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AstraZeneca shares positive results from Imfinzi trial

AstraZeneca has shared positive results from phase 3 trial for Imfinzi treating lung cancer

Pharma giant AstraZeneca has shared positive results from a phase 3 trial on Imfinzi (durvlalumab), its resectable non-small cell lung cancer treatment, having shown a 'significantly improved' event-free survival.

The company shared results from the phase 3 AEGEAN trial, which demonstrated that treatment with Imfinzi, either before or after surgery, 'significantly increased' the time patients continued to live without recurrence or progression events. Pathologic response analyses were consistent with previous positive results from prior trials.

The trial will continue to assess secondary endpoints, such as disease-free survival and overall survival, as initially planned.

John V Heymach MD PhD, professor and chair thoracic/head and neck medical oncology at the University of Texas MD Anderson Cancer Center, commented: "Treating patients early with durvalumab both before and after surgery delivers a significant and clinically meaningful benefit in resectable non-small cell lung cancer, where new options are urgently needed to offer patients the best chance of long-term survival. The AEGEAN results provide compelling evidence that this novel durvalumab regimen can drive improved outcomes in this curative-intent setting."

Susan Galbraith, executive vice president of Oncology R&D at AstraZeneca, added: "Patients with resectable non-small cell lung cancer face unacceptably high rates of recurrence, despite treatment with chemotherapy and surgery. We have shown that adding Imfinzi both before and after surgery significantly increased the time patients live without recurrence or progression events. We will continue to follow patients for overall survival."

£1.6bn of research and development funding "surrendered" back to UK Treasury

A pot of £1.6bn which was originally allocated as the UK's contribution to the €96bn Horizon Europe research funding programme – run by the EU – has reportedly been 'surrendered' to HM Treasury. The funds were promised as a foundation for a domestic scheme if the ongoing struggle around the UK's associate membership to Horizon Europe remained unresolved.

Associate membership to Horizon Europe was included in the Brexit 'divorce' deal between the UK and EU, however such a deal has never been finalised due to the ongoing Northern Ireland trade border disputes between the UK and EU. In 2022, the EU withheld Horizon funding for UK projects, meaning UK applicants are having their funding covered by the UK government until the associate membership is passed.

Leading science organisations, such as the Campaign for Science and Engineering (CaSE) lobby group, have admonished the decision to 'surrender' the funding by the Department of Business, Energy, and Industry Strategies (CEIS), which CaSE claims came in the Central Government Supply Estimates 2022-2023.

CaSE executive director Professor Sarah Main said the withdrawal "undermines the Prime Minister's assertions about the importance of science and innovation to the UK's future and the creation, only this month, of a new department to pursue this agenda."

Sir Adrian Smith, president of the Royal Society, said: "The failure of all sides to secure the UK's association to the EU's research programmes has now cost UK science £1.6bn. That comes on top of the talented researchers who have left the UK in order to carry on their collaborative work. How does this sit with the government's stated mission to have the UK as a science superpower? The Treasury must now ensure that this money is reinvested in research in the coming years."

Future Focus

New clinical trial aims to find new endometriosis treatment

A new clinical trial is set to begin shortly, which will be a collaboration between the universities of Edinburgh, Aberdeen and Birmingham. The study will assess the efficacy of the drug dichloroacetate in managing pain for patients with endometriosis.

Scientists are hopeful that the study will be successful, providing the first new treatment option in four decades. It would also be the first non-hormonal and non-surgical endometriosis treatment.

Endometriosis is a condition in which lining similar to the lining of the womb grows elsewhere, often in the ovaries and fallopian tubes; the condition is lifelong and can cause serious discomfort and pain. The condition is estimated to affect 1.5 million women in the UK, according to Endometriosis UK.

Approximately 100 women with endometriosis

will be invited to join the trial, half of whom will be given dichloroacetate, which has previously been used to treat rare metabolic disorders in children, while the other half will be given a placebo drug.

Dr Lucy Whitaker, study lead, Wellbeing of Women researcher and clinical lecturer at the University of Edinburgh, commented: "We know women with endometriosis desperately want more treatment options and better ways to manage the often-debilitating pain that it causes. […] Our research so far shows promising results that dichloroacetate can make a huge difference. […] I hope our new trial will confirm this and give women hope that new treatments and a better quality of life are on the horizon."

Janet Lindsay, CEO of health charity Wellbeing of Women added: "It is completely unacceptable that there have been no new treatments for endometriosis in 40 years. […] Too many women and girls are suffering from debilitating symptoms, such as chronic pelvic pain, fatigue and even fertility problems, and current hormonal and surgical treatments aren't suitable for everyone. […] Endometriosis is an extremely underfunded area of women's health, so we are very pleased to partner wit the Scottish Government and invest in medical research that could transform how the condition is treated for millions of women."

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The start of spring brings with it countless new beginnings, and this theme has carried over into the pharma world too, with new drugs, trials and treatments all in the works. This edition features the latest news, from a new clinical trial looking for endometriosis treatments (page 2) and the FDA being sued by some Democratic US states as they try to force the agency to relax restrictions to medication abortions (page 7), to Eli Lilly capping consumer insulin costs at $35 (page 7) and Elon Musk's Neuralink brain implant device being rejected by the FDA before its planned human trials (page 12).

This month's edition also features an article from Rizvan Faruk Batha at Specialist Pharmacy (page 14), who explores the origins and benefits of compounded medication, as well as considering why it might be less common in the UK than elsewhere. Batha focuses on the menopause as an indication for compounded medications, while evaluating the pros and cons of various treatment options and types of hormonal drugs for the treatment of menopause symptoms.

In addition, this month's issue includes information on the menopause that looks at its impact on sleep and considers current legislation related to the menopause and recent calls for change, as well as the help and support available for those suffering with its symptoms (page 16).

I hope you enjoy the issue, and remember to look out for next month's issue of *Pharmafocus* in May.

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AstraZeneca signs $63m agreement for gastric cancer treatment

AstraZeneca has announced that it has signed an exclusive licence agreement (ELA) with KYM Biosciences Inc for CMG901, which is an antibody drug conjugate (ADC) intended to treat gastric cancer.

The Cambridge, England-based big pharma will now be in charge of the research, development, manufacture and commercialisation of CMG901 worldwide.

Following the agreement, AstraZeneca will make an upfront payment of $63m to KYM Biosciences, as well as subsequent development and sales milestone payments up to $1.1bn, which KYM Biosciences will receive alongside tiered royalty payments.

The deal is expected to close in the first half of 2023, depending on closing conditions and regulatory clearances.

CMG901 is currently in a phase 1 trial to assess its efficacy at treating Claudin 18.2 positive solid tumours, including gastric cancer. Preliminary results appear positive, with some early signs of anti-tumour activity across the dose levels being evaluated.

Puja Sapra, senior vice president of Biologics Engineering and Oncology at AstraZeneca, commented: "We are excited by the opportunity to accelerate the development of CMG901, a potential new medicine for patients with Claudin 18.2-expressing cancers. CMG901 strengthens our growing pipeline of antibody drug conjugates and supports our ambition to expand treatment options and transform outcomes for patients with gastrointestinal cancers."

Dr Bo Chen, chief executive officer of Keymed and board chairman of KYM Biosciences, added: "We are pleased to announce our agreement with AstraZeneca, a global biopharmaceutical company with leadership in developing and commercialising novel anti-cancer therapies. This is not only a recognition of CMG901, a potential first-in-class Claudin 18.2 ADC, but also Keymed's internal discovery and development capabilities. The global scope of this agreement has the potential to benefit patients in China, and throughout the world."

Biotech centre focusing on gene therapies opens in Bristol, UK

A new state-of-the-art facility named the Clinical Biotechnology Centre (CBC) is opening in Bristol, UK. It cost approximately £10m to build, funded by the UK Government.

CBC is aiming to support the UK's cell and gene therapy (CGT) industry, from manufacturing DNA plasmids and viral vectors that are used to create gene and genetically modified cell therapies, to supporting early phase clinical trials and preclinical work.

CGT has been found to be potentially curative for currently incurable diseases such as blood cancers, sickle cell disease and cystic fibrosis. Some of these diseases require personalised treatments that are created for a single patient – it is hoped the CBC will facilitate this for UK patients.

The UK currently has a limited capacity to manufacture DNA plasmids and viral vectors, which means long delays for the developers of gene therapies, and the added cost and time of looking overseas for manufacturers.

Dr Lilian Hook, NHS Blood and Transplant's director of Cell, Apheresis and Gene Therapies said: "The CBC is basically a factory – it manufactures the building blocks (or components) needed to produce gene therapies. Researchers and developers can ask us to manufacture the specific components they require. This will enable cutting-edge research with the potential to develop cures for some critical diseases, which can currently only be treated and often ultimately prove fatal. We'll be supporting delivery of these curative treatments into the NHS, so patients can access them more quickly. The CBC will help the UK grow its cell and gene therapy industry in a rapidly growing international market. We won't be designing the treatments but we will be manufacturing them to the right scale and clinical grade. CGT is a growing area for the healthcare sector and of part of our direction of travel as an organisation."

MHRA's authority restored following Northern Ireland Brexit deal

The Medicines and Healthcare products Regulatory Agency (MHRA) has been limited to approving medicines in Great Britain (England, Scotland and Wales) in the wake of Brexit, with the EMA still responsible for Northern Ireland. However, it is looking likely that a new deal with the EU will restore the agency's authority over the whole of the United Kingdom.

