

UK medicines regulator issues its first authorisation under Project Orbis

A post-surgery treatment for lung cancer will be the first to receive an authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) under Project Orbis – only four months after the agency joined the scheme in January 2021.

Osimertinib (Tagrisso), a medicine made by AstraZeneca, is a licensed treatment for patients with mid and later stage non-small cell lung cancer (NSCLC) who test positive for a specific gene mutation called EGFR. EGFR mutations occur in approximately 12%* of lung cancer patients. The licence has now been extended to include a new population of patients in early-stage disease. The extended licence offers a novel treatment option for these patients, after their cancer has been surgically removed, in an area of significant unmet need.

Project Orbis is an innovative programme coordinated by the US Food and Drug Administration (FDA) with Canada, Australia, Switzerland, Singapore, Brazil and the UK as other participants. The programme has been set up to allow participating partners to review and approve applications for promising cancer treatments quickly and efficiently.

Prior to the UK joining, the scheme has already given the green light to many life-saving treatments for patients suffering from conditions such as breast cancer, lung cancer, liver cancer, endometrial cancer, and chronic lymphocytic leukaemia.

NHS England, NICE and AstraZeneca have reached an agreement to enable early access to osimertinib for early-stage lung cancer patients in England on a budget-neutral basis to the NHS while NICE undertakes its appraisal.

Health and Social Care Secretary Matt Hancock said:

It is absolutely vital that NHS patients have access to the most promising, cutting-edge treatments as quickly as possible.

Leaving the EU presented us with the opportunity to join Project Orbis – an international collaboration with the top regulators around the world – to speed up the time it takes to get these new medicines to patients.

I am delighted that today we are able to see the first results of our involvement in this partnership, with a groundbreaking drug for lung cancer which will soon benefit hundreds of patients, and I look forward to seeing what further innovations it will bring to

the table.

Dr June Raine CBE, Chief Executive, Medicines and Healthcare products Regulatory Agency said:

With Project Orbis, we are working to ensure that patients receive earlier access to promising, life-saving cancer treatments. We know that the earlier we can treat patients, the better their outcomes. Through international cooperation, innovation in regulation, and working with others across the whole health system, the MHRA is cementing the UK's global position at the centre of life sciences and healthcare access.

Tom Keith-Roach, President, AstraZeneca UK, said:

Project Orbis is a powerful example of how collaboration between regulatory authorities around the world can accelerate the approval of life-changing treatments and we're delighted that osimertinib is the first medicine to undergo this innovative review process with the MHRA. It's fantastic news that NHS patients in England with this specific type of early-stage lung cancer will have early access to this medicine, which could significantly improve their chance of disease-free survival. We will continue our work to secure access for patients in the devolved nations at the earliest possible opportunity.

Notes to editors

- Project Orbis is a programme coordinated by the US Food and Drug Administration involving Canada, Australia, Switzerland, Singapore Brazil and the UK to review and approve promising cancer treatments. The scheme has already given the green light to many life-saving treatments for patients suffering from conditions such as breast cancer, lung cancer, liver cancer, endometrial cancer, and chronic lymphocytic leukaemia.
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The agency is an executive agency of the Department of

Health and Social Care.

- *Midha A, Dearden S, McCormack R. EGFR mutation incidence in non-small cell lung cancer of adenocarcinoma histology: a systematic review and global map by ethnicity (mutMapII). Am J Cancer Res. 2015;5;2892-2911.

[10p plastic bag charge to come into force on 21 May](#)

The single-use carrier bag charge, which has seen a 95% cut in plastic bag sales in major supermarkets since 2015, will be increased from 5p to 10 and extended to all businesses in England from 21 May to help drive down sales further.

As a result of the carrier bag charge, the average person in England now buys just four single-use carrier bags a year from the main supermarkets, compared with 140 in 2014. By extending the charge to all retailers, it is expected that the use of single-use carrier bags will decrease by 70-80% in small and medium-sized businesses.

Small businesses across the country are being urged to prepare themselves for the changes ahead of them coming into force on 21 May. It comes as new [research finds the charge is supported overwhelmingly by the public](#) – with 95% of people in England acknowledging the wide-ranging benefits to the environment so far.

