# Europe leads effort to push for design of "green" drugs

European Union requires environmental review of new drugs. Sweden leads the way, creating database so doctors can check whether medications are "green" before prescribing them.

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Before Dr. Lars Lööf writes a prescription for his patients, he checks a new database--but it's not just to search for the typical warnings about a drug. He wants to know whether the medication might harm the environment. In some cases, he even can find a more environmentally friendly drug, all with the click of his mouse.

The new database, available to physicians in Sweden, is the first of its kind in the world, prompted by a broader law in Europe that transforms the way pharmaceuticals are evaluated before going to market.

The European Union requires pharmaceutical companies to analyze the environmental risks of new drugs, adopting guidelines in 2006 that grew out of concern about traces of drugs discovered in waterways and drinking water. Medications such as antidepressants, painkillers, antibiotics and estrogen are excreted by humans, and they wind up in treated sewage that is released into the environment, where fish and aquatic animals, even humans, can be exposed.

While the United States focuses on figuring out how to keep drugs and other chemicals out of the nation's waterways, the European Union's approach could be called "benign by design." It goes right to the source, evaluating the dangers of medications when they are created, before they enter the environment.

"Without this information, doctors and patients cannot take environmental aspects into account when choosing between products," said Lisa Anfält, a technical expert at Sweden's Environmental Ministry Division for Chemicals and Eco-management.

Evidence that a chemical may harm the environment doesn't necessary mean a product will be banned. But the new legislation does mean that all pharmaceuticals are now evaluated by the European Medicine Agency under the same standards. Products already on the market are exempt, unless their use or form has changed.

Most EU countries are simply performing the minimum required risk assessments.

But some have gone further. Germany, in a program called START, has brought together pharmaceutical industry officials and others to explore ways to reduce contamination of waterways.

Sweden, a long-standing architect of pioneering environmental legislation, has taken the biggest steps.

The Stockholm County Council, which provides public health care to Stockholm's residents, set up a regional environmental classification system for pharmaceuticals in 2003.

The European Commission thought it was too soon to act "so we took the idea back home and started it there," said Åke Wennmalm, Environmental Director of the Stockholm County Council and the driving force behind the classification system.

Called JanusInfo, the database rates pharmaceutical substances in terms of their toxicity, persistence, and bioaccumulation potential based on data given by pharmaceutical manufacturers. It is part of Stockholm's larger effort to reduce levels of the most environmentally hazardous medicines in wastewater effluent and in surface water by 2011.

The database was so well received that it was soon extended to all of Sweden. Then-prime minister of the environment, Lena Sommestad, expressed interest in obtaining more knowledge about the environmental risks of pharmaceuticals. As a result, an industry trade group, the Swedish Association of the Pharmaceutical Industry worked with government to create a standardized model for environmental classification of pharmaceuticals.

Like Stockholm's JanusInfo, the national database includes environmental hazard assessments. It also contains risk assessments, which rate substances based on the probability that they will cause adverse effects.

The hope is that doctors will use the data to pick the greener option among two drug equivalents.

Some studies have shown that drugs such as the antidepressant Prozac and birth control pills that contaminate wastewater can harm fish, amphibians and other aquatic life. Traces of drugs also have been found in some drinking water supplies, too, although the potential effects on people are unknown.

The database is located online in the Swedish Medicines Information portal, or FASS, a commonly used resource for both doctors and the general public for up-to-date pharmaceutical information.

"FASS is very well known among doctors in Sweden as a source for everything you want to know about a particular pharmaceutical, so it just felt natural to add an environmental component onto it," says Matilda Persson, a spokesperson for the Swedish pharmaceutical industry group.

So far, the database lists about 1,100 substances, although only 60 percent have been environmentally reviewed. One-fourth of those have detailed data. By 2010, all pharmaceuticals marketed in Sweden are supposed to be assessed, excluding those unlikely to have an environmental impact, such as vitamins.

Although there are no statistics available on how many doctors have used the database, Persson says that it registers about 5 million visits per month and is regarded as the most important pharmaceuticals website in Sweden.

Lööf, a physician at Central Hospital in Västerås who specializes in internal medicine and gastroenterology, said he and many of his colleagues feel the database is useful but that it needs more hard data on drugs, especially older ones that don't fall under EU legislation.

"Physicians do use the database, but it's not yet common for them to use it for every prescription because it's still lacking a lot of information on pharmaceuticals," said Lööf, chairman of the Drug Therapeutic Committee at the Centre for Clinical Research in Västerås, which works with local physicians to provide drug therapy strategies.

He adds that drugs without environmental data are often classified first as high risk, but then changed to low risk once more information is obtained, which can be confusing to physicians and patients.

"The list changes from year to year and this is a problem," Lööf said.

Still, he believes that the database is a good start in managing pharmaceutical information.

There are no plans to extend the database to the rest of Europe. That could change as the European Environmental Agency, under the European Commission, recently recommended that all EU countries introduce a drug classification system.

"We don't know whether the European Commission will accept this recommendation, but it is a very strong push on the Commission to adopt this system in all of the EU," said Wennmalm. He believes that in a few years, a drug

classification system might be introduced to all 27 EU countries, especially Germany, which has already expressed interest.

Christina Rudén, program manager of MistraPharma, a Swedish national research initiative that studies pharmaceuticals' environmental effects, said because the European Union's pharmaceutical legislation is fairly new, it may be easy to change. She said Swedish reviewers are likely to suggest an amendment that includes a classification system similar to JanusInfo.

"It's quite impressive of Sweden to put this voluntary classification system in place since these pharmaceutical industries are so multi-national," Ruden said. "There are some serious concerns internationally and particularly in the U.S. about why the industries should do this voluntary classification system, but at the end of the day the pharmaceutical industry agreed to do it, and I think that's a very positive sign."

Not all drugs can be green. Some might seep into waterways yet save people's lives. And since the environmental threats of pharmaceuticals are not yet fully understood, some experts worry about passing laws without properly assessing the risk that they pose.

"It's far worse if people in need of a treatment lose the treatment because of a poor risk assessment that overestimates something that's a small risk to the environment," said Frederick Bouder, a research associate at the King's Centre for Risk Management at King's College London who studied regulation of pharmaceuticals in the environment in the United States and Europe.

"At the same time," he said, "it would be a pity if people are contaminated by something quite bad because we haven't understood the interactions of several chemicals in the water."

The United States does not assess or classify drugs based on their environmental impacts, but legislation from Brussels—often originating in Sweden—sometimes influences U.S. policy. The EU has the world's most stringent chemical program.

Åke Bergman, head of Stockholm University's Department for Environmental Chemistry, said if some companies are persuaded by these government programs to implement green chemistry policies, it may force others to do so as well.

Some pharmaceutical companies are indeed gaining interest in green chemistry. Industry, policymakers and scientists convened at the first International Conference on Sustainable Pharmacy in Germany last April to discuss how to make drugs more environmentally friendly. In the United States, major corporations have joined the American Chemical Society's green chemistry pharmaceutical roundtable.

According to an article published by the American Chemical Society, a new, birth control pill from drug maker Schering-Plough is scheduled for animal and human drugs trials. A company representative was unwilling to comment on the product. But the article claims that the new drug uses biodegradable progesterone.

Without green chemistry, "the industry will find it more and more difficult to manufacture and sell their chemicals," Bergman said.