

# Health Hazards in the Pharmaceutical Industry

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*"Indeed, if we questioned closely those who work ... in the shops of apothecaries ... as to whether they have at any time contracted some ailment while compounding remedies that would restore others to health, they would admit that they have very often been seriously affected." (B Ramazzini, 1713)*

It has been suspected for centuries that the manufacture and handling of therapeutic drugs is potentially hazardous to health, yet this remains a neglected area of occupational health research. There have, for example, been very few studies which evaluate the effects of exposure to drugs poisonous to the bone marrow on workers in the pharmaceutical industry. There are, however, numerous clinical studies on patients who have received the drugs azathioprine and chloramphenicol for therapeutic purposes, which highlight the toxic effects of these drugs on the bone marrow. Both these drugs are also known to cause cancer when used in therapeutic settings.

These findings can not necessarily be extrapolated to workers involved in the production of these drugs. Therapeutic doses of a drug are intended to produce an appreciable effect on the human body. Furthermore, the body's handling of a drug administered therapeutically is different from inhaling a drug in an occupational setting. Finally, occupational exposure usually occurs over a length of time and, therefore, allergic sensitisation, cancer and reproductive problems become more likely.

## **CWIU Workers Affected**

The authors, with Peter Lewis of the Industrial Health Research Group investigated the effects of azathioprine and chloramphenicol on workers in a Cape Town plant. The project was requested by the Chemical Workers Industrial Union (CWIU) after a group of workers at this plant were found to have abnormalities in their blood tests, indicating bone marrow dysfunction. Workers refused to continue working with these drugs until a comprehensive health hazard evaluation of exposure to these two drugs had been conducted.

The study showed that, while none of these substances could be detected

in body fluids, changes in peripheral blood counts were suggestive of exposure. Furthermore, environmental monitoring measurements demonstrated contamination of the air inside airhoods, a form of protective equipment worn by the workers.

The project highlighted various deficiencies in the health and safety programmes of the pharmaceutical industry in this country in general and at this plant in particular. These deficiencies will be highlighted in the ensuing discussion.

## Unsafe Workplaces and Inadequate Training

In order to cut costs, employers rely on personal protective equipment rather than a safer work environment. At the plant under study, a significant reduction in dust levels was achieved through the use of airhoods, but they were not entirely effective in preventing exposure. The limitations of personal protective equipment were only made worse by the use of inappropriate or poorly maintained equipment and the lack of emphasis on training the workers. This is clearly an unsatisfactory approach. More attention needs to be paid to the work



Personal protective equipment makes work safer - but is it enough?

*Photo: IHRG*

environment, including ventilation systems and isolation of dusty processes.

Most workers are either not informed of the hazards of the substances they work with or the information provided to them is technical and poorly understood. Furthermore, the health and safety training provided for workers is inadequate in that it does not provide them with the necessary skills to monitor employers' compliance with health and safety measures.

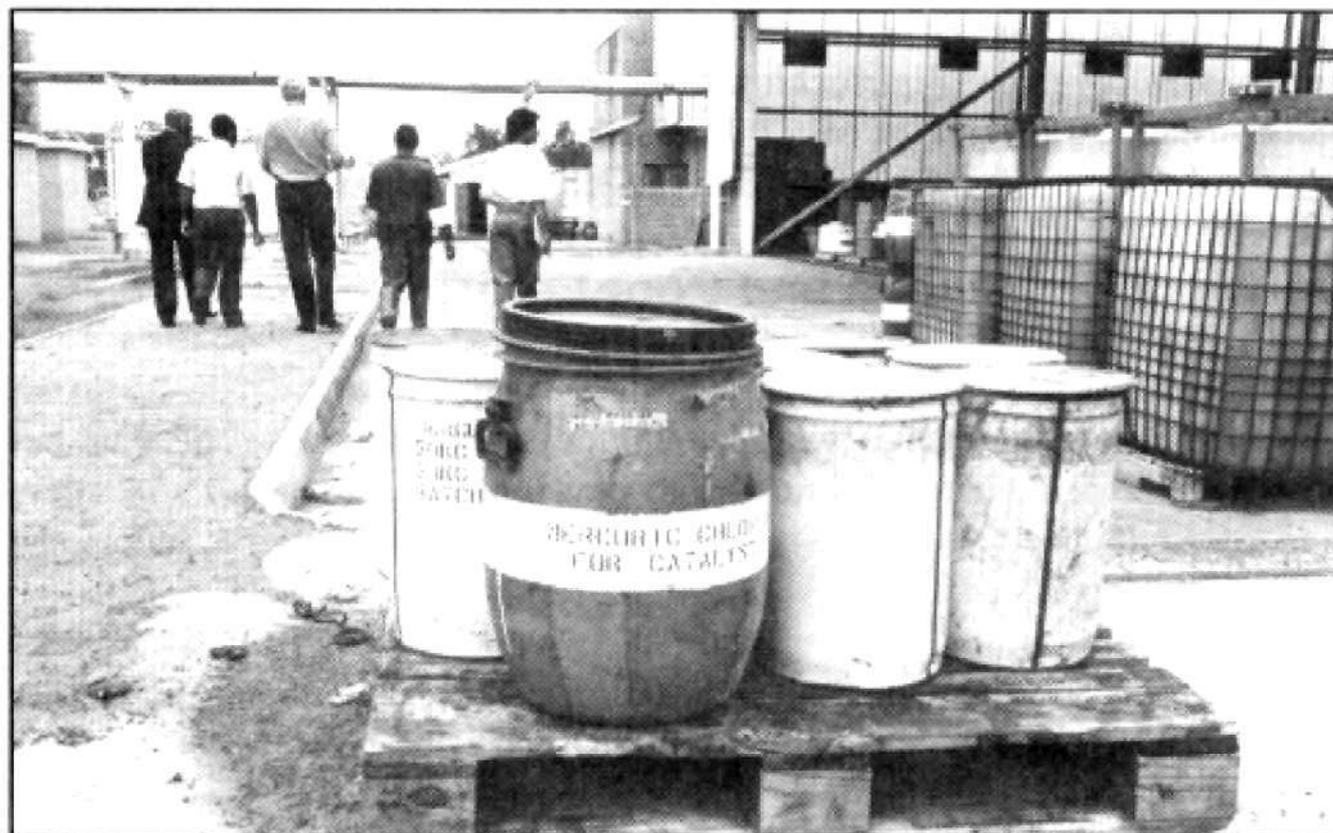
Employers usually use the issue of trade secrets as an excuse for not providing information. They only divulge such information if trade unions apply pressure and when crises develop. Trade unions argue that the right to know, the right to refuse dangerous work, and the right to appropriate health and safety training are some of the basic tenets of any health and safety programme at the workplace.