Environment Minister Rebecca Pow said:

The introduction of the 5p charge has been a phenomenal success, driving down sales of harmful plastic bags in supermarkets by a remarkable 95%.

We know we must go further to protect our natural environment and oceans, which is why we are now extending this charge to all businesses.

Over the next couple of weeks I urge all retailers of all sizes to make sure they are ready for the changes, as we work together to build back greener and strengthen our world-leading action to combat the scourge of plastic waste.

Association of Convenience Stores Chief Executive James Lowman said:

We strongly welcome the inclusion of local shops and other small businesses into the successful plastic bag charging scheme, which not only helps the environment, but is also a great way for retailers to raise money for local and national charities.

Sunjiv Shah, Uber Eats UK General Manager said:

We want to make it as easy as possible for businesses to tackle plastic waste and to support good causes. Everyone can help play a role in protecting the environment by reducing the use of single-use plastic bags.

A new [report published today from charity WRAP](#) finds a shift in attitude towards plastic bags since the charge was first brought in.

Through a survey of over 2,000 adults in England, it was revealed:

- Close to seven in ten (69%) were either 'strongly' or 'slightly' in favour of the charge when it was first introduced, and that has increased now to 73%.
- Customers are changing habits to use long-life bags made from more sustainable and environmentally-friendly materials. Of those surveyed, two in three (67%) said they used a 'bag-for-life' – either fabric or more durable plastic – to take their shopping home for a large food shop in store, with only 14% using a single-use carrier bag.
- Only one in four (26%) purchase bags from the till when doing food shops – including 4% who say they do this 'always'. This represents a significant fall since 2014 before the charge was introduced, when over twice as many (57%) reported taking plastic carrier bags from the till. Meanwhile, over half (54%) say they take less bags from the till.
- Almost half (49%) of 18-34s says they purchase carrier bags at the till at least sometimes, compared to just over one in ten (11%) of those aged 55+.

Since the introduction of the charge, retailers have donated over £150 million to good causes in charity, volunteering, environment and health sectors.

The move will help the UK build back better and greener from the pandemic, and boost our global leadership in tackling climate change and plastic pollution. As hosts of COP26 this year, President of the G7 and a key player in the CBD COP15, we are leading the international climate change agenda.

In its war against plastic pollution, the Government has already [banned microbeads in rinse-off personal care products](#) and [prohibited the supply of plastic straws, stirrers and cotton buds in England](#). A [world-leading plastic packaging tax](#) will be introduced from April 2022 for products which do not have at least 30% recycled content, while [the Government is currently consulting on landmark reforms](#) which will introduce a deposit return scheme for drinks containers and Extended Producer Responsibility for packaging.

[Addressing the 'extant threat' to peace and security posed by unresolved chemical weapons issues in Syria](#)

Thank you, Mr President. And may I start by thanking High Representative Nakamitsu for her briefing today. I'd also like to thank the Director-General of the OPCW as always for his latest monthly report.

The report raises issues of serious concern.

First, we note the discovery by the Declaration Assessment Team in September 2020 of an undeclared neat chemical warfare agent in samples collected from large volume storage containers at a previously declared chemical weapons production facility. This has led to the opening of a new outstanding issue by the Declaration Assessment Team.

Second, the OPCW Investigation and Identification Team concluded in its second report dated 12 April 2021 that there are reasonable grounds to believe that the Syrian Arab Air Force under control of the Tiger Forces dropped a canister containing chlorine on Saraqib on 4 February 2018. This brings the number of occasions on which the UN and the OPCW have found the Syrian regime responsible for the use of chemical weapons to eight.

The implications are clear. Syria is a country that by its own admission had an extensive chemical weapons programme. It failed to declare this programme in full. It retained a chemical weapons production capability beyond the 2014 destruction of its declared programme and it has been found to have used those retained chemical weapons on numerous occasions throughout the conflict. It continues to fail to comply fully with the OPCW Technical Secretariat. This has all been independently established by both the United Nations and the OPCW.

