

## Sanofi Short Guide:

# The Voluntary Scheme for Branded Medicines Pricing and Access Explained

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## Introduction

As a health journey partner, Sanofi UK appreciates the important work that patient organisations do to benefit the lives of patients. As outlined in our Patient Charter, we recognise the importance of working collaboratively with patient organisations and strive to adopt an inclusive and supportive approach to everything we do.

This booklet is designed to help those advocating on behalf of patients understand the Voluntary Scheme for Branded Medicines Pricing and Access, also known as Voluntary Scheme or 'VPAS'.

## What is the Voluntary Scheme for Branded Medicines Pricing and Access?

The Voluntary Scheme for Branded Medicines Pricing and Access (Voluntary Scheme or VPAS) is an agreement between the UK Government, NHS England and the pharmaceutical industry. Any manufacturer or supplier of branded medicines, including biosimilars and branded generics, can join the Scheme.<sup>1</sup> It has two main parts:

- 1.** It sets out measures which commit all parties to increase access and uptake in England of the most transformative and cost-effective medicines to support better patient outcomes.<sup>1</sup>
- 2.** It sets out a UK-wide affordability mechanism under which Scheme members make a financial contribution to the Department of Health and Social Care for NHS sales of branded medicines. Some exemptions for certain treatments have been incorporated in the Scheme to support and encourage innovation and growth.<sup>1</sup> The Voluntary Scheme delivered £850 million to the Department of Health and Social Care for the year 2019.<sup>2</sup>

## Pricing schemes for medicines

The first medicines pricing scheme in the UK was introduced over 50 years ago with the objective to control the growth in list prices of medicines and ensure predictability for the NHS. To ensure pricing schemes stay up to date with different economic conditions and changes to the structure of the healthcare landscape, they are generally re-negotiated every five years.<sup>3</sup>

The previous pricing scheme, the Pharmaceutical Pricing Regulation Scheme (PPRS), came to an end on 31<sup>st</sup> December 2018 and was replaced by the Voluntary Scheme for Branded Medicines Pricing and Access (Voluntary Scheme or VPAS). Compared to past PPRS agreements, the Voluntary Scheme has additional commitments to assist patient access to new medicines, improve healthcare services; alongside ensuring predictability for the NHS and at the same time fostering innovation in the UK.<sup>1</sup>

### Benefits to the NHS and the taxpayer

# 2%

The 2019 Voluntary Scheme guarantees that the NHS branded medicines bill will not grow more than two percent in any of the following five years, helping the NHS to plan future spending and resources.<sup>1</sup> The products covered by the Scheme include branded generic medicines, biosimilars and parallel imports. The Voluntary Scheme excludes centrally procured vaccines and over-the-counter medicines (OTC)<sup>1</sup> but does apply to NHS sales of branded Pharmacy and General Sales List medicines.<sup>1</sup>

Any NHS spending above the agreed two percent growth rate will be given back to the Department of Health and Social Care by the pharmaceutical industry to be reinvested in the NHS,<sup>4</sup> although there is no guarantee that the funding will be spent on medicines and vaccines. Companies signed up to the PPRS paid back on average over £1 million every day.<sup>3</sup>

## Ambitions of the Voluntary Scheme for Branded Medicines Pricing & Access

- Better access to cost-effective medicines
- Increased uptake by streamlining how patients are given access to medicines

Lead to

Improved patient outcomes

- Support industry business model to improve uptake
- Enable small- to mid-size companies to get medicines to market

Lead to

Encouraging innovation

- Deliver value to patients, the NHS and the taxpayer on branded medicines
- Provide better planning and resourcing

Lead to

Enhanced NHS patient services

## How might the Voluntary Scheme improve outcomes for patients?

The Voluntary Scheme identifies several ways to potentially improve patient access to innovative, cost-effective treatments. The Voluntary Scheme also commits the Industry, NHS England and government to look at ways to support uptake of high value medicines, including faster appraisals by the National Institute for Health and Care Excellence (NICE).<sup>1</sup> This could potentially mean that medicines recommended by NICE reach eligible patients more quickly.

### NICE assessment of new medicines

A widely held concern about previous PPRS schemes was that they did not completely address the challenge of increasing patient access to innovative medicines. The Voluntary Scheme, however, aims to accelerate NICE appraisal and support uptake of new medicines to reach patients earlier, in order to improve health outcomes.<sup>1</sup>

The Voluntary Scheme includes the commitment for all new medicines to be appraised by NICE unless there is a clear reason not to do so.<sup>1</sup> The NHS in England and Wales is legally bound to provide funding for medicines recommended by NICE, prescribed by the patients' doctor, within 90 days.<sup>5</sup>

NICE is committed to speeding up its appraisal process, potentially by up to six months,<sup>4</sup> to bring assessment times for non-cancer medicines in line with cancer medicines.<sup>5</sup>

NICE has also committed to review the way in which it appraises new medicines, in what has been called the NICE Methods Review. A public consultation will be held on the new measures proposed and should be an opportunity for all stakeholders to comment on how NICE considers the impact of new medicines beyond current quality-of-life measures, including broader aspects of the day-to-day experience of patients.<sup>6</sup> The intention is to ensure enough flexibility in the appraisal to make sure innovation reaches patients and best meets their needs, especially in disease areas where appraisal challenges may exist due to the number of patients or services in place.<sup>6</sup>



## How will the Voluntary Scheme for Branded Medicines Pricing & Access enhance NHS patient services?

### Increased uptake of new medicines

Even medicines with a positive NICE recommendation in the UK are often not used at expected levels: despite the NHS being a highly integrated, taxpayer funded healthcare system, the UK is slow to adopt new treatments.<sup>7</sup> Even if the NHS provides funding, infrastructure and services sometimes need to be set up to ensure new treatments reach patients; for example, establishing infusion capacity for new biologic medicines.

