

## New Generic Approvals

- **Lifitegrast Ophthalmic Solution 5%**  
Approved: August 4, 2023 - Micro Labs Limited  
Treatment for: Dry Eye Disease
- **Halobetasol Propionate Aerosol Foam 0.05%**  
Approved: August 11, 2023 - Padagis Israel Pharmaceuticals Ltd.  
Treatment for: Plaque Psoriasis
- **Joyeaux Tablets ethinyl estradiol 0.02 mg / levonorgestrel 0.1 mg with ferrous fumarate 75 mg**  
Approved: August 16, 2023 - Xiromed, LLC  
Treatment for: Birth Control
- **Tretinoin Gel (Microsphere) 0.08%**  
Approved: August 22, 2023 - Encube Ethicals Private Limited  
Treatment for: Acne Vulgaris
- **Lisdexamfetamine Dimesylate Capsules 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg**  
Approved: August 25, 2023 - Actavis Elizabeth LLC; Alkem Laboratories Limited; Amneal Pharmaceuticals LLC (excl. 10 mg); Apotex Corp.; Ascent Pharmaceuticals, Inc.; Hikma Pharmaceuticals USA Inc. (excl. 10 mg); Lannett Company, Inc.; Mylan Pharmaceuticals Inc.; Norwich Pharmaceuticals, Inc.; Princeton Pharmaceutical Inc.; Rhodes Pharmaceuticals L.P.; SpecGx LLC; Sun Pharmaceutical Industries, Inc.  
Treatment for: ADHD; Binge Eating Disorder
- **Lisdexamfetamine Dimesylate Chewable Tablets 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg**  
Approved: August 25, 2023 - Ascent Pharmaceuticals, Inc.; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals USA, Inc.  
Treatment for: ADHD; Binge Eating Disorder
- **Palbociclib Tablets 75mg, 100 mg and 125 mg**  
Approved: August 28, 2023 - Synthron Pharmaceuticals, Inc.  
Treatment for: Breast Cancer
- **Spironolactone Oral Suspension 25mg/5mL**  
Approved: September 5, 2023 - Amneal Pharmaceuticals LLC  
Treatment for: NYHA Class III-IV Heart Failure and Reduced Ejection Fraction
- **Tofacitinib Citrate Oral Solution 1 mg (base)/ml**  
Approved: September 25, 2023 - Slayback Pharma LLC  
Treatment for: Polyarticular Course Juvenile Idiopathic Arthritis
- **Pazopanib Hydrochloride Tablets 200 mg (base)**  
Approved: October 19, 2023 - Apotex Corp.; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals U SA, Inc.  
Treatment for: Renal Cell Carcinoma; Soft Tissue Sarcoma
- **Teriparatide Injection 600 mcg/2.4 mL (250 mcg/ml)**  
Approved: November 16, 2023 - Apotex Corp.; Teva Pharmaceuticals USA, Inc.  
Treatment for: Osteoporosis
- **Podofilox Topical Gel 0.5%**  
Approved: November 22, 2023 - Padagis US LLC  
Treatment for: Anogenital Warts
- **Bromfenac Sodium Sesquihydrate Ophthalmic Solution 0.07% (free acid)**  
Approved: November 22, 2023 - Lupin Pharmaceuticals, Inc.  
Treatment for: Ocular Inflammation and Pain After Cataract Surgery
- **Nilotinib Hydrochloride Capsules 50mg (base), 150mg (base) and 200mg (base)**  
Approved: January 5, 2024 - Apotex Corp.  
Treatment for: Chronic Myeloid Leukemia

*References: [www.drugs.com](http://www.drugs.com)*

**Information collected and compiled by**

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## New Indications & Dosage Forms for Existing Drugs

### **Casgevy (exagamglogene autotemcel) Suspension for Intravenous Infusion**

New Indication Approved: January 16, 2024  
Date of Original Approval: December 8, 2023

Casgevy (exagamglogene autotemcel) is a CRISPR/Cas9 genome-edited cell therapy for the treatment of sickle cell disease and transfusion-dependent beta-thalassemia.

### **Keytruda (pembrolizumab) for Injection**

New Indication Approved: January 12, 2024  
Date of Original Approval: September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma and triple-negative breast cancer.

