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NEWSLETTER

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As it's summer & vacation time **In This Edition** we've got a couple of articles about ensuring you keep well whilst dining out:

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Tony Dunford Editor



Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

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What we look for when eating out !!

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

Summer is here and with it the heat. High and really high temperatures are reaching 35-40°C during the day. In Madrid and most of Spain this is normal, and we are used to it. However, as a consultant specialized in aseptic operations and injectables in general; even on holiday I can't help looking at if things are kept & stored clean & cool, in ways to prevent contamination!

When one enters a bar or restaurant to have some tapas, for example, I'll eye how the tapas are kept. If they are inside the cold chain cabinets, if there is mayonnaise inside or fish, if the tapas look dry...? Equipment and machinery? Are the tables and chairs clean when we sit down, and will waiter disinfect the table when we arrive, is the coffee machine tidy and shiny...?

And what about the personnel serving us? The behaviour of the waiter, are her/his hands and fingernails, clean or dirty, do they sometimes go into the bowl of gazpacho when serving? Does their hair, or aprons, need a wash?

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And also, the premises? Floor and wall clean and painted, with no scratches ...?
And I always try to peek inside the kitchen when the door is partially open to check how things look inside i.e. how the “manufacturing operations” are being performed!
Surely a visit to the toilets is compulsory to confirm (or not) the impression that the place has a “Clean Environment”. Now we relax somewhat if the venue establishment is known, and we are routine clients. But when it’s first time there I think of my inner health.

In summary, it’s similar to Galenisys auditing a supplier / CDMO for the first time, for an on-going audit, or when we have to perform a for-cause inspection. Our auditing eyes never stop wherever we are.

Whatever the season, Galenisys experts can also support you in the process of comprehensively checking the factories and operations of your organization, & identifying any necessary improvements. Do contact us.

Bon appetite & have a great holiday!
Galenisys

José Zapata



Here are some of the risks



By Steve Biddulph

Fellow of Royal Institute of Microbiology. Board level pharma experience. QSM and Aseptic Manufacturing & Control Expertise

Steve Biddulph pinpoints some of the food dangers which can spoil the holiday

As Jose has mentioned in our 1st article there are a number of things which distinguish reliable and unreliable eateries.

On our travels I've noticed that restaurants that steam food, but are not equipped with extraction fans, can suffer from excessive condensation on floors, walls and ceilings. This can provide ideal conditions for the growth of moulds, particularly *Aspergillus* species.

All restaurants should have effective aeration and steam extraction to prevent this happening :



People can get aspergillosis by breathing in microscopic *Aspergillus* spores from the environment. Whereas most people breathe in *Aspergillus* spores every day without getting sick; people with weakened immune systems or lung diseases are at a higher risk of developing health problems due to *Aspergillus*.

Diners of a cautious disposition (or bitter memories) would do well to avoid filter feeders like cockles mussels or welks, as incomplete cooking and / or hot weather provide the opportunity for the proliferation of the bugs they've ingested.

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Another current health issue is caused by the increasing consumption of raw salmon while eating sushi:

“Owing to changes in food habits, anisakiasis [disease caused by worms from fish, causing symptoms such as pain, vomiting and diarrhoea] is a growing disease in western countries, which should be (the) suspected (cause) in patients with a history of ingestion of raw or uncooked fish. »

USDA regulations require raw salmon to be frozen

For this reason, the USDA regulations require raw salmon to be frozen before it's served in Sushi or Sashimi, specifically because it kills the parasites that could be present. Most people don't know this.

One chef, Naomichi Yasuda, became quite a celebrity in the New York sushi scene before returning to Tokyo to introduce the freezing techniques he refined over 30 years. His restaurant in NYC was considered one of the best in the region. He used blast freezers to improve the texture/taste of many types of sashimi.

So make sure that your raw fish has been frozen or you could end up meeting this guy :





Global Health Leaders plan Vaccines Research Future

CEPI & India make different sorts of pitches.

In June, global health leaders came together in Hyderabad, India, to discuss:

"Global Vaccine Research Collaborative: Building Consensus for Future Health Emergencies Prevention, Preparedness, and Response"

a co-branded event under India's G20 Presidency, organized by Department of Pharmaceuticals, of The Government of India, in collaboration with CEPI and PATH. The event took place on the side lines of the **3rd G20 Health Working Group Meeting**.

CEPI's CEO, Dr Richard Hatchett, presented the concept of a **'One World Vaccine Library'**. He explained that the creation of such a library would be a key enabler of their 100 Days Mission as it would contribute to solving many of the challenges of vaccine design in advance, helping to speed up the development of vaccines against viruses that might emerge from the 25+ viral families that are known to cause human disease.

The prior Press Release from the Indian Government included this "Background":

"The (Indian) Department of Pharmaceuticals is working with Program for Appropriate Technology in Health (PATH) and Coalition for Epidemic Preparedness Innovations (CEPI) to convene and build consensus among various stakeholders from G20 Member States as well as the special invitee countries for a proposed Global Vaccine Research Collaborative. This initiative will focus on addressing major gaps in research for vaccine development before the next pandemic, establishing a structure and principles for better vaccine R&D preparedness and creating a mechanism for improving coordination and fostering an enabling environment for vaccine R&D".

(Dr Rajiv Bahl, Secretary, Dept. of Health Research; Sir Jeremy J Farrar, Chief Scientist, WHO; Mr Nikolai Gilbert, President and CEO, PATH; Dr Richard Hatchett, CEO, CEPI; representatives from the G20 member countries, & various international organizations & Indian Health Service officials were present at the event).

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Indian Vaccines

As hosts, the Indian authorities were no doubt anxious to rehabilitate their image after the cough mixture scandal we have reported on, and to highlight their vaccine credentials.

