

Newsletter

Warning of 'Post-Antibiotic Apocalypse' by Chief Medical Officer



Professor Dame Sally Davies said that if antibiotics lose their effectiveness it will spell “the end of modern medicine”.

Without the drugs used to fight infections, common medical interventions such as caesarean sections, cancer treatments and hip replacements would become incredibly “risky”, she said.

And transplant medicine would be a “thing of the past”, she added.

Health experts have previously warned that resistance to antimicrobial drugs could cause a bigger threat to mankind than cancer.

In recent years, the UK has led a drive to raise global awareness of the threat posed to modern medicine by antimicrobial resistance (AMR).

Around 700,000 people around the world die annually due to drug-resistant infections including tuberculosis (TB), HIV and malaria.

If no action is taken, it has been estimated that drug-resistant infections will kill 10 million people a year by 2050.

In September the World Health Organisation warned that antibiotics are “running out” as a report found a “serious lack” of new drugs in the development pipeline.

The new project which will map the spread of superbugs is a collaboration between the UK Government, Wellcome Trust, Bill and Melinda Gates Foundation, the University of Oxford and Institute for Health Metrics and Evaluation.

Foreign and international development minister Alistair Burt said the project will help to “pinpoint problem areas”.

Tim Jinks, head of drug resistant infections at the health research charity the Wellcome Trust, which is investing £2.4m in the mapping project, said: “While we have seen progress in recognition around the world of the threat that superbugs pose, we need to retain momentum. High-level commitments must quickly become action.

“Together, we can stop superbugs undermining the whole of modern medicine.”

Meanwhile, the Wellcome Trust,

along with the UN Foundation, has conducted analysis on global action plans to tackle superbugs.

The research found that while 151 of 195 countries are developing a plan, just one in five commit to reducing antibiotic use, improving hygiene and preserving antibiotics of last resort

And only 5% are adequately funded and monitored, Wellcome said. [Source: The Independent]



2017 Nobel Prize in Physiology or Medicine

To Jeffrey C. Hall, Michael Rosbash and Michael W. Young for their discoveries of molecular mechanisms controlling the circadian rhythm

Life on Earth is adapted to the rotation of our planet. For many years we have known that living organisms, including humans, have an internal, biological clock that helps them anticipate and adapt to the regular rhythm of the day. But how does this clock actually work? Jeffrey C. Hall, Michael Rosbash and Michael W. Young were able to peek inside our biological clock and elucidate its inner workings.

Using fruit flies as a model organism, this year's Nobel laureates isolated a gene that controls the normal daily biological rhythm. They showed that this gene encodes a protein that accumulates in the cell during the night, and is then degraded during the day. Subsequently, they identified additional protein components of this machinery, exposing the mechanism governing the self-sustaining clockwork inside the cell. We now recognize that biological clocks function by the same principles in cells of other multicellular organisms, including humans.

This year's Nobel Laureates, who were also studying fruit flies, aimed to discover how the clock actually works. In 1984, Jeffrey Hall and Michael Rosbash, working in close collaboration at Brandeis University in Boston, and Michael Young at the Rockefeller University in New York, succeeded in isolating the period gene. Jeffrey Hall and Michael Rosbash then went on to discover that PER, the protein encoded by period, accumulated during the night and was degraded

during the day. Thus, PER protein levels oscillate over a 24-hour cycle, in synchrony with the circadian rhythm.

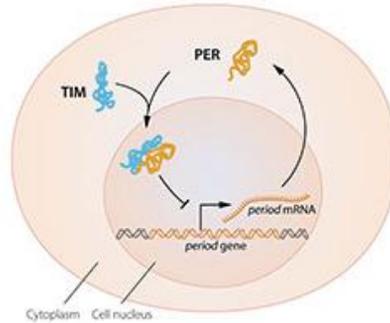


Figure (a): A simplified illustration of the molecular components of the circadian clock.

