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NEWSLETTER

Tony Dunford Editor

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You can't rest on your laurels

By The Editor
Champions need to keep in form – in Sport & Healthcare.

22nd May Here in France, things are warming up for this summer's Games, as the Olympic Flame makes its way through the country. **Past champions** in their training camps, and the organisers in Paris are entering the final lap of preparations. Can they retain their pre-eminence? They can't rest on their laurels.



The same is true for the pharmaceutical industries major players. Take Pfizer, for example. (One of Galenisys important clients).

Three years ago they were deservedly lauded for the phenomenal scientific and commercial success, of the COVID-19 vaccine, developed & rolled out worldwide in conjunction with BioNTech, in record time.

However, now they've got new challenges to rise to. Yesterday, (22nd May) Pfizer Inc announced that its multi-year cost cutting program will incur initial costs of USD1.70 billion recorded primarily in 2024, with cash outlays expected in 2025 and 2026.

The costs are expected to come primarily from severance and implementation costs, as research & production facilities are slimmed down or sold. With these costs included, the first phase of the plan is expected to save up to USD1.50 billion by 2027 through increasing operational efficiency. Pfizer says the costs of the program are subject to change.

The cost cuts are aimed at restoring profitability and addressing the 24% fall in their share price in the last 12 months.

At factory level they must also tackle the **Quality problems** which have recently arisen at **Hospira**. Pfizer says that this subsidiary has issued a recall for two of its Carpuject medications, totalling 5 batches.

The opioid pain reliever Buprenorphine HCl, and blood pressure medication Labetalol HCl, were recalled due to user reports of incomplete crimp seals and one report of a leaking vial. Hospira also made recalls at the end of last year, given reports of glass particles in vials.

The Dangerous Bacterial Contamination of Non-Sterile Drug Products



By Steve Biddulph

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

Our design, use, and control of facilities must be as persistent as these bacteria.

Following on from our recent articles on Microorganisms and the risks that they pose in products, we need to highlight the increasing risks posed to water based non-sterile products by Burkholderia cepacia.

B. cepacia comprises more than 20 species of gram-negative organisms that give rise to opportunistic infections. In drug products, contamination of this type, both B. cepacia & other gram negative bacteria, usually starts with the poorly designed, & / or poorly maintained water systems that are used. Obviously, the prevention of this type of contamination is not helped when it is compounded by deficient manufacturing practices or water sampling techniques.



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When these organisms are in the water systems used to manufacture non-sterile water-based products, patients exposed to them will certainly be at increased risk for illness, especially those patients with compromised immune systems or who are otherwise susceptible to infection.

Over the years there have been repeated recalls of contaminated antiseptic preparations, such as povidone iodine, benzalkonium chloride, and chlorhexidine gluconate. These have occurred in the USA and elsewhere. The gravity of these failings is magnified since these products are often used in hospitals with patients who are particularly vulnerable due to their medical conditions.

In a tragic USA example the FDA reported in 2016, severe B.cepacia infections occurred when contaminated docusate oral solution was used for children requiring mechanical ventilation and for other immunocompromised or susceptible patients. The distribution of this contaminated product ultimately led to criminal charges and conviction.

The world has a long history of both over-the-counter (OTC) and prescription drug recalls due to B.cepacia and other gram negative bacterial, that have been traced back to non-conformities in GMPs and to poorly designed water systems.

Our industry must be rigorously persistent in it's Contamination Prevention and Control Programmes

These examples serve to remind us that we need to be champions in water systems design maintenance and use, and keep to the strict regime of contamination prevention and control programmes for non-sterile products; just as for sterile product manufacture. We'll detail some of the specific measures needed in upcoming Newsletters.



Galenisys has expertise and experience in the design of utilities, such as water systems, and in the design and implementation of contamination prevention and control programmes. We are here to help - do contact us.

Semaglutide does it again, but rivals gear up !!

The weight loss compound can also reduce heart attack risk
By The Editor

14th May. In a UCL study presented to the European Congress on Obesity in Italy, the lead author detailed how the medication Semaglutide - the active ingredient in Novo Nordisks Wegovy and Ozempic - brought about significant cardiovascular benefits, regardless of patients starting weight, or the amount of weight they had lost. In summary the drug could provide a 20% lower risk of heart attack, stroke or death, due to cardiovascular disease.

The participants in the large study - from 41 countries - were 17,600 adults age 45 and over, with a body mass index of 27 or more. (They had also previously had a "cardiovascular event"). They were prescribed either a 2.5 milligramme weekly dose of Semaglutide, or a placebo, for an average period of 40 months. Participants on Semaglutide lost an average of 10.2% of their body weight compared with 1.5% in the placebo cohort.



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According to the British Heart Foundation there are some 7.6 million people in the UK with heart or circulatory disease.

