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S&A PHARMA NEWSLETTER

EDITORIAL

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The regulatory body of any country shall be the strongest body as it is responsible in taking all necessary action in its jurisdiction to maintaining the quality of the drug during its research, manufacturing and distribution. It plays an important role in running the health care system of the country. Any amendments made in acts and regulatory guidelines should be placed on the public domain to make an easy access of such amendments and guidelines to public and various stakeholders dealing with drug manufacturing.

We are pleased to present this Vol. III Issue IX of S&A – Pharma Newsletter. Through this newsletter, we aim to share recent information allied to regulatory reforms and updates from pharmaceutical sector in India as well as from foreign jurisdictions, based on information collated through research and appraisal of applicable statutory provisions.

In the present issue, we start with an article on Central Government imposing ban on the use of e-cigarettes and like products in order to stop its misuse/abuse in country's population especially in young population. Followed by this the current volume also discusses the ban on the open sale of the abortion pills to curb its misuse. These drugs will only available when a medical practitioner prescribes this drugs. Then the issue put some light on the recent Bill passed by central government on "*The Healthcare Service Personnel and Clinical Establishments (Prohibition of violence and damage to property) Bill, 2019*" to prevent the damage to the medical properties. Further the issue write upon the updates on banning the manufacturing of the oxytocin by single Public sector undertaking firms issued by the Supreme Court. Further the issue also put some light on how the Indian regulatory body will become a member of '*stringent regulatory bodies*' of ICH/WHO.

The volume also discusses on recent pharma updates from India presented as a separate section under '*Indian Health Care highlights 2019'*.

From the international arena, a separate section which discusses on recent regulatory updates from US FDA under the heading '*US FDA Highlights September 2019'*.

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Trust you enjoy reading this issue as well. Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

Thank you.

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CDSCO directs FDC manufacturers to conduct Active Post Marketing Surveillance

On September 19, 2019, the Central Drugs Standard Control Organization (CDSCO) directed all manufacturers of Aceclofenac, Drotaverine Hydrochloride Fixed Dose Combination (FDC) indicated for the treatment of colicky pain due to smooth muscle spasm, to conduct Active Post Marketing Surveillance on at least 200 patients as per Drugs and Cosmetic rules, 1945[1].

Background

The FDC drug was initially approved by CDSCO in favor of *Themis Medicare*. However, according to the 59th report of the Parliamentary Standing Committee, the FDC was to be referred to the New Drug Advisory Committee (NDAC)/ Subject Expert Committee (SEC) for review and examination purpose for continued marketing and updating the product monograph based upon the recent information available and regulatory changes overseas.

The matter was deliberated in a series of meetings of the NDEC/SEC where the committee decided to continue the marketing of the drug. Moreover, the manufacturer of the product was asked to conduct clinical trials for the new indication '*colicky pain due to smooth muscle spasm*' and submit the clinical trial protocol for approval of the study. However, the company, even after a number of discussions, finally surrendered its product license. Later, the 60th SEC (Reproductive and Urology) meeting initiated discussion on the earlier decision of conducting the Phase-IV clinical trial on FDC, and this decision was revoked. After detailed discussion the committee recommended that all the firms involved in the manufacturing of the FDC should conduct Active Post Marketing Surveillance in minimum 200 patients and the study should include the patients having primary dysmenorrhea, biliary colic and uretric colic. The study should be completed within a time period of one year and the result should be placed before the committee for review.

Based upon above suggestions and discussions all manufacturers under relevant jurisdiction were directed to conduct the post marketing surveillance for the new said indication of the FDC. This clinical trial was conducted in accordance to the Drug and Cosmetics Rules.

Conclusion

In order to continue the marketing and sales of Aceclofenac, Drotaverine Hydrochloride FDC, the Central Government has come out with new indications of the drug in the treatment of muscle pain. However, in order to continue the manufacturing of the drug with the new indication, the government has directed all the manufactures to conduct the clinical trial for the drug to check the safety and efficacy of the drug.