In the pharma sphere, the issues surrounding the Northern Ireland Protocol have led to supply issues, with Northern Ireland under a different regulatory jurisdiction from the rest of the UK. The EU last year attempted to solve this issue with legislation to maintain an uninterrupted supply of medicine between Northern Ireland and Great Britain, but this was unable to solve all of the related issues.

The new deal means the MHRA will regain control of medicine authorisation in Northern Ireland, so EU rules will no longer apply to medicines in Northern Ireland, for example the need to apply the EU's format of unique identifiers on medicine packets using 2D barcodes.

The Association of the British Pharmaceutical Industry (ABPI) has cautiously welcomed this deal, with the trade organisation's chief executive, Richard Torbett, commenting: "While we wait to see all the details, today's agreement appears to bring a return to a single UK market for medicines, providing the permanent solution that our members have been calling for."

Torbett warned that the industry needs an adjustment period to make these changes, and that the ABPI will need to "carefully consider the transition period for making these changes and to ensure any new guidance is clear and provided as soon as possible."

Moda Living and LloydsPharmacy partner to offer residents a prescription service

Moda Living has announced a partnership with LloydsPharmacy to bring residents a 'Health Concierge Service' through VideoGP.

VideoGP will be free of charge and offer residents access to a GP in as little as 30 minutes, between 8am-8pm. There will also be a prescription service, where medication can be delivered to the residents the next day, or collected from the nearest LloydsPharmacy on the same day.

This service is the latest healthcare aid to be offered to Moda Living residents. During COVID-19 lockdown, Moda partnered with MYNDUP, a mental health organisation, which offered digital therapy, counselling and wellness sessions.

Oscar Brooks, director at Moda Living said: "Building strong communities is at the centre of the Moda Living brand, and we're continuously looking for new ways to help support the health and well-being of our residents. We are proud to be pioneering this new service with LloydsPharmacy for our residents across the UK, and hope the launch of the Health Concierge Service with VideoGP for free virtual GP appointments and on-demand prescriptions helps take the pressure off residents who may need these services the most."

Dan Pierce, strategic business development manager at LloydsPharmacy Online Doctor continued: "We're delighted to announce our new partnership with Moda Living, which will enable Moda residents to benefit from LloydsPharmacy's VideoGP service, as part of their new health concierge service. We're looking forward to supporting Moda Living in this exciting new step, to deliver access to healthcare 8am-8pm, wherever residents are located."

NICE approved BMS's Opdivo for lung cancer

Bristol-Myers Squibb's (BMS) immunotherapy drug Opdivo (nivolumab) has become the first to be cleared for NHS use alongside chemotherapy as a pre-surgery (neoadjuvant) therapy for patients with resectable non-small cell lung cancer (NSCLC).

NICE has decided that Opdivo can be used alongside chemotherapy to reduce the size of NSCLC tumours prior to surgery, reducing the chances of disease recurrence.

Currently, surgery is the standard of care for NSCLC, however up to 55% of patients who undergo surgery experience disease recurrence and ultimately die of the disease. BMS estimates that 4,800 patients in the UK could be eligible for its new treatments.

NICE's recommendation follows positive results from the phase 3 CheckMate-816 study, which showed a 37% reduction in the risk of progression, recurrence or death when patients were treated with Opdivo and chemotherapy prior to surgery compared to chemotherapy alone.

Paula Chadwick, chief executive officer of Roy Castle Lung Cancer Foundation, commented, "Being diagnosed with lung cancer is incredibly traumatic. Being told it has returned after undergoing curative-intent treatment is nothing short of devastating, so we are delighted that treatments to reduce the risk of recurrence are being made available to people with early-stage NSCLC before surgery, and with the hope that improved outcomes are possible."

AbbVie gains positive CHMP opinion for upadacitinib for the treatment of Crohn's disease

AbbVie has announced that it has received positive feedback from the EMA's Committee for Medicinal Products for Human Use (CHMP) recommending the approval of upadacitinib (Rinvoq) for the treatment of adult patients with moderate to severe Crohn's disease who have had an inadequate response, lost response or were intolerant to conventional therapies or biologic agents.

The drug's approval follows data from two induction studies, U-EXCEED and U-EXCEL, as well as a maintenance study, U-ENDURE. Patients were treated with 45mg once daily for the induction trials and either 15mg or 30mg once daily in the maintenance study.

All three phase 3 studies showed a significantly greater proportion of patients treated with upadacitinib achieving primary endpoints of clinical remission per SF/AP (stool frequency [SF] <2.8 and abdominal pain [AP] score <1.0) and endoscopic response, when compared to the placebo groups.

Roopal Thakkar MD, senior vice president, development, regulatory affairs and chief medical officer at AbbVie, commented: "The recent CHMP recommendation to approve upadacitinib for use in Crohn's disease is a momentous step, bringing us closer to offering a first-of-its-kind, once-daily oral treatment that can make a difference for people living with this disease. We remain steadfast in our commitment to researching and developing treatment options as part of a diverse portfolio of therapies for those living with inflammatory bowel diseases."

Jean-Frédéric Colombel MD, professor of medicine and director of Inflammatory Bowel Disease Center, Icahn School of Medicine, Mount Sinai and study investigator, added: "The impact of Crohn's disease extends beyond the gut to include systemic symptoms such as fatigue, bowel symptoms and social and emotional functioning. Treatment options that achieve critical endpoints such as clinical remission and endoscopic response can make a difference in managing the challenging symptoms of this condition and health-related outcomes related to quality of life. Upadacitinib could be a promising treatment option for patients who live with uncontrolled moderate to severe Crohn's disease. I look forward to the European Commission's final decision."

CSL receives CMA from the European Commission for haemophilia B drug

CSL, a biotech company, has announced that it has received conditional marketing authorisation (CMA) from the European Commission (EC) for its haemophilia B drug Hemgenix.

Hemgenix (etranacogene dezaparvovec) is an adeno-associated virus five (AAV5)-based gene therapy. It is indicated for the treatment of moderately severe to severe haemophilia B without a Factor IX (FIX) inhibitors history – antibodies that can develop in patients treated with FIX replacement therapies.

The CMA was granted after a positive recommendation from the EMA's Human Medicines Committee in December, and approval by the FDA the previous month. Currently, Hemgenix is now under review in the UK.

These approvals were based on the HOPE-B trial, the results of which showed 96% of haemophilia B patients dosed with a single infusion of Hemgenix had a sustained increase in FIX levels, accompanied by a 64% reduction in bleed rates. Follow up showed these effects were sustained for at least two years.

However, Hemgenix is currently priced at $3.5m per dose in the US, making it the most expensive medicine in the world and above the $2.9m that the Institute for Clinical and Economic Review (ICER) claims is a fair maximum price.

CSL states that the benefits of Hemgenix, such as the reduction of FIX replacement therapies and the preventing of other healthcare-related costs associated with uncontrolled bleeds, justifies the one-off cost.

"We now need to work to ensure that as many eligible patients across Europe can access this innovative treatment as possible," said Lutz Bonacker, general manager of CSL's European commercial operations, "We are fully committed to working together with payers and other stakeholders to achieve this."

Merck to appeal EU rejection of COVID-19 drug

Life sciences giant Merck & Co has announced that it will appeal the EU's Committee for Medicinal Products for Human Use's (CHMP) decision to not recommend approval for its COVID-19 drug Lagevrio.

Both Merck and its development partner Ridgeback Therapeutics have promised they will request a re-examination, as they believe CHMP's decision "does not reflect the compelling data" for the drug.

The EMA started a review of Lagevrio in November 2021 shortly after the drug was approved for the UK market as a treatment for people with mild to moderate COVID-19 who are at an increased risk of developing severe disease. The review was based on data from the MOVe-OUT trial, which showed a 50% reduced risk of hospitalisation or death compared to placebo – cutting the rate from 14% to 7% in adults with COVID-19 who are not receiving supplemental oxygen and who are at an increased risk of developing COVID-19.

In 2022 however, the 25,000 patient-strong PANORAMIC trial compared Lagevrio to placebo and found that, while people recovered around six days faster with Lagevrio, it was no better at keeping patients from having to be hospitalised.

In its recommendation, CHMP stated that the totality of the data meant it was not possible to say if Lagevrio can "reduce the risk of hospitalisation or death or shorten the duration of illness or time to recovery in adults at risk of severe disease."

In answer, Merck's head of R&D, Dean Li stated: "Data generated from the […] MOVe-OUT trial and from real-world studies demonstrates the positive impact that Lagevrio can provide for patients by reducing the risk of hospitalisation and death among adults at increased risk for severe disease."

Eli Lilly caps consumer insulin costs at $35

Eli Lilly & Co has announced that it will cap out-of-pocket insulin costs at $35 per month, following a plea from President Joe Biden for more affordability for diabetes treatments for all Americans.

The company has announced the insulin price cap alongside other price changes, for example the list price for non-branded Insulin Lispro Injection will be cut to $25 per vial in May, and some Humalog and Humulin doses will be cut by 70% in the fourth quarter of 2023. From April, Lilly's newly launched Rezvoglar will sell at a 78% discount compared to its biosimilar, Sanofi's Lantus.

