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NEWSLETTER

Tony Dunford Editor

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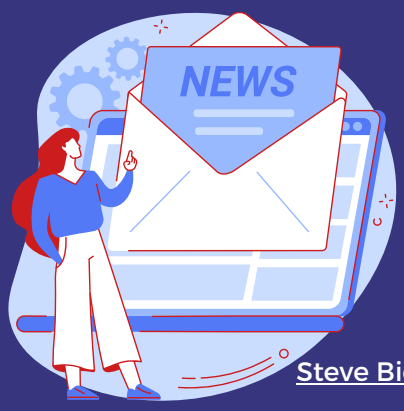

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GOOD NEWS FROM RWANDA

By The Editor

IN and OUT of the Headlines: BioNTec & Rwanda

If Rwanda is in the headlines these days, it's perhaps because it's associated with “bad news”; (seemingly the Media’s favourite sort):
The UK government has a much criticised (ie media worthy) programme, which is currently battling its’ way through the Lords (The UK’s Upper Legislative Chamber); to outsource immigrant’s asylum applications to this African nation. The issue is padded out by the Press, by harking back to the genocide in Rwanda many decades ago.

Here’s some good news about Rwanda.

Two months ago, in the Rwandan capital Kigali, the inauguration took place of a new manufacturing facility comprising BioNTainers provided by the German vaccine manufacturer BioNTec. We wrote about this modular approach to vaccine manufacture and it’s potential for lead-time reduction, in the context of the mNRA COVID vaccine, in Galenisys Newsletter March 2022.

The project’s timeline is impressive: Biontech introduced BioNTainers in February 2022. Site preparation at Akagera Medicines in Kigali, Rwandas’ capital, started in June 2022. The first 2 BioNTainers arrived there in March 2023 and inauguration of the facility occurred on 19th December. The manufacturing facility has one drug substance module (BioNTainer), and one formulation module. Each module is a high-tech clean room which BioNTech kitted out with state-of-the-art manufacturing equipment.

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Fewer Fridges

Breakthroughs in mRNA technology prevented millions of COVID deaths. But current mRNA vaccines are sensitive to heat. Because of this instability, these vaccines require cold-chain storage which - in regions lacking the necessary infrastructure – severely limits usage. **The Coalition for Epidemic Preparedness Innovations "CEPI**", is investing in programmes to enhance the thermostability of mRNA vaccines. Evidently Rwandan owned pharmaceutical manufacturer Akagera Medicines, sufficiently impressed CEPI, that it promised up to $1.46 million to fund the pre-clinical proof of concept of Akagera Medicine's innovative lipid nanoparticles (LNPs) technology to encase and protect fragile mRNA molecules.

More BioNTainers

BioNTec have stated they intend BioNTainers to provide other viable decentralized manufacturing facilities in Africa, which should offer greater independence and faster vaccine supply within the continent, (for example of their investigational malaria and tuberculosis mRNA-based vaccines), if they are successfully developed, approved, and authorized by regulatory authorities. They also plan to set up BioNTainer-based manufacturing facilities in Australia and Israel.

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New FDA labelling requirements for Cosmetics

By Steve Biddulph
Fellow of Royal Society of Biology. Board level pharma experience. QSM and Aseptic Manufacturing & Control Expertise

Allergic reactions are a common issue in the world, often occurring when someone comes into contact with a substance that their body perceives as harmful.

Whether the person is consuming an allergen through food or drink, or **contacting the substance** with their skin, if the individual's immune system attempts to fight the substance through releasing antibodies, a reaction is likely to occur.

Allergic reactions can range from a mild rash to anaphylaxis, a severe and sometimes fatal reaction.

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FDA regulates the declaration of allergens on food and beverage labeling, extensively, but the same labeling regulations do not apply to allergens in cosmetics, until now. However, with the passage of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).....

FDA now has authority to create and enforce requirements for labeling allergens in cosmetic products.

Upcoming FDA cosmetic labeling requirements means cosmetics **companies will need toupdate their product labeling** to include declaration of fragrance allergens.