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1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTAxMA==

Government banned e-Cigarettes in India

Government has declared a ban on use of Electronic Cigarettes (e-Cigarettes) in the country. The ban is extended to the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of e-Cigarettes and similar products. The ban came into force on September 18, 2019, when Union Cabinet chaired by the Prime Minister approved the Promulgation of the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Ordinance, 2019.

Electronic cigarettes are electronic devices or battery-operated devices that produce aerosol by heating a glycol and/or glycerin-based solution containing nicotine or other substance flavors, which is then inhaled by a user. The most commonly known electronic devices are e-cigarettes, heat-not-burn devices, vape, e-sheesha, e-nicotine flavoured hookah and like devices that enable nicotine delivery. At the time of ban, more than 460 brands of e-cigarette with attractive appearances and multiple flavours were available in the market. The use of e-cigarettes had increased exponentially in recent times and had acquired epidemic proportions in developed countries, especially among youth and children.

These products were usually marketed as being safer alternatives for conventional cigarettes but such notions of safety have proved to be false. Available literature too, suggests that these products may act as gateway products to induce non-smokers, especially youth and adolescents, to nicotine-use, leading to addiction and subsequent use of conventional tobacco products. E-cigarettes are usually promoted by the industry as smoking cessation aids but their efficacy and safety as a quitting aid has not yet been established.

Background

The current decision of ban has come after an advisory issued by the Government in 2018, to all States/UT governments to consider banning e-cigarettes. Then 16 States and 1 UT banned e-cigarettes in their jurisdictions. Likewise, the Central Drugs Standard Control Organization (CDSCO) on February 2019, issued an order to all State/ UT Drug Controllers to monitor and restrict the sale, manufacturing, import, distribution, trade and advertisement of any of e-cigarettes and like devices under Drugs and Cosmetic Act, 1940 and Rule thereunder. Recently, the Indian Council of Medical Research (ICMR) issued a white paper on these devices, which recommended a complete ban on e-cigarettes based on currently available scientific evidence. The World Health Organization (WHO) has also urged its member countries to take appropriate steps including prohibiting these products.

Non-compliance to the Ordinance

Upon promulgation of the ordinance, any production, manufacturing, import, export, transport, sale (including online sale), distribution or advertisement (including online advertisement) of e-cigarettes shall be a cognizable offence punishable with an imprisonment of up to one year or fine up to Rs. 1 lakh or both for the first offence; and imprisonment of up to three years and fine up to Rs. 5 lakhs for a subsequent offence. Storage of electronic cigarettes shall also be punishable with an imprisonment up to 6 months or fine up to Rs 50,000 or both.

The owners of existing stocks of e-cigarettes, on the date of commencement of the Ordinance, have to suomoto declare and deposit these stocks with the nearest police station. The Sub-Inspector of Police has been designated as the Authorized Officer to take action under the Ordinance. The Central or State Governments may also designate any other equivalent officer(s) as Authorized Officer for enforcement of the provisions of the Ordinance.

Conclusion

The ban on e-cigarettes is an effort towards tobacco control and to protect population, especially the youth and children, from the risk of addiction through e-cigarettes. Enforcement of the Ordinance will complement government's efforts towards the tobacco control and will help in reduction of tobacco use and reduction in associated economic and disease burden.

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Government bans the open retail sale of abortion pills

The Central Drugs Standard Control Organization (CDSCO) had earlier issued an advisory on labelling requirements of Combi Kit (Misoprostol and Mifepristone tablets) to curb its misuse. The advisory dated August 09, 2019, summarizes that the Combi kit of Misoprostol and Mifepristone tablets (1 uncoated mifepristone 200 mg tablet + 4 uncoated misoprostol 200 meg tablets) for MTP was first approved by CDSCO on December 24, 2008 with a warning that "***The Product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003***". Now therefore, all the State/Union Territory Drugs Controllers are directed for the effective implementation of the above said labeling requirements of combi kit in their jurisdictions mandated as per provisions of Drugs and Cosmetics Act, 1940 & Rules, 1945 and MTP Act, 2002 & MTP Rules, 2003[1].