The decision to reduce insulin prices follows both President Biden's Inflation Reduction Act as well as the company facing a backlash when a fake Lilly twitter account posted a viral tweet late last year, reading: 'We are excited to announce insulin is free now.' The prank tweet caused the company's stock to drop over 4.37% and brought further public attention to the problems with the company's insulin pricing.

In a statement made yesterday, Biden said: "For far too long, American families have been crushed by drug costs many times higher than what people in other countries are charged for the same prescriptions. Insulin costs less than $10 to make, but Americans are sometimes forced to pay over $300 for it."

David A Ricks, Lilly's chief executive officer, commented: "While the current healthcare system provides access to insulin for most people with diabetes, it still does not provide affordable insulin for everyone and that needs to change. The aggressive price cuts we're announcing today should make a real difference for Americans with diabetes."

FDA grants de novo approval to Neuromod's tinnitus device

The FDA has granted de novo approval to Neuromod's Lenire device, which includes Bluetooth headphones, a handheld controller and the Tonguetip intraoral device to treat tinnitus.

The device is non-invasive and the company claims it is the first of its kind to receive this sort of approval from the FDA. The device combines acoustic and electrical intraoral stimulation to provide relief to patients suffering with tinnitus, which is a complex neurological condition.

The therapy includes three elements: Bluetooth headphones to deliver customised sound stimuli to the auditory nerve; a lightweight, handheld controller, which lets patients adjust the length and intensity of treatment; and an intraoral device known as Tonguetip, which provides gentle electrical stimulation to the surface of the tongue to activate the patient's nerves.

The sounds and tongue stimulation are intended to work alongside each other to reduce the severity of the patient's symptoms. The device is the first non-invasive bimodal neuromodulation tinnitus treatment device, which has appeared to relieve tinnitus throughout three large-scale clinical trials.

Neuromod Devices founder and CEO, Ross O'Neill commented: "Lenire's approval not only means that millions of Americans living with tinnitus can get the treatment they need but further validates over a decade of R&D that resulted in a safe solution that provides relief for tinnitus patients. […] Lenire is the first bimodal neuromodulation device to go through the rigours of the FDA's de novo process. […] For patients that are at least moderately impacted by their tinnitus, Lenire has now been shown to be more effective than sound therapy, which is one of the current clinical standards of treatment."

FDA sued by US states over abortion pill access

Attorneys general (AGs) from 12 Democrat-led US states have made complaints to the FDA in an attempt to force the body and commissioner Robert Califf to relax restrictions on access to abortion drug mifepristone.

Mifepristone is often used alongside misoprostol as a pharmacological way to terminate pregnancies, however this has been controversial recently with a previous complaint from 25 House Republicans claiming that the FDA's decision to allow wider access to the drug was harmful to pregnant people and turned "many post offices and pharmacies into abortion clinics."

The drug is regulated through its risk evaluation and mitigation strategy (REMS), which is usually used to protect patients from harmful effects of new drugs and to ensure new drugs are used in accordance with the approved label. The AGs claimed that mifepristone has been approved for 22 years, so the continued enforcement of REMS is "excessive."

The complaint states: "FDA's decision to continue these burdensome restrictions… on a drug that has been on the market for more than two decades with only 'exceedingly rare' adverse events has no basis in science. […] It only serves to make mifepristone harder for doctors to prescribe, harder for pharmacies to fill, harder for patients to access, and more burdensome for the plaintiff states and their healthcare providers to dispense."

Since the overturning of Roe vs Wade, which removed the constitutional protection for the right to abortion, the FDA has attempted to improve access to abortions, for example by allowing mifepristone/misoprostol medication abortions to be dispensed by retail pharmacies and via mail order.

Ellen Rosenblum, Oregon AG, said the restrictions "expose patients to needless anguish and confusion. […] Our coalition stands by our belief that abortion is healthcare, and healthcare is a human right."

Horizon Therapeutics announces real-world treatment results for dysthyroid optic neuropathy drug

Biopharma company Horizon Therapeutics has announced real-world treatment results for its thyroid eye disease (TED) drug in patients with dysthyroid optic neuropathy (DON) who have not responded to previous treatment.

TEPEZZA (teprotumumab-trbw) is the first FDA-approved treatment for TED – a serious, progressive and potentially vision-threatening rare autoimmune disease. DON is a complication of TED, which is characterised by thyroid-related impairment of visual function. It can lead to permanent sight loss related to optic nerve compression.

Between January 2020 and September 2022, 24 patients with TED and DON who had previously received treatment by way of oral or intravenous steroids, surgery and/or radiation were treated with TEPEZZA. After treatment with TEPEZZA, meaningful improvement was observed in visual acuity in eyes with DON, proptosis, diplopia and Clinical Activity Score (CAS).

Madhura A Tamhankar, MD, study author and associate professor of ophthalmology and neurology at the Hospital of the University of Pennsylvania, stated: "We know how devastating thyroid eye disease can be for patients, and the risk of blindness in those with dysthyroid optic neuropathy is one of the most worrisome complications, especially when traditional therapies fail. This data is encouraging for physicians looking for an option to treat patients at the highest risk of losing their sight and provide evidence that TEPEZZA can help improve symptoms and preserve visual acuity."

Mologic's COVID-19 rapid antigen self-test receives FDA Emergency Use Authorization for home use

US subsidiary of Global Access Diagnostics (GADx) – a developer of lateral flow and rapid diagnostic technologies, products and services – Mologic , has announced that its COVID-19 rapid antigen self-test has received FDA Emergency Use Authorization (EUA).

COVI-Go COVID-19 Self-Test is a differentiated, rapid antigen test composed of an anterior nasal swab and test device – eliminating the need for the mixing and pouring of buffer solutions. The test qualitatively detects nucleocapsid protein antigen from SARS-CoV-2 in around 20 minutes.

Mark Davis, CEO of GADx, stated: "Validation of the COVI-Go Self-Test by the FDA under EUA is a significant step in supporting the global fight against the threat of COVID-19. GADx has been invaluable in supporting the product prototype through clinical trial and EUA registration. Accordingly, we are prioritising US manufacturing, deployment and equitable access to testing across the country. As a social enterprise, we will be leveraging manufacturing scale, knowledge and FDA authorisation in launching COVI-Go. Being focused on accessibility for all, the device is unique in having been developed specifically for the home user whatever their situation. COVI-Go was made for everyday people, and we look forward to supporting our partners in marketing its positive accessibility aspects, which also received positive feedback from accessibility groups like the Americans with Disabilities Act (ADA), highlighting its unique unitised design and easy to use functionality. As COVID-19 is here to stay alongside associated health challenges, the ability to leverage such a platform with the inclusion of additional respiratory diseases will be paramount to our continued strategy."

Sun Pharma recalls at least 34,000 bottles of generic drug

Mumbai-based pharma company, Sun Pharma, has announced that it is recalling over 34,000 bottles of a generic drug, diltiazem hydrochloride, from the US market. The drug is used for treating high blood pressure, angina and some types of irregular heartbeat.

This recall follows the FDA's Enforcement Report, which saw 'failed impurity (Deacetyl Diltiazem Hydrochloride) specification during stability testing and failed dissolution testing at FDA laboratory.'

This batch of the drug was produced at the company's Halol-based manufacturing facility in Gujarat, and was later distributed on the US market by the company's US unit.

Last month, the company announced a Class II nationwide recall in the US.

According to the FDA, a Class II recall is 'a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.'

In January, the company was noted by the FDA as having various lapses, including its failure to follow the correct written procedures, which have been designed to prevent microbiological contamination of drug products, at its Gurarat branch. The FDA's warning letter also pointed out various other lapses at the Halol plant, which produces the company's finished pharmaceutical products.

Abbott announces positive clinical study data for both TriClip system and MitraClip therapy

Abbott has announced positive data from two separate studies, which looked at its TriClip transcatheter edge-to-edge repair (TEER) system and its MitraClip therapy for treating leaky valves in people with mitral regurgitation (MR).

The TriClip system's safety and effectiveness were researched in the TRILUMINATE clinical study, which established it as superior to medical therapy used to treat patients with tricuspid regurgitation (TR) who are at risk for open-heart surgery. It found that 87% of patients who received the TriClip system experienced a significant reduction in TR grade moderate or less at 30 days, compared to 4.8% in the control group.

Speaking on the results, Abbott's structural heart business senior vice president Michael Dale said, "[This] TRILUMINATE Pivotal data show[s] TriClip is the first minimally invasive device therapy for the treatment of tricuspid regurgitation to provide durable improvements in TR severity and quality of life that go beyond taking medication to manage symptoms. When left unaddressed, TR can be debilitating and life-threatening. By repairing the damage caused by structural heart disease, TriClip G4 and our latest technological innovations are helping people reclaim their lives so they can get back to doing what they love."

Abbott has also announced positive five-year data for its MitraClip therapy, which shows its long-term benefits in treating leaky valves in people with MR.

It's COAPT trial found MitraClip to be safe and effective, and that it cut hospitalisations by almost 50% while improving survival for heart failure patients with severe secondary MR. It reduced the risk of death by 30% and achieved durable MR reduction in 95% of patients with moderate-to-severe or severe to mild or moderate.