Such a regulatory feedback mechanism explained how this oscillation of cellular protein levels emerged, but questions lingered. What controlled the frequency of the oscillations? Michael Young identified yet another gene, doubletime, encoding the DBT protein that delayed the accumulation of the PER protein. This provided insight into how an oscillation is adjusted to more closely match a 24-hour cycle.

The paradigm-shifting discoveries by the laureates established key mechanistic principles for the biological clock. During the following years other molecular components of the clockwork mechanism were elucidated, explaining its stability and function. For example, this year's laureates identified additional proteins required for the activation of the period gene, as well as for the mechanism by which light can synchronize the clock.

The biological clock is involved in many aspects of our complex physiology. We now know that all multicellular organisms, including humans, utilize a similar mechanism to control circadian rhythms. A large proportion of our genes are regulated by the biological clock and, consequently, a carefully calibrated circadian rhythm adapts our physiology to the different phases of the day (Figure b). Since the seminal discoveries by the three laureates, circadian biology has developed into a vast and highly dynamic research field, with implications for our health and wellbeing.

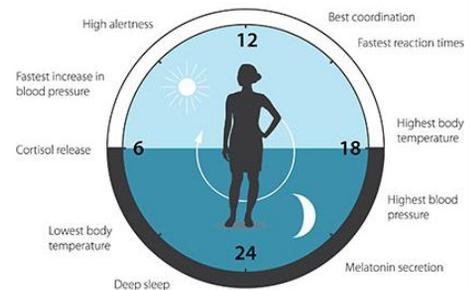


Figure (b): The circadian clock anticipates and adapts our physiology to the different phases of the day. Our biological clock helps to regulate sleep patterns, feeding behavior, hormone release, blood pressure, and body temperature.

[Source: Nobel Prize]



Obituary

Geoffrey Christopher Schild



Microbiologist who opened the way for a universal flu vaccine, and led pioneering research to combat Aids

The microbiologist Geoffrey Schild, who has died aged 82, did much to help halt the spread of influenza, polio and Aids. It was he who proposed the concept of a universal flu vaccine, a goal still sought today.

In 1975 Geoffrey became head of the viral products division at the National Institute for Biological Standards and Control (NIBSC) in Hampstead, north London. There he focused his efforts, alongside the virologist John Wood, on standardising conventional influenza vaccines to ensure that, when manufactured, they would always contain the same quantity of influenza protein. The WHO quickly identified this as a breakthrough, and by 1978 Geoffrey's method of standardising vaccines was made obligatory for all new influenza vaccines around the world.

On being appointed the director of NIBSC in 1985, Geoffrey set up a polio research group. At the time, children were being given live polio vaccine. Geoffrey's team followed what happened when children were given the polio virus to swallow. He

realised that live polio virus could occasionally mutate and become virulent again. Though it was rare, it did happen. Thanks to the team's work, live polio vaccine is no longer in use.

In this period, too, when the Aids crisis first broke, Geoffrey was given the task of directing the Medical Research Council's (MRC) Aids programme in Britain, bringing together medics and scientists from the UK, the US and the rest of the EU to develop vaccines for the prevention of Aids, and drugs for the treatment of HIV infection. Geoffrey's aim was to get work on Aids moving quickly and efficiently. He divided teams into two arms: the strategic programme, which worked on the nature of Aids and its treatment, as well as monitoring the spread of HIV, and the second arm, which focused on developing drugs and vaccines.

The job of directing multinational researchers could be tumultuous. Geoffrey's technique when faced with a room full of squabbling scientists was to wink, surreptitiously. He had such an open face and such a smiley one; it always worked.

Born in Sheffield, Geoffrey was one of four children of Christopher Schild, a travelling salesman, and his wife, Georgina (nee Kirby). He went to High Storrs grammar school in

Sheffield and then Reading University, where he completed a degree in microbiology in 1958.

After graduating, Geoffrey worked for the pharmaceutical company Johnson & Johnson for two years, then decided to do a PhD, at Sheffield University, focusing on the common cold virus.