The State Drug Controller, Haryana, raised a concern regarding the advisory on labelling requirements, and requested the Drugs Consultative Committee (DCC) of CDSCO that instead of an advisory on labelling requirements restriction to be imposed on the combi kit, the wholesalers shall supply the kits only to the recognized centres to prevent the misuse of this kit in line with the provisions of MTP Act 2002 & MTP Rules 2003[2]. Taking it into consideration, the 57th meeting of DCC has recommended:

- To make provisions in Drugs and Cosmetics Rules for empowering DCGI to issue the advisories on the matters related to implementation of Drugs and Cosmetics Act and Rules made thereunder in the country.
- Subsequently, advisory should be circulated to all manufacturers.
- All State Drugs Controllers are requested to include the prescribed conditions issued as advisory as a condition while granting licenses and for old licenses.
- All SDCs may interact with all the stakeholders for creating awareness about the advisories issued by DCG (I) especially Chemist and Druggist Associations, and other relevant players.

The DCC also agreed to the suggestion of the sale of MTP kits containing Misoprostol and Mifepristone by wholesalers only to the approved MTP centres having required facilities and services of duly qualified and experienced Registered Medical Practitioner under MTP Act[3].

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1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDg0OQ==

2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTE1

3 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTYz

The Healthcare Service Personnel and Clinical Establishments (Prohibition of Violence and Damage to Property) Bill, 2019

On September 02, 2019, the Ministry of Health and Family Welfare (MoHFW) prepared the Healthcare Service Personnel and Clinical Establishments (Prohibition of violence and damage to property) Bill, 2019 (Bill), a step taken to stop violence against healthcare service personnel and damage or loss to property of clinical establishments and for matters connected therewith and incidental thereto.[1]

Background

In the past there have been several cases of brutal attacks against doctors. This made the union government to come up with strong legislation to avoid such cases of attacks on medical practitioner. The Health ministry came with a proposal to prepare a legislation which addresses all such issues of violence against the healthcare service professionals and damage to property of clinical establishments.

Key Points

The new Bill will be known as the Healthcare Service Personnel and Clinical Establishments (Prohibition of violence and damage to property) Bill, 2019. The act will extend to entire India and will come into force when notified to the public via gazette notification.

As per this new legislation the following penalties and offence have been listed:

Prohibition of violence: According to this, no person shall indulge in any activities of violence against a healthcare service personnel or cause any damage to property listed under the clinical establishment act.

Offences and penalties: Any individual found guilty shall be punished with imprisonment for a term which shall not be less than six months but which may extend to five years, and with fine, which shall not be less than fifty thousand rupees but which may extend to five lakh rupees.

Information of offence: The officer entitled as in-charge of a clinical establishment is obliged to inform the officer in-charge of the concerned police station about any written complaint of violence by any health care professional under this Bill.

Offence to be cognizable and non-bailable: Any offence or case registered under this Bill shall be cognizable and non-bailable.

Investigation of offence: According to this, any case registered under this Bill shall be investigated by a police officer not below the rank of Deputy Superintendent of Police.

Compensation for Act of Violence:

In addition to the punishment provided, the convicted person is also liable for penalties as described:

i. An amount, twice the amount of fair market value of the damaged property or the loss caused, as may be determined by the court;

ii. One lakh rupees for causing hurt to healthcare service personnel and five lakh rupees for causing grievous hurt to healthcare service personnel.

1 file://192.168.10.10/GGN%20Common/Arnika/Draft%20Bill%20(2).pdf

iii. If the convicted person does not pay the compensation granted under sub-section (1), the said sum shall be recovered as an arrear of land revenue under the Revenue Recovery Act, 1890.

Conclusion

Due to repeated number of cases filed for violence against the healthcare professionals, the central government has come out with a draft legislation to prevent such issues of violence. The legislation will provide a way to take a stringent action against the person convicted or involved in the case of violence against the health care professionals.