After all, the export of pharmaceutical products is a major industry for the country. It is the world's largest exporter of generic drugs — its sales exceeded \$22 billion last year. And during the COVID-19 pandemic, India supplied 235 million doses of vaccines to 98 countries, most of them in the Global South.

The senior Federal (or "Union") Government Minister Dr Mandaviya spoke of India's leadership in vaccine R&D for several decades, with experience in developing, producing, and distributing vaccines for polio, small pox, and measles.

He said that India, as a leading player can play a critical role in building greater global collaboration, and "The development and deployment of effective vaccines can help to mitigate the impact of pandemics, and we must prioritize research efforts to achieve this objective".

He mentioned India's initiatives to boost vaccine production and distribution, stating that "the government has provided financial incentives and streamlined regulatory processes to encourage vaccine manufacturers to increase their production capacity..... "we must leverage India's experience in these fields and accelerate vaccine development, especially for emerging and pandemic-potential pathogens".

Other Indian speakers also took the opportunity to highlight India's capacity and track record in vaccine R&D production & supply, and pitch for future exports. For example, the Principal Secretary, Govt of Telangana mentioned that "9 billion vaccine doses p.a. are produced in Hyderabad, which is equivalent to one-third of the total".

He stated that India's first indigenous COVID-19 vaccine, COVAXIN was entirely researched and produced there, and part of "Sputnik" R&D carried out. He invited global vaccine manufacturers to collaborate with domestic firms and set up R&D and production centres in the city.

One can't help feeling that as Union Minister for "Chemicals & Fertilizers and Health & Family Welfare", Dr Mandaviya has a very large portfolio!

One hopes he's got time to ensure that the 38 individual states adequately supervise Quality Assurance in India's huge pharma industry.

The Editor

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COUGH MIXTURES UNDER FIRE

The Editor

“Death by Cough Mixture”

Cough syrups were again in the news, as outlets gave updates on the Indian manufactured cough syrups linked to deaths in the Gambia, Uzbekistan, and elsewhere. Several hundred Indian fatalities of infants & young people caused by adulterated cough mixtures have also been notified. We reported on the scandal in earlier Galenisys Newsletters **

- “After these international incidents the Indian regulators should have the batches of these syrups from the market and conducted a thorough investigation but nothing of that sort happened” according to an Indian expert.
- “This global scandal exposed India's weak drug regulations” pronounced Health Policy Watch in February this year.
- In 2013 the Indian government had introduced a bill to amend the 1940 (!) Drugs and Cosmetic Act but that bill never went through parliament, and the subsequent government withdrew the bill.
- India is the world's largest exporter of generic drugs valued at > \$22 billion in 2022.
- Following their investigation, the WHO announced on 05.10.22 that “four cough syrups made by Maiden Pharmaceuticals Ltd limited India contained unacceptable amount of diethylene glycol and ethylene glycol as contaminants”.
- However, India's federal drugs regulator said in December 2022 its own tests found no toxins in the syrups and Maiden has denied any wrongdoing.

As always, the issue is whether there is verified compliance. India has Regulators in each of the 38 States, each one of which could authorise a drug! It's claimed a local Regulator was bribed.

Indian Regulatory reaction has been slow. **So, The Scandal Rumbles On:**

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- The South China Morning Post reported that only on 09.03.23 did India suspend production at the Delhi based firm that supplied ingredients to Marion Biotech whose cough syrups were linked to the deaths of 19 children in Uzbekistan.
- On 20th June this year the Daily Telegraph (a UK newspaper) reported that; “the Indian authorities were investigating bribe claims surrounding ‘switched samples’ of lethal cough syrup at Maiden Pharmaceuticals. (Bribery of the local Regulator). The manufacturer is one of two companies at the centre of an international poisoning scandal which has left scores of children dead and badly dented trust in India’s \$41 billion medicines industry”.
- The BBC reported that (only on!) 18.07.23 “the Indian government has made it compulsory for cough syrup makers to get samples tested before exporting their products”.

And as we went to press (20th July) the Daily Telegraph carried this:

- “A company pretending to be British has been caught selling toxic cough syrup in Cameroon, with officials now racing to determine the true manufacturers of the product.... In the latest of a series of alerts about deadly contaminated medicines, (WHO) said a cough syrup sold under the brand name Naturcold had more than 200 times the acceptable amount of the solvent diethylene glycol.
- It is not yet clear where the toxic children’s medicine was manufactured. ...(It’s) packaging lists the producer as ‘Fraken International (England)’, but no company under this name exists in Britain, according to the UK’s health regulators.
- “Enquiries are still underway to determine the origin of the product,” said the WHO, adding that... it could be available in other countries”.

** See “A Scandal Repeats” November 2022 and “Why does it take so long?” February 2023

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Drug addicts are using cough mixtures

Cough syrups or linctus containing codeine phosphate could become prescription only in UK because of addiction fears. They would no longer be available as OTC products, as they are linked with a rising number of reports of drug abuse and dependence on codeine.

The MHRA (UK medicines safety regulator) has invited views on reclassifying these products as prescription only. The body say the rules regarding access need tightening, although “codeine linctus is an effective medicine”.

The worries about overdose risk are echoed by pharmacists. The President of the Royal Pharmaceutical Society said “there are many non-codeine-based products which people could use for a dry cough which would probably go away on its own anyway”.

The misuse and abuse codeine linctus can have major health consequences. According to the agency these problems have increased over the last five years because of criminal activity and social media comment, and serious and fatal adverse reactions are exceeding 200 per year.

The MHRA consultation runs until the 15th of August 2023.

The Editor