COAPT trial co-principal investigator Gregg W Stone said, "Secondary mitral regurgitation is difficult to diagnose and manage, and is often associated with a poor prognosis. These five-year COAPT results further confirm that MitraClip is safe and effective at treating secondary MR in advanced heart failure patients, durably reducing hospitalisations and helping patients live longer."

Wearable sensor helps detect heart attacks

RCE Technologies has developed a bracelet-like device that can measure levels of troponin-I in the patient's blood, providing a more efficient way of detecting heart attacks. The device was assessed in a real-world study with results presented at the American College of Cardiology (ACC) annual meeting.

The study found that this device was able to predict levels of the biomarker and obstructed arteries with 90% accuracy within a five-minute time frame.

Troponin-I is already used as a diagnostic tool for acute myocardial infarction, which is often detected in blood samples. It is hoped that this wearable device should lessen the time it takes to detect heart attacks and allow treatment to start faster – treatment beginning sooner has potential to preserve heart muscle often affected by the heart attack.

Lead study author Partho Sengupta of Robert Wood Johnson University Hospital, US, and advisor to RCE, commented: "This is an exciting opportunity because it increases our capability for early diagnosis of heart attacks in both community settings and in acute care environments. […] With this level of accuracy, if you use this device and it comes out positive, you're fairly sure this patient can be admitted for fast-tracking diagnostic tests, treatment and intervention."

Atandra Burman, RCE's chief executive and founder, added: "With this wrist-worn sensor, we can provide real-time monitoring of heart muscle injury that can empower clinicians in a much-needed timely intervention in patients with an impending heart attack."

The device is still undergoing tests to assess whether there are variations in results depending on skin tone, wrist size, skin health and other factors.

Nasal spray that relieves migraines in minutes approved by FDA

Pfizer is planning to launch a fast-acting nasal spray that can relieve pain from migraines in as little as 15 minutes for some patients. Zavzpret (zavegepant) has been approved by the FDA as the first calcitonin gene-related peptide (CGRP) inhibitor formulated as a nasal spray to treat acute migraines in adults with or without aura.

This approval marks a positive step in the treatment of migraines, however it is likely to be highly expensive once it hits the market. A Pfizer spokesperson said Zavzpret "is expected to be comparable in price to other FDA approved CGRP migraine medications." As an example, eight doses of Nurtec, another CGRP-inhibiting tablet taken daily to prevent and treat migraines, can cost over $1,000.

The approval follows data from a phase 3 study including over 1,400 patients given a single 10mg dose of the drug. The trial showed that the drug relieved migraine pain in 15-30 minutes, providing relief for up to 48 hours. However, only 22.5% patients were pain free after two hours, compared to 15.5% from the placebo group.

Kathleen Mullin MD, associate medical director at New England Institute for Neurology and Headache, commented: "When a migraine hits, it has a significant negative impact on a person's daily life. Among my migraine patients, one of the most important attributes of an acute treatment option is how quickly it works. As a nasal spray with rapid drug absorption, Zavzpret offers an alternative treatment option for people who need pain relief or cannot take oral medications due to nausea or vomiting, so they can get back to normal function quickly."

Angela Hwang, chief commercial officer and president of Pfizer's Global Biopharmaceuticals Business, added: "The FDA approval of Zavzpret marks a significant breakthrough for people with migraine who need freedom from pain and prefer alternative options to oral medications."

Funding to increase access to early phase clinical trials given to Yale Cancer Center

Yale Cancer Center has announced it has received collaborative funding aiming to support and increase access to early phase clinical trials for patients at community sites for cancer care in Connecticut, US.

The Yale Cancer Center Consortium to Advance Equity in Early-Phase Clinical Trials, led by Patricia M LoRusso DO PhD FASCO, aims to address disparities in participation in clinical trials.

Companies collaborating with Yale Cancer Center on this initiative include: Genentech, Gilead Sciences and Boehringer Ingelheim, all of which have provided funding and support for the Consortium which will help to improve access to phase 1 clinical trials. The Consortium's main goal is to increase access to these early phase clinical trials for cancer patients who would otherwise not receive novel investigational therapeutic interventions.

Dr LoRusso commented: "We strongly believe that by bringing these trials closer to where our patients live and work, and helping them overcome social and structural barriers that negatively impact both accessibility and the treatment of their cancer, the likelihood of research participation by these patient populations will increase, which could significantly improve both their treatment options and quality of life. […] Our project addresses the lack of representation of underrepresented and minoritised populations in early phase cancer clinical trials from a lack of accessibility. Black patients account for 13% and Hispanic patients represent 18% of the US population, yet each population accounts for less than four percent of all patients enrolled onto cancer clinical trials; representation is even less on early phase trials. One of the largest representation barriers is not having availability of trials close to where the patients live and work."

Gilead Sciences wins $175m in ongoing HIV fraud case

Gilead Sciences, a research-based biopharmaceutical company, has won again in the lawsuit levelled against clinics, prescribers, medical labs and pharmacies in relation to fraudulent claims for HIV medications.

Gilead set up the Advancing Access medication assistance programme (MAP) in 2004, which aimed to provide eligible, uninsured people with free medication to protect them from contracting HIV.

The company claims that companies and individuals enrolled patients in MAP, who were then prescribed heavily discounted pre-exposure prophylaxis (PrEP) medicines Truvada (emtricitabine/tenofovir disoproxil fumarate) and Descovy (emtricitabine/tenofovir alafenamide), which they then bought back from the patients so that the medication could be resold. As part of this scheme, Gilead maintains that the prescribers in the network performed fake wellness checks on patients, used their credentials to write fraudulent prescriptions and then submitted illegal redemption claims for money, which was then divided between the conspirators.

In this most recent win, Gilead proved claims under the federal and Florida Racketeer Influenced and Corrupt Organizations (RICO) and was awarded $175m, bringing the total throughout the entire lawsuit to $250m.

A final default judgement has now been put forward against Baikal Marketing Group, Arsen Bazylenko and Tatiana Rozenblyum, which, if won, could increase Gilead's payout by $131.4m. Another $43.7m has been entered against Priority Health Medical Centre and Nick Myrtil.

Moderna to pay $400m to US government over new COVID-19 vaccine licence

Moderna, a leader in the development of COVID-19 vaccines, announced that it has paid the National Institute of Allergy and Infectious Diseases (NIAID) $400m in a "catch-up payment", under a new royalty-bearing licence agreement between the organisations.

The deal surrounds Moderna's use of a molecular stabilising technique developed by NIAID and collaborators from Dartmouth and the Scripps Research Institute, which was published in a 2017 study. The mRNA-based vaccine delivers genetic code for the spike protein, which is then translated by human cells into protein. NIAID's method made it so that, when translated, the spike protein would stay locked in a specific formation best for generating an immune response. The method was developed using a spike protein from MERS-CoV.

Moderna is paying NIAID the $400m in regards to accessing "certain patent rights concerning stabilising prefusion coronavirus spike proteins," stated Moderna's CFO Jamie Mock. Moderna also agreed to pay NIAID "low, single-digit royalties" on COVID-19 vaccine sales, according to Mock. NIAID has reported that it will share the payment with Dartmouth and Scripps.

Moderna posted around $36bn in COVID-19 sales across 2021 and 2022, meaning the $400m payment only represents 1% of the company's total vaccine sales over that span. However, the company recently recorded around $2.8bn in charges related to decreased demand – including a $1.3bn charge for inventory write-downs, plus $725m for contract cancellations. Moderna also paid $776m for unused manufacturing capacity and CDMO charges.

The deal with NIAID is just one of many that Moderna face. Both Pfizer and BioNTech, mRNA rivals of Moderna, have brought patent suits against it, and a separate case is being pursued by Arbutus and Roivant's Genevant Sciences.

Medtronic's extravascular defibrillator receives CE mark

Medtronic has received the CE mark for its extravascular defibrillator. The Aurora EV-ICD™ MRI SureScan™ and Epsila EV™ MRI SureScan™ defibrillation lead treat abnormally fast heart rhythms, which can lead to sudden cardiac arrest.

Implantable cardioverter-defibrillators (ICDs) are a highly effective treatment for sudden cardiac arrest (SCA). They detect when the patient is experiencing an abnormally fast heart rate and deliver therapy to terminate a potentially fatal arrhythmia.

The Aurora EV-ICD system offers the same defibrillation, anti-tachycardia pacing (ATP) and back-up pacing therapies as traditional ICDs, however its thin wire is placed outside of the heart and veins. Traditional transvenous ICDs are implanted in the chest and attached to leads, which are threaded through veins into the heart. Aurora EV-ICD is implanted below the left armpit, with the Epsila EV lead being placed under the sternum, avoiding any intrusion into the veins and heart. This avoids certain long-term risks such as vessel occlusion and blood infections.

Aurora EV-ICD received its CE mark after the Extravascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study met its safety and effectiveness endpoints.

Alan Cheng, MD, chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic stated, "We are proud to be the first company to offer a complete one-system, one-procedure extravascular ICD solution, which maintains the patient benefits of traditional, transvenous ICDs without the risk of leads in the heart and vasculature. This approval is a significant milestone in achieving our goal of delivering a defibrillation solution that treats sudden cardiac arrest while improving the patient experience."

Moderna chooses Oxfordshire for new UK facility

US biotech firm Moderna has chosen Harwell Science Campus in Oxfordshire for its new UK R&D facility. The campus is already home to more than 70 organisations and sits within the UK's 'golden triangle', an area rich in life sciences facilities, between Oxford, Cambridge and London.

