

WHO's New Essential Medicines List Includes a 40-Year First

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The latest [update](#) to the World Health Organization's (WHO's) Essential Medicines List contains the biggest change to the antibiotics section in the list's 40-year history: creation of three categories — access, watch, and reserve — for guidance in deciding when certain antibiotics should be used.

"Access" indicates drugs that have lower potential for resistance and should be available at all times. This category includes drugs such as amoxicillin. The "watch" antibiotics are second-choice treatments that should be used only for a small number of infections. This category includes ciprofloxacin, used to treat uncomplicated cystitis and upper respiratory tract infections. The "reserve" group contains the last-resort drugs, such as colistin and some new-generation cephalosporins, that should be used for life-threatening infections involving multidrug-resistant bacteria.

The categories are aimed at improving outcomes, reducing emergence of drug-resistant bacteria, and making sure "last resort" antibiotics work when all others fail.

The list is updated every 2 years. This version adds 30 medicines for adults and 25 for children and specifies new uses for nine products. A total of 433 drugs are considered essential for public health needs.

In a conference call with reporters on Tuesday, Marie-Paule Kieny, MD, assistant director-general for health systems and innovation at the WHO, said, "These medicines are chosen according to evidence of safety, efficacy, and public health relevance."

She noted that programs targeted to changing prescribers' behavior — in particular with antibiotics — "have yielded modest results only," and the hope is that the categorization will increase commitment to attack the problem.

"Our intention is to work with countries to keep this issue high on their agenda," she said.

Two Oral Cancer Drugs and an HCV Combo Drug

Among the other additions are two oral cancer drugs, dasatinib and nilotinib, for treating chronic myeloid leukemia that has not responded to standard treatment. Another addition to the list is sofosbuvir plus velpatasvir, which is the first combination treatment for all six types of hepatitis C.

Suzanne Hill, PhD, director of essential medicines and health products for the WHO, said the combination hepatitis C drug has two major benefits: "First, it means that countries without sophisticated diagnostic equipment can actually have an option to go straight to a one-treatment approach even without knowing what type of hepatitis C virus they're dealing with." Also, because it is administered as a once-daily dose, it is simple to use.

Other additions include the following:

- Dolutegravir for HIV infection. "The latest evidence shows that treatments containing this medicine are the most successful in suppressing the virus and also better-tolerated by patients," Dr Hill said.
- Preexposure prophylaxis with tenofovir alone or in combination with emtricitabine or lamivudine to prevent HIV infection.
- Delamanid for children and adolescents who have multidrug-resistant tuberculosis (MDR-TB), and clofazimine for children and adults with MDR-TB. Until now, clofazimine was only used for the treatment of leprosy, Dr Hill noted.
- Child-friendly fixed-dose combinations of isoniazid, rifampicin, ethambutol, and pyrazinamide for treating pediatric TB.
- Fentanyl skin patches and methadone for pain relief in cancer patients.

Dr Hill noted that some of these medicines are extremely expensive. The hope is that inclusion on this list will send a strong message to all public health decision makers that these are the medicines that provide true benefits.

The WHO held the first fair-pricing forum 3 weeks ago. The forum, which was conducted jointly with the Netherlands government, started a conversation between governments, industry, payers, and patients to make medicines more affordable.

"When we designate a medicine as essential, buyers have some leverage in negotiating for the final purchase price," Dr Hill said.

Not included on the essential list is the "polypill," a combination drug containing a statin, a beta blocker, aspirin, and a blood pressure medication.

Dr Hill said that currently, there are at least a dozen fixed-dose combination products for cardiovascular disease. The committee considered two polypill versions but was unable to determine whether one was more effective than the other, though they acknowledge the benefits of such a combination.

"Combination products also have risks," Dr Hill said, "and if you just assume the single dose of the product that's in the polypill is the right dose for all patients, you may be causing some patients to have more side effects."

Oseltamivir in Limbo

The experts said further evaluation of data is required to decide whether the controversial flu medication oseltamivir (*Tamiflu*, Roche) warrants being listed as an essential drug.

Dr Hill said this report suggests that "the size of the effect of oseltamivir in the context of pandemic influenza is less than previously thought. However, this is still the only product available with an antiviral, particularly for patients who are severely ill with influenza. For example, pregnant women can get very ill with influenza."

In balancing benefit and harms, the committee recommended that the use of oseltamivir be restricted to the most severely ill patients in hospitals or in critical care and has asked that the data continue to be reevaluated.

Dr Hill said one of the most important results of this year's report may be that having the last-resort category of antibiotics will change the way we think of paying for antibiotics.

"What we need to do is stop paying for antibiotics based on how many times they're prescribed and to discourage use. We don't want colistin used very frequently. In fact, we don't want it used at all. What we need to do as a global community is work out how we pay the company *not* to market colistin and *not* to promote it and to keep it in reserve." Such steps might involve stockpiling or a buyout of the license, among other measures.

The secretariat of the Essential Medicines List, assisted by the Office of Compliance, Risk Management, and Ethics, concluded that there were no significant relevant financial relationships that would prevent any member from participating fully in the expert committee process.

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