In light of this catalogue of breaches of UN Security Council resolutions, the Chemical Weapons Convention and fundamental international norms, the action taken by the OPCW Conference of States Parties on 21 April was minimal, proportionate and entirely in accordance with Articles VIII and XII of the Chemical Weapons Convention and the obligation on the Conference of

States Parties to take necessary measures to ensure compliance with the Convention. This is a clear case of the situation that these provisions are designed to address.

The next steps for Syria are clearly set out in the decision: its rights and privileges will be reinstated by the Conference of States Parties once the Director-General has reported to the Executive Council that Syria has resolved all the outstanding issues in its declaration and declared all outstanding production facilities and stockpiles, including those used in the 24, 25, and 30 March 2017 attacks.

While these issues remain unresolved, and particularly in light of Syria's identified use of chemical weapons, there is an extant threat to international peace and security, on which basis this Council should remain seized of this matter.

Thank you, Mr President.

[Foreign Secretary meeting with Foreign Minister Chung Eui-yong of the Republic of Korea, 6 May](#)

Press release

Foreign Secretary Dominic Raab met Foreign Minister Chung Eui-yong of the Republic of Korea following the G7 Foreign and Development Ministerial meeting.



A Foreign, Commonwealth & Development Office spokesperson said:

Foreign Secretary Dominic Raab met Foreign Minister Chung Eui-yong of the Republic of Korea today for the sixth UK-ROK Strategic

Dialogue, following the G7 Foreign and Development Ministerial meeting.

The UK and the Republic of Korea agreed a renewed ambition to tackle climate change. They also discussed trade, equitable access to COVID-19 vaccines, global challenges and the UK-ROK defence partnership.

The Foreign Ministers agreed to strengthen UK-ROK cooperation ahead of COP26. They agreed that the upcoming Partnering for Green Growth and the Global Goals 2030 Summit was a milestone to galvanise international action on climate ahead of COP26. The Foreign Secretary welcomed Republic of Korea's announcement at the Earth Day Summit 22 April to end international coal financing.

Both countries committed to continue working closely together as a force for good to address shared global challenges. They agreed on the importance of ensuring equitable access to COVID-19 vaccines and committed to cooperate closely through COVAX. The Foreign Ministers also agreed on the need to work together more closely in opposition to the coup in Myanmar and to stand up for the Myanmar people against the military regime.

On trade, the Foreign Secretary emphasised the UK's ambition to deepen the trading relationship with the Republic of Korea, through the expansion of the UK-ROK continuity Free Trade Agreement signed in August 2019.

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[Foreign Secretary virtual meeting with Dr Jaishankar Indian Minister of External Affairs, 6 May](#)

Foreign Secretary Dominic Raab spoke with Indian Minister of External Affairs Dr Jaishankar today (Thursday 6 May) via video call.

Both Ministers welcomed the Comprehensive Strategic Partnership between the UK and India, and discussed how they could coordinate efforts to deliver deeper cooperation and collaboration between the two countries.

They noted the importance of working together to tackle global challenges such as climate change, coronavirus and countering shared threats including

malign cyber activity.

The two Ministers reflected on key achievements, such as the Enhanced Trade Partnership announced earlier this week, which removes market barriers and will help create new British and Indian jobs, including in strategic areas like science and technology.

They discussed priority areas for further progress, across trade, defence and security, climate, and health. They also welcomed the Migration and Mobility Partnership, announced this week, which will strengthen the 'living bridge' of people between the UK and India.

Building on their discussions in New Delhi last December, the Ministers agreed to ensure delivery of the 2030 Roadmap for India-UK future relations, agreed by the Prime Minister and Prime Minister Modi on 4 May, as the foundation of an elevated UK-India relationship.

On climate change both ministers agreed that it was important to build on the momentum growing among the international community ahead of COP26 in Glasgow.

They discussed regional issues including the UK's successful application for ASEAN Dialogue Partner status, and how the two countries and ASEAN nations could work together to bring an end to the military coup in Myanmar.

Finally, they discussed the need for deeper collaboration to tackle the Covid-19 pandemic and agreed on the need for swift and equitable access to vaccines around the world.