Other companies based at this campus include the UK Health Security Agency (UKHSA), the Rosalind Franklin Institute, Oxford Nanopore, Agilent Technologies and Karus Therapeutics, among others. Moderna is already working alongside the UKHSA on early vaccine development for future pandemic threats.

Plans for Moderna's Innovation and Technology Centre (MITC) were revealed last June and finalised in December, with the facility expected to create over 150 highly skilled jobs and the capacity to produce nearly 250 million vaccines each year in the event of another pandemic. The company has a target of being able to develop vaccines for emerging threats within 100 days.

The company aims to use the MITC to provide the UK with access to mRNA vaccines for a range of respiratory diseases. The site is also linked to a clinical biomarker laboratory in Cramlington, Northumberland.

The biotech will also run a number of clinical trials in the UK while providing funding grants to UK universities, in a ten-year alliance between Moderna and the UK Government.

Darian Hughes, UK general manager of Moderna, commented: "We are delighted to reach this important milestone – we look forward to joining the Harwell Campus health tech cluster and contributing to the UK's science and innovation community through investments in R&D. […] When constructed, our facility at Harwell will harness mRNA science that aims to develop and deliver innovative vaccines to the UK public that address emerging threats from respiratory viruses facing our population."

REGENXBIO presents interim phase 2 data from drug developed on NAVXpress platform

REGENXBIO, a clinical-stage biotech company, has announced positive phase 2 data for its drug RXG-314, which was developed by the company's NAVXpress bioreactor platform process.

RXG-314 is a potentially one-time treatment for wet AMD, diabetic retinopathy and other chronic retinal conditions. It contains the NAV AAV8 vector, which encodes an antibody fragment designed to inhibit vascular endothelial growth factor (VEGF), and is believed to inhibit the VEGF pathway, where new, leaky blood vessels contribute to the accumulation of fluid in the retina.

The pharmacodynamics, safety and efficacy of RXG-314 is being tested in the phase 2 bridging study, where 60 patients with wet AMD are given subretinal doses in two different measures (6.4x1010 GC/eye and 1.311 GC/eye). At each dose level, half the patients are given RXG-314 produced by the NAVXpress platform process, and the other half are given RXG-314 produced by the adherent cell culture manufacturing process that was used in phase 1/2a of the trial.

As of November 2022, RGX-314 was well-tolerated across 46 patients. The two high dose cohorts have completed six-month visit assessments, where it was found that target protein concentrations in the eye were similar between the manufacturing processes.

Curran Simpson, chief operating officer of REGENXBIO said, "The interim results observed in the phase 2 bridging study show a similar clinical profile between our manufacturing processes. We believe our approach, focused on early product quality and process control, allows us to efficiently transition from clinical trials to commercial readiness. This update provides validation of our plans for the NAVXpress platform process to support the production of RGX-314 in anticipation of future commercialisation."

"There is a significant need for treatment options that can reduce the burden of frequent injections for wet AMD patients while maintaining optimal function and anatomic outcomes. The clinical profile of RGX-314 manufactured using the commercial-scale process is encouraging, as is the potential of a one-time therapy for the treatment of wet AMD," said Dr Charles C Wykoff MD PhD, director of Research at Retina Consultants of Texas, chairman of Research, Retina Consultants of America and deputy chair of Ophthalmology for the Blanton Eye Institute, Houston Methodist Hospital.

Bristol Myers Squibb and Viz.ai sign multi-year partnership for HCM device

Bristol Myers Squibb and Viz.ai, an AI-powered medical imaging company, have signed a deal to use AI to detect and triage patients with suspected hypertrophic cardiomyopathy (HCM).

The Viz HCM provider workflow software automatically reviews routine electrocardiograms (ECGs), detects cases of suspected HCM and alerts the cardiologist who performed the ECG. It is hoped that this will help physicians to diagnose HCM faster and in a more efficient way.

Viz.ai has filed a de novo request to the FDA for the software as a Software-as-a-Medical-Device (SaMD), which has been accepted for review.

Currently, Viz.ai has the Viz.ai Cardio Suite for US hospitals. It provides a mobile-based ECG viewer with AI alerts and communication tools, all aiming to improve cardiac care communication. If Viz HCM is approved, it will be added into the suite.

Viz.ai CEO Chris Mansi said: "HCM can be a devastating disease. The agreement with Bristol Myers Squibb gives us the opportunity to enable underdiagnosed and underserved HCM patients to get the care they need from appropriate providers at the right time. Incorporating the new HCM module into the Viz Cardio Suite is expected to enhance detection, expedite care and empower clinicians and patients."

Suhas Krishna, vice president and head of Digital Health Product Management at Bristol Myers Squibb, commented: "At BMS, we believe that the use of AI to detect key, subtle characteristics in bio signals to aid physicians in the screening, diagnosis, treatment and monitoring of diseases will have a critical and positive impact on patients' lives. We are excited to continue building momentum in our support of Viz.ai's R&D programme. The speed and quality in which this novel AI algorithm & workflow sequencing product was designed, verified, validated and submitted by Viz.ai for agency review is testament to the ability to drive rapid and meaningful innovation in healthcare."

Elon Musk's Neuralink rejected by FDA for human trials

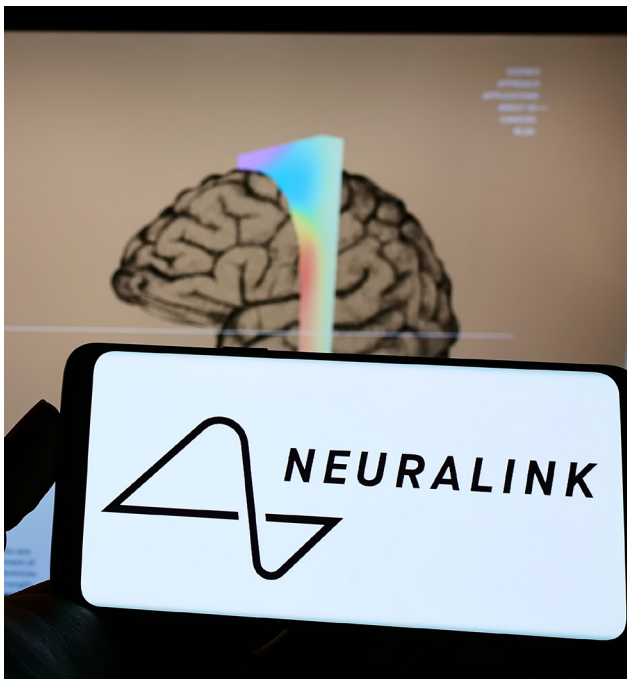
The FDA has reportedly rejected a bid by Elon Musk's Neuralink in which it proposed the initiation of human testing for its brain chip implants. The company has been working on brain implants that allow for a computer-brain interface, which could allegedly restore vision to the blind and help paralysed people to walk again.

Neuralink previously applied to the FDA for human testing in early 2022, however this was also rejected with Reuters reporting that there were 'dozens of issues the company must address.' The FDA's concerns included the fact that the implants use lithium batteries and that the wires used could 'migrate' to elsewhere within the brain. There was also a concern that the implant may not be able to be removed without causing brain damage or injury.

In November 2022, Musk stated that the company expected to undertake human trials in "about six months," also tweeting in November that the implant was 'ready for humans' with the timing for beginning trials due to 'working through the FDA approval process.'

Reuters have reported that since 2018, nearly 1,500 monkeys, pigs and mice have been killed in testing for Neuralink, however the company has defended its animal testing, stating that "all novel medical devices and treatments must be tested on animals before human trials can commence."

Kip Ludwig, former programme director for neural engineering at the US National Institutes of Health, told Reuters that "Neuralink doesn't appear to have the mindset or experience that's needed to get this to market anytime soon."



Sooma receives FDA Breakthrough Device designation for depression therapy device

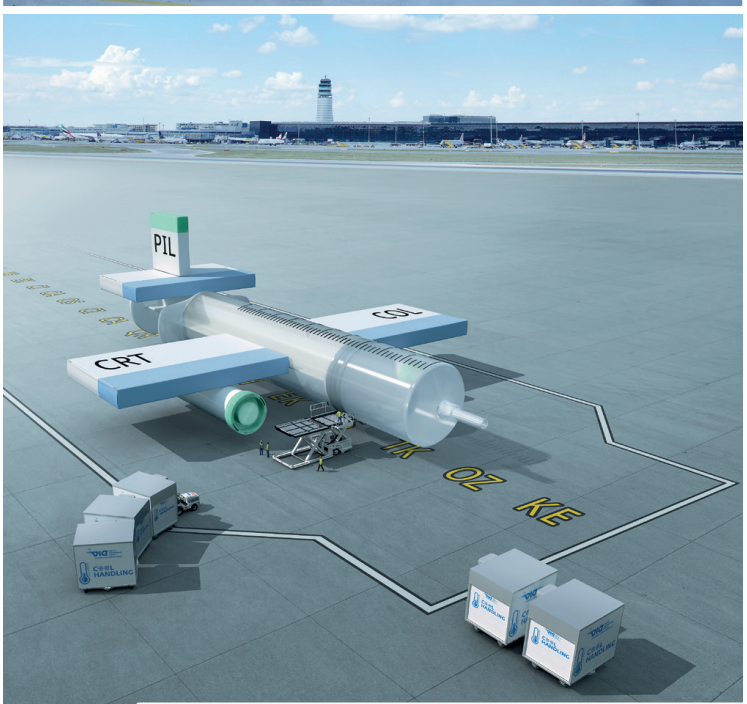
Finnish company Sooma Medical has received Breakthrough Device designation by the FDA for its portable, at-home neuromodulation device to treat depression.