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Supreme Court to decide on restricting manufacturing of Oxytocin to Single PSU

On August 22, 2019, the Supreme Court has referred the case on "government imposed ban of manufacturing and sale of Oxytocin by all other than a single public sector undertaking (PSU)" to a large bench of judges which will decide whether imposing a ban on private companies to manufacture the controversial but life-saving drug is in public interest or not[1].

Background

On December 14, 2018, Delhi High Court passed its final order that banned all except a single PSU from manufacturing and sale of Oxytocin. The ban also covered ampoules for domestic use; and restricted manufacture to only one PSU - Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL). Oxytocin, a life-saving drug, is used in the augmentation of labour for easy childbirth. The drug is mostly used in the treatment of postpartum haemorrhage (PPH). However, the drug also showed various adverse events in some pre-clinical studies. A recent study, where Oxytocin was injected into cattle showed that milk sample collected after the experiment contains residue of Oxytocin which is harmful to human health.[2] Based on such observations, Delhi High Court passed the order restricting manufacturing of Oxytocin to a PSU. Hence, the government restricted its imports and decided to confine manufacturing to Karnataka Antibiotics and Pharmaceuticals Ltd, a government company.

However, after the release of the order domestic drug firms and non-government organization - All India Drugs Action Network (AIDAN) resisted the move to regulate the lifesaving drug and approached the court. Private manufacturers raised concern that there will be a fall in the availability of this life saving drug if government allows only one manufacturer to produce it. Due to all such oppositions the court decided to forward the case to the large bench of judges and decided to proceed with the petition based on some worthy questions such as:

- Does the impugned notification, namely, GSR 411(E) dated 27.04.2018 (2), fall within the scope of Article 19(6) of the Constitution of India?
- Is the impugned notification ultra vires of the provisions of the Drugs (and Cosmetics) Act?
- Whether the impugned notification is arbitrary and therefore, unsustainable?

About the Drug

Oxytocin, is a uterine stimulant hormone, prescribed for the initiation of uterine contractions and induction of labour in pregnant women. It is also used to help abort the foetus in cases of incomplete abortion or miscarriage, and to control bleeding after childbirth. It may be used for breast engorgement. However, it is also used widely in the dairy industry, agriculture and horticulture to boost production.

Conclusion

Oxytocin is the drug used in the treatment of postpartum hemorrhage (PPH) and is widely used in pregnant ladies. However, due to recent reports of various adverse events emnating from the drug, the Delhi High Court released an order banning the drug manufacturing by all but one PSU. Since this order will lead to shortage of the drug, hence, for easy availability of the same to patients who need it, the legal bodies should consider other options for preventing its misuse.

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1 https://www.livelaw.in/pdf_upload/pdf_upload-358386.pdf

2 https://ijme.in/articles/the-oxytocin-ban-the-judgment-and-legal-issues/?galley=html

Indian Drug Regulatory System to become Stringent Regulatory Authority of WHO

The 57th meeting of the Drugs Consultative Committee (DCC) of Central Drugs Standard Control Organisation (CDSCO) has reviewed the proposal to make Indian drug regulatory system as a Stringent Regulatory Authority (SRA)/ International Council for Harmonization (ICH) for global recognition.

With this view, the committee recommended the need for strengthening of Indian Regulatory System in order to become SRA/ICH or another international member. Further to this, formation of a dedicated cell was recommended preferably for self-assessment, gap analysis and preparation of plan for strengthening the drug regulatory system in the country. Advice of experts/ consultants for Regulatory System Strengthening may be required in this endeavour[1].

About SRA

The 'SRA' is commonly recognized term for regulatory authorities having a well-developed regulatory system, commonly used for a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or observer or associates with an ICH member through mutual recognition agreement. The term SRA was developed by the World Health Organization (WHO) Secretariat and the Global Fund to promote reliance on the product evaluations and decisions of SRAs by other authorities when making their own regulatory decisions.

Criterion of a regulatory system to pass for SRA

The regional or National Regulatory System (NRA) can be assessed by its maturity level in the implementation of the various regulatory functions like - Registration and Market Authorization, Vigilance, Clinical Trial Oversight, Laboratory Access and Testing, Quality Management System including Market Surveillance and Control, Licensing Premises, and Regulatory Inspections.