24th May In a separate study published today Novo Nordisk stated that Ozempic slows the progression of chronic kidney disease as well as the above mentioned benefits. This follows the headline trial summary in March that the drug cuts the risk of kidney disease-related events in diabetic patients by 24%.

A New drug in development which could be more effective than Ozempic

So important are these markets and the promise of this class of drugs, that rivals are already showing their promise. In a different study featuring **Retatrutide**, better slimming results than the products already on the market, were claimed. Over a 48 week the 338 participants with obesity showed an average 24% loss of body weight.

Retatrutide, a weekly injection, works by suppressing appetite and also by helping the body burn more fat. The active ingredient acts on 3 different receptors related to body weight, not just 2 as with Semaglutide. Researchers say it is more effective for weight loss than Ozempic or Wegovy, which only work by suppressing appetite.

The next phase of clinical trials is in progress and is due to be published in 2026, with researchers saying that the medication may be available on the UK NHS as early as 2026.

24th May Meanwhile, rival **Eli Lilly**, has announced today that it will spend an additional \$5.3 billion on expanding capacity for its blockbuster obesity product Zepbound and the similar diabetes product Mounjaro, which have been in short supply. The money will be spent at the facility under construction in Indiana, USA where \$3.7billion had been already been committed. (Don't people count the "small change" anymore?)

As mentioned in our last Newsletter, specialists believe many other chronic diseases including several types of cancer, osteoarthritis, and anxiety and depression would benefit from effective weight management. In terms of galenical form Pharmas' next big challenge is delivering these GLP 1 type products as tablets or capsules.

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A second human case of Avian Flu is raising concern of a potential H5N1 pandemic

Already in milk products says the FDA
The Editor

The COVID epidemic scarred us so concern about H5N1 is understandable.

On May 22nd, the US Centre for Disease Control and Prevention confirmed a human infection with the H5N1 avian influenza virus, that has spread rapidly among **dairy cows** in America.

Both human cases were farm workers with mild symptoms, probably infected by cows.

Though no evidence yet exists of human-to-human transmission, America's public health authorities are on high alert. Half the national pandemic stockpile of H5N1 vaccine is being made ready to deploy.

Influenza viruses infect many species. However, an avian influenza virus that has crossed over into numerous bird and some mammalian species is one of those with pandemic potential because humans possess no immunity.

Since H5N1 was first detected in geese in China there have been around 900 known human infections worldwide, usually from contact with infected poultry. Nearly half of these were fatal, although the fatality rate is likely lower owing to unreported cases with mild symptoms etc.

In 2022, H5N1 in wild bird species carried it around the world, infecting numerous species of wild mammals, farmed poultry, & mink. So farms in Europe, America and Asia have all had to cull hundreds of millions of birds (in which its lethal) in an attempt to stop its spread.

This spring H5N1 was detected on a Texas dairy farm, & since in dairy herds in nine states -, probably more - in early May, the FDA found it in about 20% of milk samples from stores across USA Note- . **It is killed by pasteurisation.**

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Farm testing is bad for business & the farm workers To date, only 40 people with suspected H5N1 had been tested, but encouragingly only 2 human cases linked to the cow outbreak have been confirmed so far. If this was spreading human to human, we'd know, says an epidemiologist. The immediate health risk, she says, is the infections in farmworkers arising from uncontrolled spread in cows.

Milk from infected cows is loaded with the H5N1 virus, so exposure to it at milking stations would invariably lead to human infections. If serious symptoms from such infections were common more cases probably would have been logged by now adds an evolutionary biologist.

H5N1 can most easily infect human cells that have the same receptors as cells in birds. These are in human eyes, & lungs, but fortunately not in our upper respiratory tract. Ongoing genetic testing needs to watch for mutations that would allow H5N1 to infect the human upper respiratory tract, thus enabling human to human infection.

The results are "so far so good", but the scale of this testing needs ramping up, given the intensive human to animal contact now (eg Wuhan) compared to the past. Surveillance programmes that can detect, track and limit the spread of new pathogens in farmed animals are essential to prevent future pandemics. This outbreak spread in a new host (cattle) "under our noses" before detection.

"Tailpiece"

You should "FLiRT" this autumn.

The acronym may help you remember to get a COVID-19 booster jab this autumn, if you're eligible
Why??

The variants of SARS-CoV-2 coronavirus that cause COVID-19, with the acronym FLiRT, have been the dominant forms of the virus circulating globally in 2024, according to the WHO. The name comes from the locations of the mutations the variants share on the virus' spike protein. One of them, called KP.2, has become the most commonly circulating variant in the USA over the past month, according to the U.S. Centers for Disease Control and Prevention. Regional Health Authorities have already, or may well soon, recommend vaccine manufacturers to concentrate on this for the next jabs.
The Editor