Sooma Depression Therapy is a painless, medication-free, prescribed device, which uses a mild electrical current to stimulate targeted areas of the brain. It involves daily 30-minute sessions over a minimum of a three-week period and has been proven to provide "significant improvement" for patients with Major Depressive Disorder (MDD), according to Sooma.

Current treatments for MDD, such as antidepressants and psychotherapy, can be effective, but limitations and medication side effects make it difficult for patients to engage with them on a long-term basis. Sooma Depression Therapy can be used as a stand-alone treatment or in conjunction with medication, and as it is pharmaceutical-free there is no risk of drug interactions, which can be dangerous.

According to Sooma's post-market data, over half of patients felt they achieved a complete clinical response, meaning a 50% or higher improvement in their depressive symptoms.

Sooma CEO Tuomas Neuvonen commented: "We are thrilled to receive this Breakthrough designation from the FDA. 21 million people worldwide are estimated to suffer at least one major depressive episode in their lives. This designation recognises that our device is a perfect solution, enabling a fast, effective and affordable treatment on a greater scale. We are committed to making this innovative treatment accessible to patients in the US as quickly as possible."



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VIENNA AIRPORTCITY

Industry Insight

Compounded Medication: What Do We Need To Know?

Rizvan Faruk Batha from Specialist Pharmacy tells *Pharmafocus* about the history and benefits of compounded medication and why it's not as common in the UK as the rest of Europe, North America and Australia

Put simply, compounding is the process by which one or more individual ingredients are combined to create an individually customised medicine, where the exact strength, dosage or form required by the patient is created in a tailor-made and unique manner. Compounding pharmacies can create medications in a variety of dosage formulations such as creams, capsules, suppositories and injectable solutions whilst also being able to adjust the dose or flavour of these medicines to create a combination that is not commercially available from pharmaceutical drug manufacturers.

The origins of pharmacy can be traced back to the Sumerians, Egyptians and Greeks; natural products derived from plants, animals and minerals were used, however the first recorded evidence of pharmaceutical methods dates back to around 2600BC in the Mesopotamian era.

The ancient Egyptians developed a sophisticated pharmacy system and from then on pharmacists and physicians have been able to compound medicines to treat a wide variety of ailments. By 1815, apothecaries in the UK became known as general practitioners (GPs); chemists and druggists (the modern day pharmacists) were left to manufacture, pack, wholesale, retail and dispense medicines. In 1841, the Pharmaceutical Society of Great Britain was formed, followed by the role of pharmacists and pharmacies being enshrined in law in 1868.

Before the advent of mass production of medications, pharmacists would routinely compound medications for their patients by hand, based on their specific needs. However, with the advent of mass-produced medications and the increasing regulation of the pharmaceutical industry, the practice of compounding began to decline.

The founding of the NHS in 1948 meant increased marketing and therefore awareness of these mass-produced medicines and pharmacists began to spend their time dispensing medication, rather than compounding. The NHS provides free or low-cost healthcare to all. Due to the nature of the NHS budget and the guidelines that follow that regulate which medicines are available through its services the need for compounded medicines started to decline.

Whilst mass manufacturing of medicines may meet the needs of the majority of patients, it's important to recognise that up to 20% of all hospital admissions are medicine-related.[1] There remains a subset of patients who do not respond well to manufactured, mass-produced medicines, either due to allergies, sensitivity to one of the excipients or the formulation of the licensed medicine not being suitable for them. The very nature of mass manufacturing becomes a 'one-size-fits-all' approach, therefore the need for compounding still exists today.

There may also be clinical needs that cannot be met by a licensed medicinal product or a suitable alternative, and the risk of the patient not having treatment takes precedence over the potential risk of compounding the medicine. In addition, it can be necessary for a patient to have an exact dosage strength that does not currently exist as a licensed product. Rather than taking half a tablet or cutting a patch in half, where there is no certainty of dose, a pharmacist can compound the exact dose that is required for the patient. In these scenarios compounding pharmacies can work with healthcare providers and patients to ensure the specific needs of the patient can be met.

It is important that compounding pharmacies are subject to regulatory oversight and must adhere to strict quality standards to ensure the safety and effectiveness of their medications. In the UK, compounding pharmacies are regulated by the General Pharmaceutical Council (GPhC) and operate under the exemption of Section 10 of the Medicines Act 1968 and Regulation 4 of the Human Medicines Regulations 2012. Regulated compounding pharmacies with sufficient risk management and quality management systems allow a pharmacist to prepare and supply unlicensed medicines.

Pharmacists are experts in medicines and acquire the knowledge and expertise required to compound during their initial education prior to registration. The GPhC guidance explicitly mentions that patients would expect that 'when an unlicensed medicine is prepared by, or under the supervision of, a pharmacist in a registered pharmacy, it is of an equivalent quality to any licensed medicine they will receive (such as those produced by a regulated and licensed manufacturer)'. Therefore, compounding pharmacies are expected to ensure that they can maintain these high standards and are regularly inspected by the GPhC.

Today, the UK has only a handful of compounding pharmacies, compared with Germany for example, which has over 2,000, so why are they less common in the UK than in many other countries in Europe, North America and Asia? There are several factors at play.

Each individual country has its own governance and attitude towards unlicensed medicine and this dictates its compounding landscape. Continuing with Germany as an example, historically it has not wanted to rely on imports, to prevent being caught out during the all-too-common shortages of licensed medication. Perhaps more significantly, it has always promoted patient choice, whether that be with complementary therapies or compounded medication. It is therefore mandatory for all pharmacies in Germany to fulfil both licensed and compounded prescriptions, highlighting its more patient-centric approach to healthcare.

Patient care in the UK on the other hand, is dominated and led by the NHS and its commissioning bodies. GPs rely heavily on commissioned pathways for the medications they prescribe to their patients, primarily based on a cost-benefit ratio, which helps them stay within their limited medicines budget, however it also means that patients seeking compounded medication often have to go private. This ultimately leads to health inequality as access to these treatments only becomes available to those who can afford it.

The benefits of compounded medication are numerous. It allows healthcare providers greater flexibility to change ingredients, dosage forms and customise medications to accommodate for patients' allergies, preferences and compliance, ultimately leading to better patient treatment outcomes. Additionally, compounding allows for medicines to be made during shortages of licensed products. Recently in the UK we have heard news of shortages of antibiotics, hormone replacement therapy and other medicines. Compounding pharmacies are best placed to help during these times of shortages. Unfortunately, these benefits have not been fully realised in the UK.

Compounding of bioidentical hormones

Hormone imbalances affect many women at various points throughout their lifetime, particularly as they reach peri-menopause, typically from the age of 40. Healthcare providers may prescribe women synthetic or licensed body identical HRT, available on the NHS, or compounded bioidentical hormones, available from a compounding pharmacy. Compounded bioidentical hormones use the same raw powdered hormones that are used in body identical licensed HRT. The main difference is that they can be modified by being compounded into different strengths and formulations, based on the patient's needs. They are a great option for patients who cannot tolerate conventional HRT, for various reasons such as allergies or the formulation not being suitable (such as an inability to swallow). Take Utrogestan as an example. This is a licensed bioidentical progesterone, which is available in one strength (100mg) and contains peanut oil. What alternative is there for patients with peanut allegies, who have an inability to swallow or who cannot tolerate such a high dose of progesterone? A compounding pharmacy can make bioidentical progesterone capsules without peanut oil, in a lower strength or in a cream or suspension. Each patient's individual needs can be evaluated and an appropriate prescription prescribed by the healthcare professional. Additionally, compounding allows for pharmacies to make formulations of body identical hormones during periods of shortages to ensure that women are not left without any hormones.

How do compounded hormones differ from licensed body identical and synthetic hormones?

Bioidentical hormones simply refer to compounded hormones whose chemical structure is identical to our endogenous hormones and are derived from plant sources such as yams or soybeans. Body identical hormones are also bioidentical, however, they refer to licensed, mass-produced hormones. The terms bioidentical and body identical are interchangeable and refer to the same chemically identical hormones.

Synthetic hormones differ drastically in their chemical structure from our natural hormones. They are recognised as foreign to the body and do not fit the receptor sites in the same way as our endogenous hormones. They try to mimic the actions of our natural hormones; however, due to their inability to fit perfectly and the action of their metabolites are often associated with more side effects and potentially do not have the beneficial effects associated with endogenous or chemically identical hormones. For example progestins, such as medroxyprogesterone acetate (MPA) are a synthetic form of progesterone and have many side effects such as fluid retention, risk of depression, bloating and an increased risk of breast cancer.

How can compounded hormones be used successfully in personalised menopause care?

Personalised menopause care is multifaceted and does not always involve the use of medicines. Menopause care should be an ongoing process that involves regular monitoring and adjustment of treatment plans. A more holistic and functional approach is now appearing to be the gold standard of treatment taking into account diet, gut health, genetics and individual patient choice.