In 1993 Geoffrey was appointed CBE, and nine years later he retired from the NIBSC. Part of his legacy there is the library of carefully grown viruses that he helped set up so that scientists around the world could access the high-quality specimens needed for their research.

He was also author of at least 300 scientific papers. One of the most important, co-authored with the virologist John Skehel, introduced a new system for classifying the thousands of influenza strains isolated in animals and humans. The classification system is still in use by WHO laboratories today.

Geoffrey is survived by Tora, their three children, Oystein, Ingrid and Peter, and two grandchildren. [Source: The Guardian]



October 16:

World Food Day

According to the FAO: 'World Food Day is a chance to show our commitment to Sustainable Development Goal (SDG) 2 – to achieve Zero Hunger by 2030.'

1/3 of all food produced globally is wasted or spoiled

Tips to save food and to be more sustainable:

- **Don't shop too much**

make smart and practical purchases and restrict the number of visits to the supermarket.

- **Portion sizes**

Avoiding large plates will help and using smaller plates will not only be more sustainable, but it could help with your overall health too.

- **Save your food**

Canning is also beneficial as it is a method of preserving food in which the contents are processed and sealed in an airtight container – providing a longer shelf life.

- **Maintain your fridge space**

Move the older products to the front of the fridge and keep the new products at the back, so we can consume the older ones first.

News

Meeting with GSI and USAID:

In September, Ulrike Kresya (VP – Healthcare GSI) visited Pharma Bureau accompanied by her team and USAID team. DRAP regulation on Barcoding was discussed during the meeting with Pharma Bureau member company representative. It was appreciated that DRAP's efforts would be helpful in controlling the sale of Counterfeit and Spurious Drugs in Pakistan. It was decided that Pharma Bureau will continue its efforts to coordinate with DRAP for the successful implementation of barcoding regulation.

Discussion on Orphan and Critically needed Drugs:

In October, there was a meeting of member company CEOs in which DRAP regulation on Orphan and Critically needed Drugs was discussed. DRAP's efforts were appreciated to promote innovation and create an environment that would help the availability of drugs that are economically unviable to manufacture in the normal circumstances.

Presentation on DRIS by DRAP MIS team:

At the end of October, DRAP MIS team gave a presentation on the Drug Regulatory Information System (DRIS) at Pharma Bureau. Pharmaceutical Companies would have to get registered separately for their import and manufacturing businesses. Once registered, companies will have to register their SKUs (Products). Then information for every batch produced will be shared with DRAP through DRIS. Companies can upload an excel file listing all serial numbers of a particular batch, it will be optional for 2 years.

Meeting with the new Federal Secretary for Health:

A delegation from the Pharma Bureau met with the new Secretary Health, Mr. Naveed Kamran Baloch, on Wednesday, October 25.

The PB was represented by Dr. Asim Jamal, Chairman, Dr. Farid Khan, Mr. Farrukh Rehan, Ms. Seema Khan, Mr. Syed Wajeehuddin, Mr. Syed Raza Abbas and Ayesha T Haq.

Dr. Asim Jamal introduced the Pharma Bureau talked about its members and their role in and contributions to Pakistan. He identified the following 3 key areas that need tackling immediately:

- Registration and pricing of new products
- Generally looking at the functioning of the DRAP and specifically revisiting key policies i.e. DPP and Contract Manufacturing
- Bar Coding

