Association of the British Pharmaceutical Industry (ABPI).

ABPI has stated that the manufacturers of branded medicines will be required to return almost £3.3 billion in sales revenue to the government in 2023 – a significant increase from the repayments of £563 million and £1.8 billion, in 2021 and 2022 respectively. ABPI has further warned ministers that this level of revenue clawback occurring in the wake of the COVID-19 pandemic is actively harming the life sciences ecosystem of the UK, at a rate almost double that of any comparable country.

Richard Torbett, Chief Executive at the ABPI, stated: “...following the pandemic, the existing system has been forced beyond breaking point and is now well outside anything seen anywhere else in the developed world.” Representatives of pharmaceutical companies have made statements sharing this sentiment, with Todd Manning, the UK General Manager of AbbVie, saying: “Unless we receive a clear signal from the Government that we can bring these payment rates down to reasonable levels, we face the very real risk of locking in a downward investment into future years while will be incredibly difficult to reverse”.

The 2019 VPAS agreement has driven significant improvements in patient access to clinically and cost-effective medicines, whilst ensuring sustainable and predictable spend growth for the NHS and industry. The current VPAS agreement is due to end in December 2023, and in the wake of this, ABPI has called for a reform of the VPAS agreement in a more mutually beneficial nature.

Richard Torbett stated: “Next year we must start again with a clean sheet of paper to agree on what an internationally competitive scheme looks like. We have received important assurances from the Government that we will come together in partnership to agree on a mutually beneficial approach. We need a new settlement which focuses on improving the health and productivity of the whole country, ensures rapid UK launch and adoption of new medicines, and supports clinical research, all while continuing our enduring commitment to ensuring value for money for the NHS.”

Sources

1. The 2019 voluntary scheme for branded medicines pricing and access: payment percentage for 2023. Department of Health and Social Care. <https://www.gov.uk/government/publications/the-2019-voluntary-scheme-for-branded-medicines-pricing-and-access-payment-percentage-for-2023/the-2019-voluntary-scheme-for-branded-medicines-pricing-and-access-payment-percentage-for-2023>. Accessed December 19th 2022.



FR – Health benefits paid by supplementary bodies jumped by 11.6% last year

The annual Directorate of Research, Studies, Evaluation and Statistics (DREES) report, published on Friday, illustrated a turnaround for health benefits from a 2020 marked by a particularly low consumption of care. According to the report, complementary health insurers paid €31.6 billion in benefits in 2021, this was a record increase of 11.6% year-on-year, with €3.3 billion more being paid than in 2020. Disregarding 2014 and 2020, the level of benefits paid has been increasing by between 4.2 and 0.6% for the past decade and was at 2% just before the COVID-19 pandemic.

Although this increase does exclude the large contribution paid by complementary bodies to cover expenses related to the management of the COVID-19 pandemic, it still represents an increase in health benefits over a year where overall consumption of care and medical goods were reduced. The increase in health benefits could be attributed to the introduction of the '100% Healthcare' policy which caused a sharp upturn in the amount of reimbursement paid out for certain types of care.

The next report on the value of health benefits paid out by complementary health insurers in 2022 will be telling. Will the year-on-year increase in benefits paid return to the previous range, or, will an increase in consumption of care and '100% healthcare' have a lasting effect on the amount of reimbursement being paid.

Sources:

1. Health: supplementary reimbursements jumped by 11.6% last year| Les Echos

2. 2022 report on the financial situation of complementary organizations providing | health coverage Research, Studies, Evaluation and Statistics Branch (solidarites-sante.gouv.fr)



Our latest articles:

[EU HTA – looking back on 2022](#)

In early 2022, the EU HTA regulation was formally ratified with the aim of establishing an EU-wide joint assessment of clinical effectiveness with an accompanying process for joint early scientific dialogue with EU HTA agencies. With the first products anticipated to go through this process in 2025, we discuss the developments that have been made to the process in 2022, linking them back to predictions we made at the beginning of the year, and looking at what we can expect in 2023.

[Effective P & R Processes to Ensure the Future of Gene Therapies in the EU - a 2022 review](#)

At the end of 2021 we predicted what 2022 may behold for the pricing and reimbursement landscape of Gene therapies in Europe. We anticipated a shift in payment models, a more collaborative approach to assessments, growing use of real-world evidence and how this can be implemented in post-authorisation follow ups to aid valuation of benefits. As another year draws to a close, we reflect on the 2022 trends and establish what changes have been made, if any, to the gene therapy pricing and reimbursement landscape in Europe.

[Reflecting on the Pricing & Market Access trends that shaped 2022](#)

In December, we reviewed our predictions and examined the impact these trends had on the European pricing and market access landscape the year unfolded.



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**