Bioidentical hormones can be successfully used in personalised menopause care by practitioners who have carried out an assessment of the patient's symptoms and overall health, including blood tests, genetic tests, urine metabolite tests, a pelvic ultrasound scan and a mammogram (where appropriate). The healthcare practitioner can then write a prescription for the patient based on their individual needs and concerns, which may include a mix of licensed body identical and compounded bioidentical hormones and other treatments including lifestyle changes.

This protocol means that the practitioner has an understanding of the current hormone levels of the patient, how the patient's body metabolises hormones, that the endometrium is not thickened and that the uterus, ovaries and breasts are healthy. The practitioner can then prescribe their patient with the lowest possible dose of hormones needed to manage their symptoms, while monitoring them at regular, given intervals. For example, a licensed body identical oestrogen patch may be the right dose and preferred route of administration for a patient, but they may require progesterone at 50mg in a cream form and testosterone in a cream form (there is currently no testosterone available on the NHS licensed for women), which would need to be compounded.

There is growing cognizance that patient choice and personalisation should be at the heart of healthcare treatment and by offering compounded hormone options, this concept is getting closer to realisation, although the economic disparities remain.

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Author bio:

***Rizvan Faruk Batha** is the superintendent pharmacist and director of operations at **Specialist Pharmacy**. With over 14 years of experience within the pharmacy sector, he has extensive experience from working within GMP facilities, quality assurance & quality control roles, clinical trials & research GCP and within many specialities as a clinical pharmacist. Rizvan's broad experience and background of working in licensed and unlicensed MHRA facilities has led him to now manage and drive his team to successfully lead the compounding industry in the UK, increasing access to medicines for patients needing a more personalised approach to their therapy. Rizvan is currently working towards becoming a clinically enhanced pharmacist independent prescriber specialising in menopause with King's College London.*

Menopause legislation, charities and support

Pharmafocus' Betsy Goodfellow explores the range of legislation, charities and support available for women going through menopause

Many women struggle with their symptoms during menopause. It is estimated that three in five menopausal women have been negatively impacted at work, with many women leaving their jobs due to symptoms that are not sustainable in a work environment.[1] As a result, there have been various calls for further legislation to protect menopausal women from discrimination in the workplace.

Under the Equality Act 2010, age, sex and disability are all protected characteristics, which largely covers the menopause. Calls to add the menopause as a separate protected characteristic were rejected by the UK government on the grounds that this could lead to discrimination against men, with calls for a pilot programme for menopause leave also being rejected on the same grounds.[2]

The Health and Safety at Work Act 1974 also extends to working while experiencing symptoms of menopause, however many still want an extension to legislation requiring employers to implement a workplace menopause policy.[1]

While legislation remains unchanged, there are various charities offering support for women struggling with menopause. These include The Menopause Charity and the British Menopause Society, both of which aim to educate healthcare professionals and employers about menopause.[3,4]

On its website, The Menopause Charity states that it 'works to help everyone understand perimenopause and menopause, […] help educate healthcare professionals and employers in the menopause, […] and provide inclusive, fact-based information, advice and support'.[3]

The British Menopause Society focuses more on education for healthcare professionals, providing information and raising awareness.[4]

The NHS also provides help and support for women in need of direct assistance with their symptoms.[5] The health service can provide access to nurses and GPs, as well as counselling or cognitive behavioural therapy to help with mental health symptoms. It can also put patients in touch with menopause specialists and charities that can offer information and support.

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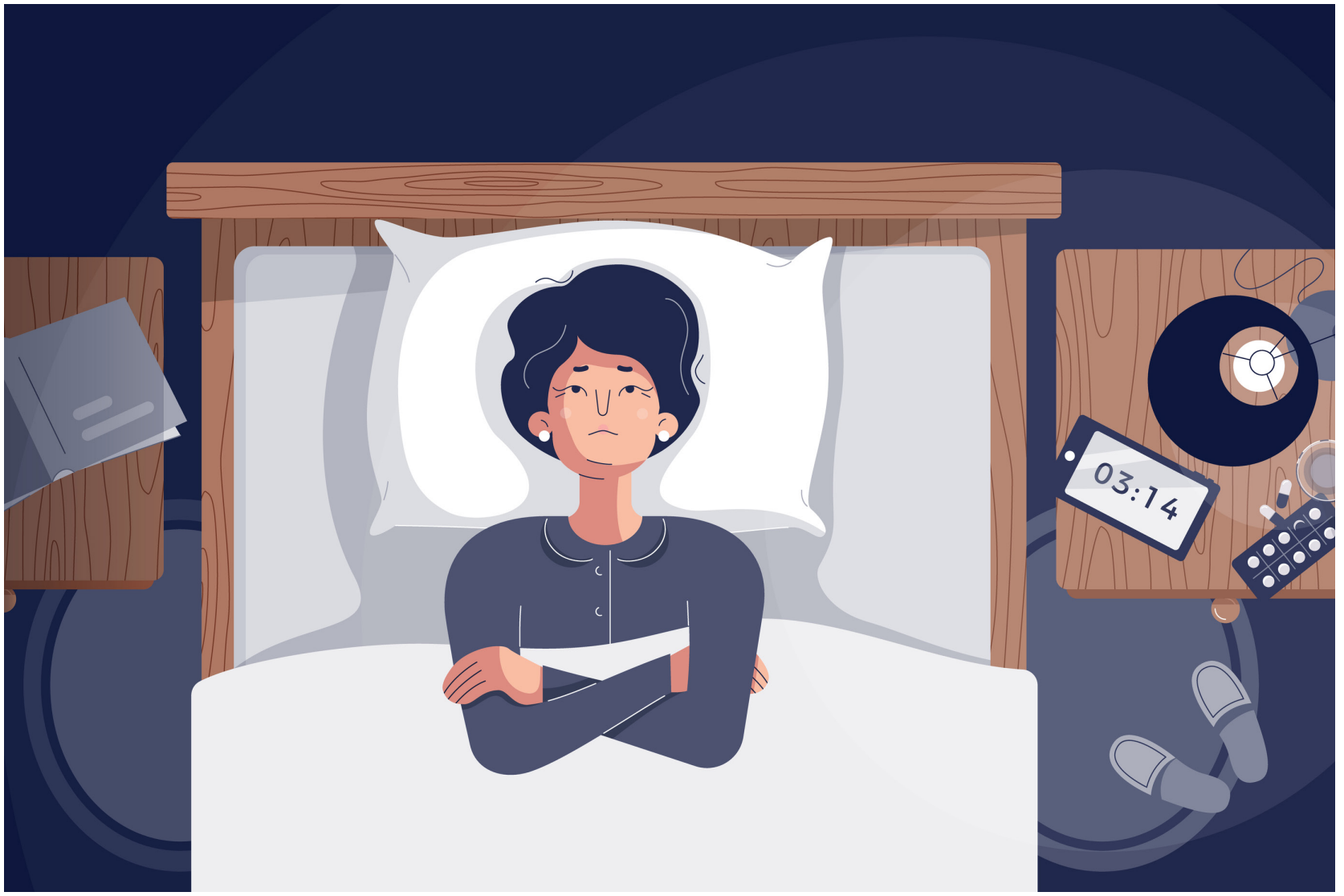

Menopause and sleep disruption

Betsy Goodfellow from *Pharmafocus* considers the impact menopause has on sleep and why so many women struggle with disrupted sleeping

Many women going through menopause experience sleep disruption, with 39-47% of perimenopausal women and 35-60% of postmenopausal women reporting that they have had difficulties sleeping.[1] The most reported issues include hot flashes, insomnia and breathing disorders during sleep, or sleep apnoea, among others.

Hot flashes affect 75-85% of women during menopause and usually last anywhere between 30 seconds to five minutes.[1] Hot flashes that occur at night are often referred to as 'night sweats'. This term refers to the sudden and unexpected sensation of heat all over the body due to a rise in body temperature and blood flow increasing to the face, which causes sleep disruption.

Insomnia is another common symptom of menopause, affecting up to 61% of postmenopausal women.[1] Women with insomnia find it more difficult to get to sleep, wake up multiple times throughout the night and often find it difficult to go back to sleep, which can lead to tiredness, irritability and difficulties with concentration during the day.[2] Sleep deprivation can also cause feelings of anxiety, have an impact on focus and memory and can result in headaches and inflammation.[1]

Breathing disorders during sleep also increase due to the effects of menopause. Snoring and sleep apnoea are both more common in postmenopausal women, and once perimenopause begins, the risk of experiencing breathing disorders during sleep increases by 4% each year.[1] It is thought that lower progesterone levels, such as those in postmenopausal women, contribute to the development of sleep apnoea, as progesterone can help to prevent the upper airways from relaxing, which causes the pauses in breathing common in people with sleep apnoea.[1]

Although these are the main causes of disrupted sleep in menopausal women, there are a few other associated sleep disorders, such as restless legs syndrome and periodic limb movement disorder, that cause involuntary movements that can cause discomfort and disrupt sleep.[1]

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Move of the month

BenevolentAI appoints Marcello Damiani to its board of directors

BenevolentAI has appointed Marcello Damiani to its board of directors. Damiani is expected to act as an independent non-executive director of the company.