### **Udenyca (pegfilgrastim-cbqv) Injection**

New Dosage Regimen: December 22, 2023  
Date of Original Approval: November 2, 2018

Udenyca (pegfilgrastim-cbqv) is a PEGylated growth colony-stimulating factor biosimilar to Neulasta (pegfilgrastim) indicated to reduce the duration of febrile neutropenia in patients treated with chemotherapy and to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

### **Brukina (zanubrutinib) Capsules**

Labeling Revision Approved: December 21, 2023  
Date of Original Approval: November 14, 2019

Brukina (zanubrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor used for the treatment of mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM), marginal zone lymphoma (MZL), and chronic lymphocytic leukemia or small lymphocytic lymphoma (SLL).

### **Yescarta (axicabtagene ciloleucel) Suspension for Intravenous Infusion**

Labeling Revision Approved: December 21, 2023  
Date of Original Approval: October 18, 2017

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy (CAR T-cell therapy) used for the treatment of large B-cell lymphoma and follicular lymphoma.

### **Tarpeyo (budesonide) Delayed Release Capsules**

Labeling Revision Approved: December 20, 2023  
Date of Original Approval: December 15, 2021

Tarpeyo (budesonide) is a targeted release formulation of the approved corticosteroid budesonide indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

### **Padcev (enfortumab vedotin-ejfv) Lyophilized Powder for Injection**

New Indication Approved: December 15, 2023  
Date of Original Approval: December 18, 2019

Padcev (enfortumab vedotin-ejfv) is a Nectin-4 directed antibody-drug conjugate (ADC) for the treatment of urothelial cancer.

### **Zoryve (roflumilast) Cream and Foam**

New Indication Approved: December 15, 2023  
Date of Original Approval: July 29, 2022

Zoryve (roflumilast) is a topical phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of plaque psoriasis (cream formulation) and seborrheic dermatitis (foam formulation).

**Adbry (tralokinumab-ldrm) Injection**

Patient Population Altered: December 14, 2023  
Date of Original Approval: December 27, 2021

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist used for the treatment of moderate-to-severe atopic dermatitis.

**Welireg (belzutifan) Tablets**

New Indication Approved: December 14, 2023  
Date of Original Approval: August 13, 2021

Welireg (belzutifan) is a selective inhibitor of hypoxia-inducible factor 2 alpha (HIF-2 $\alpha$ ) for the treatment of von Hippel-Lindau (VHL) disease and advanced renal cell carcinoma.

**Nexletol (bempedoic acid) Tablets**

Labeling Revision Approved: December 13, 2023  
Date of Original Approval: February 21, 2020

Nexletol (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

**Trogarzo (ibalizumab-uiyk) Injection**

New Dosage Regimen: December 12, 2023  
Date of Original Approval: March 6, 2018

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment HIV-1 inhibitor for the treatment of multidrug resistant human immunodeficiency virus-1 (HIV-1) infection.

**Cresemba (isavuconazonium) Capsules and Injection**

Patient Population Altered: December 8, 2023  
Date of Original Approval: March 6, 2015

Cresemba (isavuconazonium) is an azole antifungal indicated for the treatment of invasive aspergillosis and invasive mucormycosis.

**Bivigam (immune globulin intravenous) Infusion**

Patient Population Altered: December 8, 2023  
Date of Original Approval: December 21, 2012

Bivigam is an immune globulin intravenous (human) indicated for the treatment of primary humoral immunodeficiency.

**Jaypirca (pirtobrutinib) Tablets**

New Indication Approved: December 1, 2023  
Date of Original Approval: January 27, 2023

Jaypirca (pirtobrutinib) is a non-covalent (reversible) Bruton's tyrosine kinase (BTK) inhibitor for use in the treatment of mantle cell lymphoma (MCL), and chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL).

**Wilate (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) Injection**

New Indication Approved: December 1, 2023  
Date of Original Approval: December 4, 2009

Wilate (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) is used in the management of von Willebrand disease and hemophilia A.

**Xtandi (enzalutamide) Capsules and Tablets**

New Indication Approved: November 16, 2023  
Date of Original Approval: August 31, 2012

Xtandi (enzalutamide) is an androgen receptor inhibitor used for the treatment of prostate cancer.