The Global Benchmarking Tool (GBT) followed by WHO for NRA assessment represents the primary means by which the WHO objectively evaluates regulatory systems, as mandated under WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables the WHO and regulatory authorities to:

- identify strengths and areas for improvement;
- facilitate the formulation of an Institutional Development Plan (IDP) to build upon strengths and address the identified gaps;
- prioritize IDP interventions; and
- monitor progress and achievements.
- Indian Drug Regulatory System

India has been an observer in ICH since 2015 and is exploring to move forward to become full member. However, the Indian National Regulatory Authority (NRA) is not a member of the ICH guidelines of Technical Requirements for Pharmaceuticals for Human Use (ICH). India is evolving as a significant player in clinical research and pharmaceutical field and being a large contributor to the pharma industry, needs to have strict reliable regulations imposed upon the pharmaceutical activities. Now, therefore, the DCC of CDSCO has recommended the

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTYz

strengthening of Indian regulatory system to become a member of ICH from being just an observer, which is a step forward towards making the country's NRA to SRA with global standards.

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India Healthcare Highlights September 2019

This segment of the newsletter shares recent information related to regulatory reforms from Healthcare and Pharmaceutical sectors from Indian jurisdiction. This segment collates information on a monthly basis via conducting research and appraisal of applicable statutory provisions. Below are the highlights for September 2019.

1. Zydus Cadila receives DCGI nod to market rabies drug in India[1]

Zydus Cadila announced that it has received marketing authorization approval for Twinrab™ (RabiMabs) from the Drug Controller General of India (DCGI). Twinrab™ is a novel biologic product indicated in combination with rabies vaccine for rabies post-exposure prophylaxis. Twinrab™ is cell-culture derived monoclonal antibodies, offering high levels of purity including freedom from risk of infections as compared to the human serum derived products. The use of rabies monoclonal antibodies could emerge as an innovative therapy and form a potent alternative to current blood derived rabies immunoglobulins (RIG's) produced by vaccinating horses (ERIG) or humans (HRIG). Rabies is a fatal disease and is prevalent in 150 countries across the globe. The disease transmits through the bite of a rabid animal and infects the central nervous system, causing encephalopathy (disease of the brain) and could ultimately result in death, if medical treatment is not sought before the symptoms appear. Zydus also manufactures and markets the rabies vaccine - VaxiRab N™ which is a WHO pre-qualified vaccine.

2. Lupin and Boehringer partnership to develop and commercialize novel oncology drug[2]

Boehringer Ingelheim and Lupin Limited have announced a licensing, development and commercialization agreement for Lupin's MEK inhibitor compound (LNP3794) as a potential targeted therapy for patients with difficult-to-treat cancers. The partnership aims to develop Lupin's lead MEK inhibitor compound in combination with one of Boehringer Ingelheim's innovative KRAS inhibitors for patients with gastrointestinal and lung cancers harboring a broad range of oncogenic KRAS mutations. Lupin will receive an upfront payment of $20 million and potential additional payments for successful achievement of defined clinical, regulatory and commercial milestones for a total deal value of more than $700 million. Additionally, Lupin will be entitled to receive double-digit royalties on the sales of the product, whereas, Boehringer Ingelheim will strengthen its pipeline portfolio for patients with gastrointestinal and lung cancers with this new licensing, development and commercialization agreement.

3. CDSCO approves manufacturing of new drug in multiple facilities[3]

Central Drugs Standard Control Organization (CDSCO) has issued clarification notice regarding multiple manufacturing of new drug owned by a manufacturer. The notice says that the manufacturer needs to generate Chemistry, Manufacturing and Control (CMC) data at one of its manufacturing facilities for obtaining license/ permission from concerned licensing authority.