Damiani has over 25 years' experience in senior executive roles in the aerospace, high-tech and biotech industries. Previously, he worked as chief digital and operational officer at Moderna. Prior to this, he was senior vice president and group CIO at bioMérieux from 2010 to 2015, working as executive director of IT Global Infrastructure Services from 2009.

Damiani said: "Technologies such as artificial intelligence offer huge promise to unlock complex biology and uncover new medicines for a broad range of debilitating diseases. I am delighted to work alongside BenevolentAI's Board of Directors and leadership team to deliver on this promise and, in so doing, deliver a new generation of transformative medicines to patients."

Dr François Nader, chairman of BenevolentAI, commented: "We are pleased to welcome Marcello to our Board as a non-executive director. Drawing from his senior executive leadership experience at global organisations such as Moderna and bioMérieux, Marcello offers a unique perspective and understanding of innovation in the technology and biotech sectors. His experience will further strengthen the existing diversity and knowledge of our Board as BenevolentAI continues to execute its ambitious growth strategy."

Finally, Joanna Shields, CEO and board director of BenevolentAI, added: "BenevolentAI is, at its core, a technology development company with a mission to understand complex disease biology and enable scientists to make novel discoveries. Marcello's expertise in driving innovation in biopharma will be an invaluable addition to our Board as we continue to scale the impact of our platform and AI tools."

Deepak Singh appointed as CN Bio's vice president of Sales and Marketing

CN Bio has announced the appointment of Deepak Singh as vice president of Sales and Marketing, supporting the company's next phase of commercial development as it aims to expand international operations, product research and development and sales in key global markets.

Singh has over 30 years of commercial experience within the life sciences sphere. His appointment follows that of Dr Paul Brooks as chief executive officer in December 2022; both appointments mark part of the company's aim to increase its international operations on both the product and service sides of the business.

Throughout his career, Singh has provided leadership to various sales and marketing teams, establishing new technologies from commercialisation through to global scale-up, as well as overseeing the expansion of some existing products and services into the drug discovery, bioproduction, research and diagnostics markets.

Prior to CN Bio, Singh was head of global commercial at PerkinElmer's Horizon Discovery – before this he was vice president of EMEA operations at Pacific Biosciences. He has previously held senior-level sales and marketing roles at Affymetrix and the Genetic Analysis Unit of Applied Biosystems. He holds a BSc in Biotechnology from the Polytechnic of Central London.

Commenting on his appointment, Singh said: "Having had extensive experience within the life science industry, I am excited by the possibilities of OOC technology, and how fast the potential of this technology is being realized. As evidenced by the recent FDA Modernization Act 2.0 legislation in the US, this is a very promising time for the technology, and I am looking forward to joining the CN Bio team to bring their cutting-edge systems to more researchers across the globe, to enable decision-making within drug discovery workflows to be made with more confidence and earlier than ever before."

Dr Paul Brooks, CEO at CN Bio, added: "Deepak's business and leadership experience, alongside his life science background, is of huge value to CN Bio as we drive forward with the Company's commercial excellence strategy and build our capabilities in 2023 and beyond. Following the successful launch of our PhysioMimix Single-organ HT System in February, Deepak joins us at an exciting time and will be pivotal for the international scale-up of the marketing and distribution of this new system and our existing portfolio of MPS products and services."

Karen Harrison appointed chief operating officer for Avacta's Therapeutics Division

Avacta has appointed Karen Harrison as chief operating officer of its Therapeutics Division.

Harrison has over 30 years' experience in high level roles. In the last 15 years, she has held senior positions in the healthcare and life sciences industries, for example as vice president for talent at Astellas Pharma. In her new role, Harrison will be responsible for R&D across Avacta's therapeutics division, focusing exclusively on ensuring maximum value for the company's stakeholders.

Dr Alastair Smith, chief executive officer at Avacta Group plc, commented: "Karen's industry experience is extensive, we're really pleased to welcome her as chief operating officer of our Therapeutics Division. Karen's guidance to strategise and prioritise Avacta's operational requirements, establish achievable performance measures and set comprehensive goals for the Therapeutics' business growth and success will benefit the division greatly and help shape its future strategy as we continue our mission to transform treatment outcomes for cancer patients."

Speaking on her new position, Karen Harrison, said: "Avacta is a pioneer of next-generation cancer therapies, and I'm delighted to join and support the company's vision to revolutionise the treatability of solid tumours. The Therapeutics Division is at such a pivotal stage, with the latest clinical data for AVA6000 confirming the tumour-targeting potential of our pre|CISION technology. I look forward to the opportunity to help drive our promising platforms further in the clinic and ultimately improve the lives of patients suffering from cancer."

Richard Stedman appointed to CEO of ACG's Engineering Division

ACG, a leading supplier of integrated manufacturing solutions to the global pharmaceutical and nutraceutical industries, has announced that Richard Stedman will rejoin the company as group chief executive officer of the Engineering Division.

Throughout his career, Stedman has gained over 35 years of experience in the packaging, engineering and pharmaceutical manufacturing spheres, having led and transformed various businesses in multiple countries, including South Africa, Singapore, India, Australia and India.

Stedman previously held the role of CEO of the Engineering Division at ACG from 2017 to 2021, and brings his wealth of engineering experience back to the role. Previously in this role, Stedman oversaw significant growth and achievement, including the successful completion of several high-profile projects. He was also a key player in expanding ACG's presence in key global markets.

Karan Singh, managing director at ACG, commented: "We are thrilled to have Richard back with us. Richard has a proven track record of success, and his leadership will be invaluable as we continue to grow and expand our operations."

Commenting on his reappointment, Stedman said: "I am excited to be returning to ACG Engineering as CEO. I have always had a deep respect for the company's culture, values and commitment to excellence, and I look forward to working with the team to build on the success we have achieved in the past."

Five facts about about reproductive health

1. Approximately one in seven couples in the UK have fertility issues, although 84% of couples conceive within a year.[1] Couples who have been trying to conceive for three or more years without success have a probability of one in four of conceiving within the next year, however this probability can be lower than that.[1] While there are many reasons a couple may struggle to conceive, there are also various treatment options for infertility available on the NHS.[1]

2. In vitro fertilisation (IVF) is one of the predominant techniques to help people with fertility issues to conceive, IVF involves the removal of an egg from the woman's ovaries and fertilising it with sperm in a laboratory before returning the embryo back to the woman's womb.[2] NICE recommends that IVF can offered to women under the age of 43 who have been trying to conceive naturally for at least two years, or who have had 12 cycles of artificial insemination, with six of these using intrauterine insemination.[2]

3. Polycystic ovary syndrome (PCOS) is a condition that affects a woman's ovaries, the main features being irregular periods (and irregular ovulation), excess androgen (high levels of 'male' hormones leading to symptoms such as excess facial hair) and polycystic ovaries (where the ovaries are enlarged and contain many fluid-filled follicles).[3] PCOS can often lead to difficulty getting pregnant due to irregular or non-existent ovulation.[3] There is currently no cure for PCOS, however there are treatments for the symptoms and a simple surgical procedure called laparoscopic ovarian drilling (LOD) can be recommended to help with fertility issues.[3]

4. Endometriosis is a condition where tissue similar to the lining of the womb grows elsewhere in the body, often in the ovaries or fallopian tubes, which can be very painful and may cause fertility issues.[4] Symptoms include lower abdominal and back pain; extremely painful periods; painful sex; pain going to the toilet while menstruating; feeling sick, constipation, diarrhoea or blood in urine or stool while menstruating, and difficulty conceiving.[4] Treatment can range from over-the-counter painkillers to hormonal medicines and contraceptives, as well as surgery to remove the endometriosis tissue and even surgery to remove part or all of the organs affected by endometriosis, for example with a hysterectomy.[4]

5. Abortion refers to the procedure to terminate a pregnancy, this can either be done with medicine or a surgical procedure.[5] In the UK, abortions can be carried out at NHS hospitals or licensed clinics and are usually available free on the NHS. Waiting times are usually no more than two weeks from first contact with an abortion provider to the abortion being done.[5] In England, Wales and Scotland, most abortions take place before 24 weeks of pregnancy. Some can take place after 24 weeks in limited circumstances when either the mother or baby's life would be at risk from continuing the pregnancy.[5] The choice to have an abortion lies with the pregnant person alone, and there are various support and advice organisations available via the NHS.

References:
1. *Visit: nhs.uk/conditions/infertility/*
2. *Visit: nhs.uk/conditions/ivf/*
3. *Visit: nhs.uk/conditions/polycystic-ovary-syndrome-pcos/*
4. *Visit: nhs.uk/conditions/endometriosis/*
5. *Visit: nhs.uk/conditions/abortion/*

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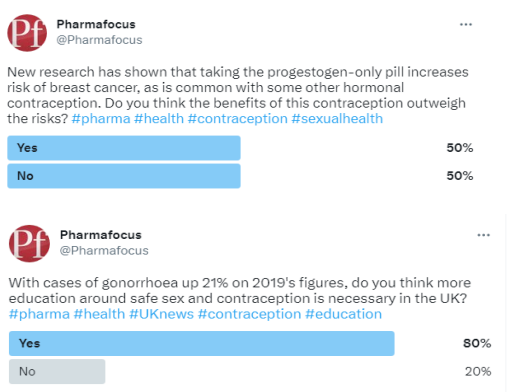

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