**Tirosint-SOL (levothyroxine sodium) Oral Solution**

New Dosage Regimen: November 16, 2023  
Date of Original Approval: December 15, 2016

Tirosint-SOL is an oral liquid formulation of levothyroxine (T4) for the treatment of hypothyroidism and for pituitary thyrotropin (thyroid stimulating hormone, TSH) suppression.

**Exparel (bupivacaine liposome) Injectable Suspension**

New Indication Approved: November 9, 2023  
Date of Original Approval: October 28, 2011

Exparel (bupivacaine liposome) is a long-acting amide local anesthetic used for postsurgical analgesia.

**Voquezna Triple Pak (amoxicillin, clarithromycin, and vonoprazan) Co-Packaged Capsules and Tablets**

New Formulation Approved: October 31, 2023

Date of Original Approval: May 3, 2022

Voquezna Triple Pak (amoxicillin, clarithromycin, and vonoprazan) is a co-packaged product containing amoxicillin (penicillin class antibacterial), clarithromycin (macrolide antimicrobial), and vonoprazan (potassium-competitive acid blocker (PCAB)) indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.

**Cosentyx (secukinumab) Injection**

New Indication Approved: October 31, 2023

Date of Original Approval: January 21, 2015

Cosentyx (secukinumab) is a selective interleukin-17A (IL-17A) inhibitor for the treatment of plaque psoriasis ankylosing spondylitis, psoriatic arthritis, non-radiographic axial spondyloarthritis, enthesitis-related arthritis, and hidradenitis suppurativa.

**Keytruda (pembrolizumab) for Injection**

New Indication Approved: October 31, 2023

Date of Original Approval: September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma and triple-negative breast cancer.

**Vabysmo (faricimab-svoa) Intravitreal Injection**

New Indication Approved: October 26, 2023

Date of Original Approval: January 28, 2022

Vabysmo (faricimab-svoa) is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO).

**Tibsovo (ivosidenib) Tablets**

New Indication Approved: October 24, 2023

Date of Original Approval: July 20, 2018

Tibsovo (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor used in the treatment of patients with IDH1-mutated acute myeloid leukemia (AML), IDH1-mutated cholangiocarcinoma and IDH1-mutated myelodysplastic syndromes.

**Rozlytrek (entrectinib) Capsules and Oral Pellets**

Patient Population Altered: October 20, 2023

Date of Original Approval: August 15, 2019

Rozlytrek (entrectinib) is a selective tyrosine kinase inhibitor for the treatment of patients with ROS1-positive, metastatic non-small cell lung cancer and neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors.

**Voxzogo (vosoritide) Lyophilized Powder for Injection**

Patient Population Altered: October 20, 2023

Date of Original Approval: November 19, 2021

Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog used to increase linear growth in pediatric patients with achondroplasia.

**Opdivo (nivolumab) Injection**

New Indication Approved: October 13, 2023

Date of Original Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer and gastroesophageal junction cancer.

**Braftovi (encorafenib) Capsules**

New Indication Approved: October 11, 2023  
Date of Original Approval: June 27, 2018

Braftovi (encorafenib) is a kinase inhibitor used for the treatment of melanoma, colorectal cancer, and non-small cell lung cancer.

**Cosentyx (secukinumab) Injection**

New Formulation Approved: October 6, 2023  
Date of Original Approval: January 21, 2015

Cosentyx (secukinumab) is a selective interleukin-17A (IL-17A) inhibitor for the treatment of plaque psoriasis, ankylosing spondylitis, psoriatic arthritis, non-radiographic axial spondyloarthritis, enthesitis-related arthritis and hidradenitis suppurativa.

**Zoryve (roflumilast) Cream and Foam**

Patient Population Altered: October 5, 2023  
Date of Original Approval: July 29, 2022

Zoryve (roflumilast) is a topical phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of plaque psoriasis (cream formulation) and seborrheic dermatitis (foam formulation).

**Abrilada (adalimumab-afzb) Injection**

Labeling Revision Approved: October 4, 2023  
Date of Original Approval: November 15, 2019

Abrilada (adalimumab-afzb) is a tumor necrosis factor (TNF) blocker interchangeable biosimilar to Humira indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis.