Once the authority has examined the matter with CMC data related to one of this manufacturing facility and basis the data approval/permission has been granted to the manufacturer for manufacturing of the new drug in that facility, the same data may be utilized by the same manufacturer for manufacturing of the same product in its additional manufacturing sites with necessary permissions, provided that the manufacturer establishes the similarity by way of technology transfer with respect to manufacturing process, equipment, process parameters, process capability and bridging validation for technology transfer etc. wherever required between the proposed additional manufacturing sites and the approved manufacturing site.

1 https://zyduscadila.com/public/pdf/pressrelease/Zydus%20to%20launch%20novel%20biologic%20for%20rabies_WHO.pdf

2 https://www.lupin.com/portfolio/lupin-and-boehringer-ingelheim-announce-partnership-to-develop-and-commercialize-novel-oncology-drug-to-treat-kras-driven-cancers/

3 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDkxMA==

USFDA Pharma Highlights September 2019

This segment discusses the recent drug approvals from the United State Food and Drug Administration (USFDA) for various severe diseases. The write-ups describe the role of a new drug in the treatment of serious conditions such as community-acquired bacterial pneumonia and rare lung condition - scleroderma. The FDA is the strongest regulatory body in USA which takes care of health of the public by assuring the safety and effectiveness of the human drugs, medical devices and other products used in health care.

1. FDA approves new antibiotic to treat community-acquired bacterial pneumonia[1]

The USFDA approved new antibiotic - Xenleta (lefamulin) to treat adults with community-acquired bacterial pneumonia. Pneumonia is a type of lung infection where severity can range from mild to severe illness and can affect people of all ages. Community-acquired bacterial pneumonia (CABP) occurs when someone develops pneumonia in the community. The approval is followed by two efficacy trials of Xenleta (orally or intravenously) conducted on 1,289 patients with CABP. The patients, who received treatment with Xenleta had similar rates of clinical success as those treated with standard drugs (moxifloxacin with or without linezolid). The approval of Xenleta was granted to Nabriva Therapeutics.

2. FDA approves first treatment for patients with rare type of lung disease[2]

The USFDA on September 06, 2019, approved Ofev (nintedanib) capsules to improve the pulmonary function in adults with interstitial lung disease (ILD) associated with systemic sclerosis (SSc) or scleroderma, called SSc-ILD. It is the first FDA-approval for this rare lung condition. Scleroderma is a rare disease that causes the tissue, throughout the body including the lungs and other organs, to thicken and scar. Interstitial lung disease or ILD is a condition affecting the interstitium, which is part of the lung's structure, and is one of the most common disease manifestations of sclerderma. The approval is followed by an efficacy trial conducted on 576 patients ages 20-79. Patients received treatment for 52 weeks, and few patients were treated up to 100 weeks. Those who took Ofev had less lung function decline compared to those on placebo. Ofev was originally approved in 2014 for adult patients with idiopathic pulmonary fibrosis (IPF), which is another interstitial lung condition. The approval of Ofev to treat SSc-ILD was granted to Boehringer Ingelheim Pharmaceuticals Inc.

3. FDA sends warning to company for selling unapproved stem cell therapy[3]

The USFDA issued a warning letter to *Stemell Inc.* with address - San Juan Capistrano, California, for manufacturing and distributing unapproved stem cell products derived from umbilical cord blood and umbilical cord. The warning followed by inspection of Stemell facility by an FDA Committee revealed that the company was involved in manufacturing products derived from human umbilical cord blood and umbilical cord for use in recipients unrelated to the donors of the products. The inspection reported significant deviations from current good tissue practice (CGTP) and current good manufacturing practice (CGMP) requirements, including deficient donor eligibility practices and environmental monitoring, creating potential significant safety concerns that put patients at risk. The unapproved umbilical cord products derived from Stemell are StemL UCB-Plus and StemL UCT-Plus.

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1 https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibiotic-treat-community-acquired-bacterial-pneumonia

2 https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-rare-type-lung-disease

3 https://www.fda.gov/news-events/press-announcements/fda-sends-warning-company-selling-unapproved-umbilical-cord-blood-and-umbilical-cord-products-may

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