For every 100 patients that get a new medicine in its first year of launch in comparable countries, such as France and Germany, only 21 patients in the UK receive the medicine. There is also significant variation across the UK when it comes to being able to prescribe different types of medicines.<sup>7</sup>



The Voluntary Scheme has now seen NHS England commit to achieving a level of uptake for new medicines in line with top performing countries worldwide. It is set to announce five areas of greatest healthcare gain where the uptake of innovative medicines will be prioritised by the NHS.<sup>1</sup> These five areas should reflect the current care available, the evolution of the market and the state of innovation. Early engagement of all relevant stakeholders is key to the success of this commitment and involving patient groups would help ensure patient voice is part of the process.



### Developing the data infrastructure

To help address poor uptake and ensure targets are met in the five highest health gain categories, new ways to measure and increase the use of new medicines are being developed. For example, the Innovation Scorecard is being further developed and refined to help local NHS organisations to monitor regional progress on the implementation of NICE recommendations and identify if changes to procedures are needed.<sup>1</sup>



The Voluntary Scheme also includes a commitment to improve horizon scanning, a technique that helps predict future trends and incoming innovations, to allow more predictability and resource planning for the NHS. This should help to increase the uptake of innovative cost-effective medicine through early identification of changes in financial needs and service design requirements.<sup>1</sup>

## How will the Voluntary Scheme for Branded Medicines Pricing & Access encourage innovation for all patients?

### Maintaining value for money

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The Voluntary Scheme commits the government to maintain the NICE cost-effectiveness threshold at between £20,000 and £30,000 per QALY\* until 2025,<sup>1</sup> although the threshold has remained at this level since NICE was set up. The Scheme retains freedom to set list pricing on new active substances and subsequent line extensions,<sup>1</sup> which encourages companies to launch new medicines in the UK, subject to NICE approval.

\*A QALY or Quality-Adjusted Life Year quantifies the impact a health intervention will have on a patient's quality and quantity of life. This is further explained in the Sanofi Short Guide The QALY Explained, which can be found on Sanofi UK website: <https://www.sanofi.co.uk/>

### Creating a context to foster research investment in the UK

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The Voluntary Scheme also includes a commitment to develop an NHS England Commercial Framework and submit it for stakeholder consultation.<sup>1</sup> The objective is to create a clearer framework for the NHS to negotiate with the pharmaceutical industry and develop new models to provide access to medicines.

Additionally, companies signed up to the Voluntary Scheme are offered a number of exemptions.<sup>1</sup> These and the introduction of more flexibility through the NHS England Commercial Framework aim to foster an economic environment encouraging pharmaceutical companies' investment in research and innovation in the UK.

### How does this help patients get new medicines faster?

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Research and development for new medicines is a global effort. Countries that have incentives designed to reward innovation create environments where companies want to launch their medicines early, where clinicians are keen to adopt the latest treatments and technologies, and where patients benefit from new medicines.

## What is the alternative to the Voluntary Scheme?

Those companies that choose not to join the Voluntary Scheme are automatically enrolled into a Statutory Scheme.<sup>1</sup> Some of the incentives offered to industry members within the Voluntary Scheme are not available to members of the Statutory Scheme which operates by consultation, not negotiation. Since 2019, the fixed price threshold for when companies must start paying back to the Department of Health and Social Care has been replaced by percentage of NHS sales<sup>8</sup> to be more aligned with the Voluntary Scheme.

## What does the Voluntary Scheme do for the NHS?

The Voluntary Scheme aims to positively impact patient outcomes, encourage innovation in the UK, and provide a predictable level of spending on medicines for the NHS. In 2019, the Voluntary Scheme returned £850 million to the Department of Health and Social Care (DHSC).<sup>2</sup>

But is the Voluntary Scheme meeting its objectives? From the start of the Voluntary Scheme through to July 2020, Members of Parliament have only asked around 60 written Parliamentary Questions on specific aspects of the Voluntary Scheme.<sup>9</sup> There has been no public scrutiny of whether the Voluntary Scheme (or previous PPRS agreements) is delivering on its objectives of ensuring improved uptake of medicines to support better patient outcomes and provide predictability and affordability of branded medicines for the NHS.

## About Sanofi in the UK

Sanofi is a global life sciences company committed to discover, develop and distribute therapeutic solutions focused on patients' needs. Sanofi in the UK partners with a number of different patient organisations to pursue goals which benefit patients. Our Patient Charter outlines our pledges for working with patients and patient organisations. To view the Patient Charter and learn more about our work with patient organisations, please visit [www.sanofi.co.uk](http://www.sanofi.co.uk).

Life is a health journey, with ups and downs, which can be big or small, lifelong or momentary. We, at Sanofi, are there for those challenges, as a health journey partner. Many patients are depending on us. We aim to protect, enable and support people facing health challenges, so they can live life to its full potential.

## References

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