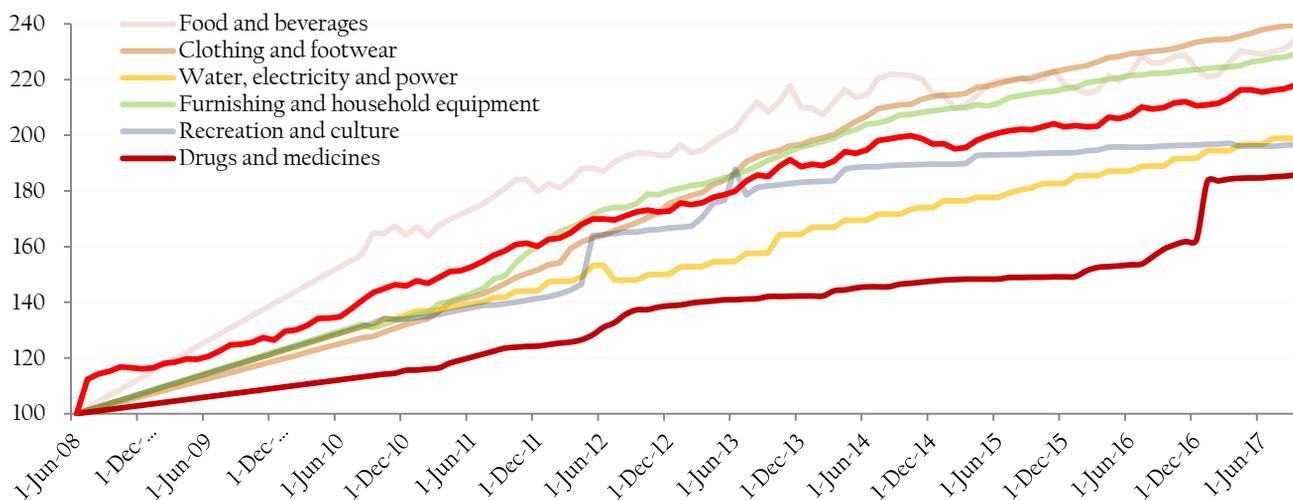
The Secretary was aware of some of the issues and concerns of the industry in particular pending cabinet approvals. Approximately 89 products have gone through all the committees and the cabinet has to sign off on these which he assured us would be done at the meeting to be held later that afternoon. He also said that the cabinet would be meeting every week so things would move a lot faster now.

Dr. Asim Jamal invited the Secretary to visit a manufacturing facility in Pakistan and meet with all the CEO's in Karachi



Market Update

Inflation (Consumer Price Index)*



% Increase in CPI vs. Same Month Last Year

Major increase was due to house rent increase of 7.19% as compared to the previous year. It has a contribution of 21.81% in the Consumer Price Index (CPI). Price of onions increased by 153% that has increased the CPI.

	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008
Jan	3.7	3.3	3.9	7.9	8.1	10.1	13.9	11.3	-	-
Feb	4.2	4.0	3.2	7.9	7.4	11.1	12.9	10.2	-	-
Mar	4.9	3.9	2.5	8.5	6.6	10.8	13.2	12.9	19.1	-
Apr	4.8	4.2	2.1	9.2	5.8	11.3	12.5	13.3	17.2	-
May	5.0	3.2	3.2	8.3	5.1	12.3	13.2	13.1	14.4	-
Jun	3.9	3.2	3.2	8.2	5.9	11.3	13.1	12.7	13.1	Base
Jul	2.9	4.1	1.9	7.9	8.3	9.6	13.8	12.3	11.2	Year
Aug	3.4	3.6	1.8	7.0	8.5	9.1	11.6	12.8	9.1	-
Sep	3.9	3.9	1.3	7.7	7.4	8.8	10.5	14.9	8.4	-
Oct	-	4.2	1.6	5.8	9.1	7.7	11.0	15.3	7.5	-
Nov	-	3.8	2.7	4.0	10.9	6.9	10.2	15.0	9.3	-
Dec	-	3.7	3.2	4.3	9.2	7.9	9.8	15.5	8.8	-