FDA has determined the allergens that cause most allergic reactions due to use of a cosmetic product. These allergens are divided into 5 classes:

- Preservatives
- Metals
- Fragrances
- Natural rubber
- Dyes

The Fair Packaging and Labeling Act (FPLA) gives FDA the authority to require an ingredient declaration on retail cosmetic products.

FDA will establish and publish guidelines on exactly what is required for Cosmetic product labelling and the declaration of, possible allergens in cosmetic products.

This article continues Galenisys recent series on the new range of FDA regulations & intentions regarding cosmetics and their manufacturers & distributors in the USA.

The past articles & Newsletters are below:

July 2023: “Cosmetics and the FDA” - cosmetics which improving “wellbeing” are OTC drugs for FDA

September 2023: “Was Voluntary, Now Compulsory” - The draft guidance, - MoCRA requirements.

October 2023: “Regulatory action against Cosmetic company”

December 2023: “FDA requirements for Cosmetics Manufacturers” for ALL cosmetics from 31.12.2023

Galenisys will keep our clients informed of further guidelines as they are published.

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Wegovy and an OVERSIZED problem

By The Editor

Panorama is the principle investigative news programme on UK's BBC TV channels. Last month they ran a programme during prime time about the use and misuse of **Wegovy**, Novo Nordisk's new slimming product, by patients suffering from obesity. Naturally, as we had already reported on this (see Newsletter Issue 25 April 2023), we were interested to compare coverage.

One in four UK adults are obese. It's an oversized problem elsewhere too. Bad diet & lack of exercise are at the root of the problem. Panorama interviewed both users who had been obtaining the drug on the Internet and administering it without (the specified & required) medical supervision; as well as patients using the drug under specialist supervision.
The drug is available to a limited extent via the NHS. Bought privately Wegovy costs approximately £200 per month. Its high cost and the large number of obese adults is being reflected in the steep rise of Novo Nordisk's share price.

However, in 2023 the cost to the NHS of obesity was reportedly £19 billion; to the people themselves £63 billion; and to the economy £16 billion - mainly illness causing lost productivity. So, the advent of Wegovy and similar products ("GLP-1 Agonists"), which do reduce weight, can only be a benefit.....

.....for some when used correctly:.....

The drug is not without its side effects: including headaches nausea and tiredness. As these effects leave patients disinclined to exercise there is a loss of muscle mass as a consequence. Users must continue to exercise because of this. In fact, the drug should only be used where obesity is a danger to health, and under medical supervision.
And the experts stress that without exercise and a healthy diet, discontinuing the use of the drug results in weight being regained.

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THE EMA PUBLISH its 2023 highlights

By Jose Zapata
Galenisys Pharma Senior Expert. Pharmacist with frontline experience in Quality, Operations & Project Management.
PDD Certified

Two weeks ago, the European Medicines Agency published an interesting list of the applications for marketing authorization which they had considered, and approved or otherwise last year, for commercialization in the EU.

Success and new molecules

The EMA recommended 77 medicines for marketing authorisation. 3 received a negative opinion and 19 applications were withdrawn.
It's notable that of the 77, 39 had a new active substance which had never been authorised in the European Union (EU) before. This points to strong output from the R&D departments in our industry. Congratulations.

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Galenisys are very proud of the part we have played over the years in assisting clients along the road to marketing approval.

At one company we recently assisted them coming into compliance with new requirements (Eudralex Vol 4 Annex 1) for the sterile manufacture of a new entity.

For a French based client, we defined & implemented the structure of their QA Management System for manufacture & control, and non-clinical testing (GMP & GLP). Also, for a US company, our team defined and verified requirements for their various suppliers of clinical supplies of development products.

Therapeutic areas

There are a number of medicines that stand out due to their contribution to address public health needs, or the innovation they represent:

The therapeutic area with most approvals was **Cancer** followed by **Neurology**.

The Agency also recommended two vaccines to protect against lower respiratory tract disease caused by respiratory syncytial virus (RSV), and the first advanced therapy medicinal product using a ground-breaking gene-editing technology known as CRISPR/Cas9 to treat two rare blood disorders. EMA also adopted two positive opinions for medicines for use in countries outside the EU.

For more in the review do access the following link:

https://www.ema.europa.eu/en/news/human-medicines-highlights-2023