*References: [www.drugs.com](http://www.drugs.com)*

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## Current Health News

### **Why Fruit Juice Without Added Sugar is Still Linked to Weight Gain**

January 19, 2024

A new systematic review and meta-analysis found a link between drinking 100% fruit juice and weight gain among children and adults. One of the reasons fruit juice contributes to weight gain is that it does not make us feel full, which leads to consuming more calories. The healthiest beverage swap for both children and adults is water. And if you do drink fruit juice, cut it with water or seltzer.

### **Taking a Daily Multivitamin May Help Slow Cognitive Aging and Boost Memory**

January 18, 2024

A new study finds that taking a daily multivitamin may help your cognition and memory. Researchers found individuals who were given multivitamin had a modest benefit in their memory and cognitive function over two years. The vitamin may help with cognitive aging.

### **People Who Go Into Type 2 Diabetes Remission See 40% Drop in Heart Disease Risk**

January 18, 2024

A new study looks at how diabetes remission can impact your heart health. If a person is able to be in remission for a long-period of time, the effects on heart and kidney health can be substantial. However it can be difficult to maintain diabetes remission through lifestyle changes alone.

### **Therapy vs. Antidepressants: Which Is Best for People with Heart Disease?**

January 18, 2024

A new study shows behavioral activation therapy improved depression symptoms as effectively as medication in people with heart failure. Depression is common among people with heart failure and can severely impact their quality of life. Experts say that expanding access to mental health options, especially

non-pharmacological interventions, for people with chronic illnesses is an important step.

### **Taking Meds for Both Chest Pain and Erectile Dysfunction Linked to Heart Failure Risk**

January 17, 2024

People with cardiovascular disease who took an erectile dysfunction (ED) drug and a medication for angina, or chest pain, had a higher risk of early death. The ED drugs examined in the study are phosphodiesterase type 5 inhibitors (PDE5i), sold under the brand names Viagra, Levitra, Cialis and others. People taking both of these types of medications should talk to their doctor about stopping one or both of the medications, or possible alternative treatments.

### **Getting More Plant Protein May Help Women Avoid Cancer, Diabetes and Other Conditions**

January 17, 2024

A new study indicates that plant protein is an important factor for healthy aging in women. Researchers found that every 3% of daily calories that were derived from plant protein resulted in significant health benefits. Other protein sources, like meat and dairy, didn't share the same robust health benefits.

### **Energy Drinks Linked to ADHD, Anxiety, and Depression In Kids, Young Adults**

January 17, 2024

A new research review adds to a growing body of evidence demonstrating the harmful health effects of energy drink consumption, particularly among people 21 and under. Young people who consume energy drinks may experience sleep disturbances and have an increased risk of ADHD, anxiety, and mood changes, and in severe cases, heart complications. Health experts recommend avoiding energy drinks due to the negative side effects. Healthier beverage options include water, and if kids are drinking caffeine, it should be in low amounts.

**People with Perinatal or Postpartum Depression Face Higher Suicide Risk**

January 12, 2024

A new study shows women with perinatal depression are associated with a greater risk of dying by suicide, particularly during the first year of their diagnosis. Many factors affect perinatal depression onset, including hormone changes during and after pregnancy, personal or family history of depression, major life stressors, and marital conflict. To treat this type of depression, experts recommend psychotherapy and antidepressants in serious cases.

**Eli Lilly Warns Against Using GLP-1 Drugs Like Mounjaro for Cosmetic Weight Loss**

January 12, 2024

Pharmaceutical company Eli Lilly is urging people not to use its tirzepatide medications Mounjaro and Zepbound for cosmetic weight loss. They said the drugs are designed for serious diseases and can pose potentially serious health risks to people using them for other purposes. Experts say the benefits of these drugs outweigh the risks for people with obesity, but that balance may not be true for someone trying to lose a minimal amount of weight.

**New Vaccine May Help Stop Recurrence of Certain Pancreatic, Colorectal Cancers**

January 10, 2024

Researchers are investigating a potential vaccine that could help prevent certain cancers from returning. The vaccine, labeled the ELI-002 vaccine, appeared to reduce the risk of relapse in some people with pancreatic and colorectal cancers. All of the patients had a specific tumor mutation called mKRAS mutation, which is one of the more common gene mutations linked to cancer.