	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008
Jan	0.2	0.2	0.1	0.5	1.7	1.5	1.3	2.4	0.4	1.9
Feb	0.3	0.3	0.9	0.3	0.3	0.3	0.7	0.4	1.0	0.5
Mar	0.8	0.2	0.2	1.0	0.4	1.2	1.5	1.3	1.4	3.1
Apr	1.4	1.5	1.3	1.7	1.1	1.8	1.4	1.7	1.4	3.0
May	0.0	0.2	0.8	0.3	0.5	1.1	0.2	0.1	0.2	2.7
Jun	0.4	0.6	0.6	0.6	0.7	0.4	0.6	0.7	1.0	2.1
Jul	0.3	1.3	0.4	1.7	2.0	0.2	1.8	1.2	1.5	3.3
Aug	0.2	0.3	0.2	0.3	1.2	0.9	1.4	2.5	1.7	2.1
Sep	0.6	0.2	0.1	0.4	0.3	0.8	1.0	2.7	0.5	1.0
Oct	-	0.8	0.5	0.2	2.0	1.4	1.4	0.6	1.0	2.1
Nov	-	0.2	0.6	0.5	1.3	0.4	0.3	1.5	1.4	0.1
Dec	-	0.7	0.6	1.0	1.3	0.2	0.7	0.5	0.5	0.5

% Increase in CPI vs. Previous Month

Major increase was due to increase in prices of food items such as Onions (98.33%), Tomatoes (58.46%) and Sugar (6.69%) as compared to the previous month.

*Data extracted from September's Monthly CPI Review Report released by Pakistan Bureau of Statistics



Foreign Currencies

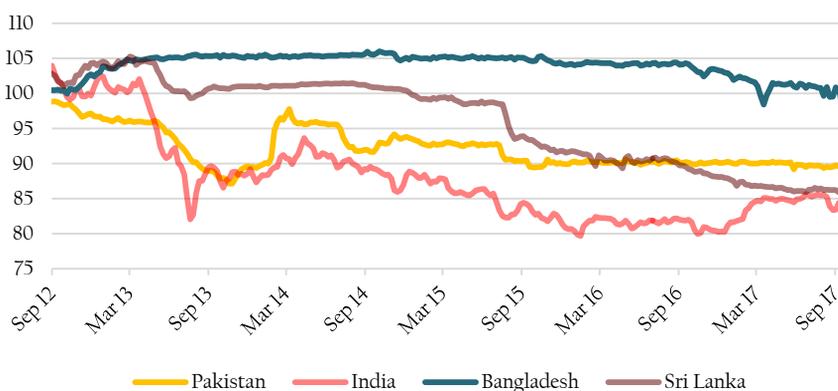


PKR vs. Major Foreign Currencies

Pakistan Rupee has appreciated against US Dollar (0.1%), Pound Sterling (2.5%), Euro (2.3%) and Japanese Yen (1.3%) in October 2017

USD vs. Major South Asian Currencies

USD depreciated against Pakistan Rupee (0.1%), Indian Rupee (0.35%) and appreciated against Bangladesh Taka (1.15%) and Sri lankan Rupee (0.37%)



Questions? We'd love to hear from you

Address: Chamber of Commerce Building, Talpur Road, Karachi – 74000, Pakistan

Phone: +92-21-32477509

Fax: +92-21-32477503

Email: ayesha.t@oicci.org

anwar.khan@oicci.org

Website: www.pharmabureau.org

The Pharma Bureau is a representative body of multinational pharmaceuticals in Pakistan. Part of the Overseas Investors' Chamber of Commerce & Industry, the Pharma Bureau was founded in October, 1988, when a small group of like-minded research based multinational pharmaceutical companies felt the need to have their own separate forum to articulate and resolve the problems and issues confronting overseas investors in the pharmaceutical industry in Pakistan.

Pharma Bureau Mission: Work closely with the relevant Government authorities to tackle and help resolve health industry related issues. Assist member firms in Product Registration Procedures. Protection of Intellectual Property Rights of members by respecting international patent laws. Bring about positive changes in the Health Administration set-ups by encouraging the Government to bring about improvements and changes in the structure and workings of health administrations

Our members: Provide quality drugs to the population at affordable prices without compromising on stringent industry standards. Introduce innovative drugs and medicines in Pakistan to enhance patient welfare and quality of life. Provide refresher courses to doctors on latest health topics / trends and educate them on new medication. Introduce, uphold and promote Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Are conscientious and ethical members of society, providing social care and support during national disasters.

