NEWS IN BRIEF

High Court Revokes Ban on 344 Fixed-dose Combinations

It is said that we live in a "post-truth" era – a time, when truth is considered largely irrelevant. In March 2016, The Union Government of India imposed a ban on 344 fixed-dose combination (FDC) drugs. The ban was based on a report by the Kokate Committee which had compiled a list of FDC's, which they considered as irrational. The ban impacted over 6000 brands, and pharmaceutical companies were quick to react by filing a total of 453 separate petitions challenging the validity of the ban. The Government had defended its decision, saying these medicines are potential health and safety hazards. The companies, on the other hand, had contended that no enquiry was made from them or show cause notice issued prior to the notification.

On December 1, 2016, the Delhi High Court revoked the ban saying that the Centre had acted in a haphazard manner, and did not take the advice of the statutory bodies under the Drugs and Cosmetics Act before issuing the March 10 notification. Noting that the power cannot be exercised in public interest for any reason other than the drug being risky or not having any therapeutic value, the Bench said that the same had to be decided based on scientific technical reasons on the advice of the Drugs Technical Advisory Body (DTAB) and the Drugs Consultative Committee (DCC) constituted under the Drugs Act.

The story is similar to the 294 FDC's, which were banned by the Drug Controller General of India (DCGI) in 2007. Then too, important issues of patients' health, safety and economical interest were lost in legal loopholes. Consequently, those 294 irrational FDCs, banned by the Union Ministry of Health on health and safety grounds, continued to be promoted, prescribed and sold to patients across India, without any hindrance. A sense of confusion and bewilderment prevails. (*The Hindu 2 December 2016*)

HIV Self Testing

The first step towards change is awareness. Echoing this, the WHO has released new guidelines on HIV self testing to improve rates of diagnosis and therapy. According to the report 18 million people, *ie* 40% of all persons infected with HIV are unaware of their status. However between 2005 and 2015, the percentage of people who knew of their infection rose from 12% to 60%. This increase in testing meant that now 80% of the people diagnosed with HIV are on therapy. Increased diagnosis means more chances of being on treatment and less transmission. However at the current rates of detection, it will take 25 years to pick up 90% of patients living with HIV.

In India, incidence of new HIV cases has been plummeting. Rates in 2015 were 66% lower than in 2000. It is estimated that in India 2.1 million people are infected with HIV. Of them 1.5 million have been detected and tested in the integrated diagnosis and testing centers. India is also considering the options of self testing. Community-based testing has been approved in principle. The WHO also wants to encourage people to inform their partners and help them find out their infection status.

Self testing is based on detecting antibodies in saliva or blood. One of the WHO approved kits is called OraQuick. Sensitivity (96.2-100%) and specificity (99.5-100%) is higher for the blood-based test as compared to the oral fluid (80-100% and 95.1-100). Counseling support over hotlines will also need to be established to prevent self harm. Currently, 23 countries have policies which support self testing. Self testing will substantially reduce the barriers and stigma attached to hospital based testing, and reduce transmission rates. (*The Hindu 2 December 2016*)

The New Superbug – *Candida Auris*

Candia auris is emerging globally as a serious and potentially fatal fungal infection. In June 2016, the CDC issued a clinical alert about this deadly fungus, and in November 2016 published a detailed report of the first 13 cases in the US. The first report of its isolation was from the external ear of a patient in Japan. This pathogen is now reported from several countries, including India, and is recognized as emerging multidrug-resistant (MDR) yeast that can cause a wide spectrum of infections, ranging from fungemia to deep-seated infections, especially in intensive care settings such as neonatal intensive care units. Studies from tertiary care hospitals in New Delhi and Kochi showed that the fungus is uniformly resistant to fluconazole, and 37 % showed elevated minimum inhibitor concentration (MICs) against caspofungin.

Scientists from The Indian Institute of Science, Bangalore have completed the genotype sequencing of this fungus, and this is now the reference sequence around the globe. They have also developed a polymerase chain reaction based test for this fungus as it is often misdiagnosed as *Candida haemulnii* in routine laboratory tests. They found that one of the reasons for the high drug resistance is a higher drug efflux pumps compared to other species.

Although no established MIC breakpoints exist for *C. auris*, resistance testing of an international collection of isolates conducted by CDC demonstrated that nearly all isolates are highly resistant to fluconazole. More than half of *C. auris* isolates were resistant to voriconazole, one-third were resistant to amphotericin B (MIC e"2), and a few were resistant to echinocandins. Some isolates have demonstrated elevated MICs to all three major antifungal classes, including azoles, echinocandins, and polyenes, indicating that treatment options would be limited.(*http://www.cdc.gov/fungal/diseases/candidiasis/candida-auris-alert.html, The Hindu 27 November 2016*).

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