**Early Menopause, Hormone Replacement Therapy May Raise Rheumatoid Arthritis Risk**

January 10, 2024

A new study has found that hormonal factors are linked with a greater risk for rheumatoid arthritis. Women tend to be more prone to developing this autoimmune disease. However, the study was not

able to prove that hormonal factors cause the disease. Experts say that many factors that influence the development of rheumatoid arthritis are inherent. Certain lifestyle choices may help reduce your risk.

**This Treatment May Make Hypnosis More Effective for Chronic Pain**

January 8, 2024

New research from a team at Stanford University's School of Medicine have found a way to increase your hypnotizability. Hypnosis is increasingly being explored as a way to treat psychological conditions as well as pain disorders. The study indicates that transcranial deep brain stimulation does tangibly increase hypnotizability, but more research is needed in this emerging area.

**Will Blue Light From Your Phone Disrupt Your Sleep? What We Know**

January 5, 2024

A new study suggests that blue light such as from phone screens may not be as disruptive to sleep as previously thought. The study looked at how people reacted to different types of light. They found that between the blue, yellow and white light there was no conclusive evidence that blue was worse than other forms of light.

*References: [www.healthline.com/health-news](http://www.healthline.com/health-news)*

**Colon cancer is killing more younger men and women than ever, new report finds**

Jan. 17, 2024, 4:01 AM PST

Colorectal cancer is the deadliest cancer for men under age 50 — and the second deadliest cancer among women in the same age group, behind breast cancer. The incidence of colon cancer has been rising for at least the last two decades, when it was the fourth-leading cause of cancer death for both men and women under 50.

**With puberty starting earlier than ever, doctors urge greater awareness and care**

December 25, 2023

A growing number of children are showing signs of puberty at significantly younger ages than the average. Yet many families may face hurdles in getting diagnoses.

**FDA warns against unapproved 'fat-dissolving' spa treatments**

December 21, 2023, 12:30 PM PST

The Food and Drug Administration issued a warning about the dangers of using unauthorized versions of fat-dissolving injections, saying it has received reports of severe side effects, such as persistent scarring, severe infections and skin deformities.

Fat-dissolving injections, sometimes called lipolysis injections, are nonsurgical procedures that aim to melt away small amounts of fat beneath the skin.

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These injections are typically administered in so-called problem areas such as the chin, legs, upper arms and abdomen.

**Marijuana use during pregnancy linked to low birth weight, study finds**

Dec. 12, 2023

Researchers looked at data on more than 9,000 pregnant women and found that the risks associated with marijuana use went up the more marijuana a pregnant person consumed.

**References:** [www.nbcnews.com/health](http://www.nbcnews.com/health)



## Herbal and Traditional Medicine News

New test reveals origins of pangolin products illegally sold in China.

Scientists say southern Cameroon is emerging as poaching hotspot for endangered animals whose scales are prized in traditional Chinese medicine.

15 December, 2023

How facial acupuncture and retinol reduce wrinkles: Master Ruth TCM secrets

Facial acupuncture is a natural alternative to Botox as well as helping reduce wrinkles and signs of ageing, while retinol and hyaluronic acid are keys to skin radiance and hydration, says Ruth Lee.

4 November, 2023 - 11:15AM

Could traditional Chinese medicine be key to treating cardiac disease?

Clinical trial of Tongxinluo shows promising results in reducing serious heart attacks.

28 October, 2023

Hong Kong TCM practitioners 'can play bigger role' in primary healthcare

Our Hong Kong Foundation urges government to include TCM in next round of community screening scheme

16 October, 2023

We'll make it 'safer': WHO holds world's first traditional medicine summit

Policymakers and academics are aiming to gather evidence to 'inform policies, standards and regulations for the safe, cost-effective' use of TM, WHO chief said.

17 August, 2023

Licorice compound suppresses 'silent killer' pancreatic cancer: Hong Kong study

Study reveals isoliquiritigenin lowers survival rate of cancer cells, according to Baptist University.

7 August, 2023

The TCM formula poised to become a 'key treatment' for heart attack patients

A study has found Astragalus root, used in traditional Chinese medicine, reduces inflammation without side effects common to cardiovascular medicine, potentially making it a 'key treatment' for heart attack patients.

7 August, 2023

**References: [www.scmp.com](http://www.scmp.com)**

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