

Italian health sector in disarray following more scandals

Munich. The Italian pharmaceutical industry is on the brink of collapse following revelations last month of massive corruption in the registration and pricing of drugs. Former health minister Francesco De Lorenzo is under at least ten different mandates for arrest, and the scandal embraces the entire pharmaceutical industry and several university departments.

Giovane Marone, De Lorenzo's secretary, alleged last month that Lorenzo and his colleagues at the ministry — 'the Group of the Golden Pill' — arranged for pharmaceutical companies to pay bribes, or 'contributions', to guarantee registration of their drugs and 'suitable' market prices. The corruption network, he claimed, embraced every link in the chain between the manufacture and marketing of drugs. Its extent and the cynicism of its workings have shocked a nation hardened to tales of corruption.

Since the revelations, police have arrested Duilio Poggiolini, chairperson of the national commission for the registration of drugs and president of the European Commission's Committee for Proprietary Medicinal Products, and Antonio Brenna, chairperson of the national commission that sets drug prices. The government has suspended both commissions.

Elio Rondanelli, president of the Italian AIDS commission, was among the university professors arrested. Antonio Vittoria, who worked at the faculty of pharmacy in Naples, committed suicide after the first allegations. Academics were lured into the corruption web as 'independent experts' to the government and drug industry. They received a share of the 'contributions' when their advice supported the ministry.

Of those charged, only De Lorenzo is free, because he has political immunity as a member of parliament; but he will lose this in the forthcoming general election.

Italy's pharmaceutical companies are accused of collusion, and seeking to influence registration and pricing of their products. One of the most prominent industrialists implicated is Francesco della Valle, who was fired as director of Fidia last year following financial difficulties (*Nature* 364, 562; 1993). Fidia's major product, gangliosides, mysteriously found its way back onto the Italian market only a few days after it was withdrawn in Italy and several other European countries because of its association with Guillain-Barré syndrome, a type of paralysis.

Some companies claim that they were simply victims, not perpetrators, of corruption. Alberto Zambon from the Zambon Group, claims that when his company asked Marone to increase the price of its product Fluimucil in October 1990, he asked it for

IL2 billion (around US\$1.2 million), far more than it was prepared to pay. When the company consequently ran into financial trouble a year later, it was saved from bankruptcy when the Department of Industry stepped in and authorized a small price rise.

Italy's national formulary has long taken the country for a ride. Many of the drugs are useless, and exorbitantly-priced drugs — mainly reimbursable by the state — have put increasing strain on the health budget. Gianni Tognoni, a clinical pharmacologist at the Mario Negri Institute in Milan, estimates that the state could save \$3 billion simply by stopping the sale of just five popular 'but useless' drugs.

Tognoni has also fought against the flaws in Italy's drug policy but without success. It was asking for corruption, he says, because its procedures were so lax. Registration procedures were sufficiently ambiguous, he claims, that drugs could be licensed without documented proof of their efficacy as demanded by law.

Drugs registered for one indication could also be prescribed with relative ease for other, inappropriate, indications. The same drugs would also often be priced differently depending on the company. For example, Guidotti's antihypertensive Captopril cost 30 per cent more than the version sold by the US company Squibb. "At the very least this indicates some confusion on the part of the 'expert' drug price fixing committee", says Silvio Garattini, director of the Mario Negri Institute. As is now clear, high prices were for sale.

Mariapia Garavaglia, the new minister for health, is setting up a new drug registration commission. She will chair the commission, which will comprise 12 independent experts (seven elected from the regions and five by the ministry), the director of the ministry's pharmaceutical department and the director of the Higher Institute of Health — the ministry's technical body. One of the commission's first tasks will be to review the national formulary list and eliminate products with no proven efficacy. It will also introduce new methods of reimbursement to reduce the cost to the ministry of drugs not considered to be essential.

Garavaglia will not set up a new drug pricing commission; the system is too open to corruption she says. She prefers a system of free pricing where industry decides on the cost of its own products. The Department of Industry opposes such a move, and has set up a group of experts to advise it on the criteria on which drugs should be priced. It believes the government should retain control over drug costs as it reimburses much of the country's drug bill. **Alison Abbott**

Brazil's proposed law threatens animal experimentation

São Paulo. Scientists in Brazil are up in arms about a proposed animal experimentation law which they fear could threaten the future of biomedical research there.

Critics of the proposed law, which was prepared for the government by the Brazilian lawyers' association, concede that legislation is needed to end the existing free-for-all in animal experimentation in the country. But they object to the proposed structure, under which regulation will be controlled by a powerful, autonomous committee whose membership rules will explicitly exclude any scientist who has recently been involved in animal experiments.

"It has elements of extreme madness," complains Mauricio Rocha e Silva, head of the Divisão de Experimentação (Experimentation Division) at the prestigious Incor (Instituto do Coração, or Heart Institute, affiliated with the Faculty of Medicine of the University of São Paulo).

Rocha e Silva chairs a committee recently created by the Brazilian Academy of Sciences and the Federation of Experimental Biology Societies to voice scientists' views on the subject. "The project conflicts with scientific freedom," says Rocha e Silva, besides "creating a sort of a police that will stop research by force."

Circe Amado, author of the draft of the new law, does not agree. An environmentalist lawyer, Amado is engaged in a project to consolidate Brazilian laws dealing with the environment. The project deals not only with use of animals for scientific purposes, but all other instances of possible cruelty to them.

Amado denies that the project will hinder research. She says that scientists have become insensitive to animal suffering and defends the right of inspectors to close down laboratories whenever any kind of animal cruelty is detected. According to Amado, the project is based on equivalent legislation in both Britain and Sweden.

The focus of scientists' anger is a proposed organ called COSETICA, or the Comitê Superior de Ética Científica com Animais (Superior Committee for Scientific Ethics with Animals), which would have the power to close down labs in case of perceived cruelty, and to license researchers to use animals.

The project also suggests that COSETICA should have "autonomy," freeing it from the influence of the science ministry or other government departments. "It is a republic inside the republic," complains Rocha e Silva; "it is against the Constitution." Amado answers that up to now Brazil has had no animal rights law and that one with enough power is needed. **Ricardo Bonalume**