## Poor Medical Surveillance

The lack of appropriate medical surveillance programmes for workers involved in the production of toxic drugs is in stark contrast with the emphasis placed on monitoring the effects of these drugs on patients in clinical settings. In view of the fact that both chloramphenicol and azathioprine are toxic to the bone marrow and have the potential to cause cancer, there is a need for an ongoing surveillance programme at the Cape Town and similar plants. This should include monitoring workers as well as the work environment. Recommendations and protocols to this effect were submitted to the company upon completion of the study. It will, however, be necessary to evaluate whether the company is implementing effective preventive measures at a later date.

The lack of appropriate surveillance is compounded by the absence of reliable methods of monitoring exposure to drugs in the factory setting. The assessment of exposure is fraught with difficulties. Workers each have different exposure times to hazardous drugs at their workplaces, they may or may not have absorbed biologically active amounts of the drugs, they may also be exposed to other industrial pollutants and may be taking other drugs for therapeutic purposes.

More sensitive analytical methods need to be developed to evaluate workers' absorption of chemicals toxic to the bone marrow. Reliable data are essential to data collection. Accumulation of exposure data and adverse health effects over a lengthy period of time may provide opportunities for more detailed analysis of the risks associated with chronic exposure to these substances.



**Exposure to corrosion on floors at a mercury acetate plant - how is safety ensured? Photo: Rafs Mayet**

## **No Standards, Double Standards and Unethical Practice**

There are no workplace exposure standards for most pharmacologically active substances, including chloramphenicol and azathioprine. There is an urgent need to develop standard occupational exposure limits for the pharmaceutical industry worldwide. Many multinational companies have their own in-house standards in their factories in Europe or the United States, but they fail to apply the same standards in South Africa and other developing countries. In-house standards are themselves limited. While having a role in regulating exposure of workers to toxic substances, they are based on economic considerations and technical feasibility, rather than the prevention of adverse effects in healthy workers.

Medical surveillance programmes can encounter serious problems if occupational health personnel are insensitive to ethical issues in the workplace, such as obtaining informed consent prior to testing workers. Confidentiality is also of utmost importance, as it is not unusual for workers to be discriminated against on the basis of ill health. In the Cape Town workplace, confidential medical results were made available to the management by the company

doctor without obtaining prior consent from workers. The results were used in a discriminatory manner in blocking the promotion of workers with suboptimal blood results. Arguably, the only information employers are entitled to relates to the capacity of a worker to perform the job that he/she was employed for.

## **Deficient Legislation and Poor Enforcement**

From the above, it is clear that employers in the pharmaceutical industry do not adhere to acceptable occupational health and safety practices. The state has been party to allowing this situation to develop. Current health and safety legislation is biased towards the interests of employers and does not address the issue of occupational diseases resulting from pharmaceutical production. Employers are not obliged to monitor their workers for illnesses they may develop from exposure to pharmaceutical drugs. There are no sound guidelines for workers affected by occupational diseases on issues such as job security, compensation and rehabilitation.

In the current legislation there is a great reliance on self-regulation in occupational health and safety on employers. Furthermore, there is a lack of an efficient inspectorate responsible for enforcement of the legislation, and fines charged to employers contravening the law are very small. The lack of trade union participation in drawing up the current legislation is also evident.

In conclusion, for successful implementation of any health and safety programme at the workplace, the participation of all parties is essential. Employers need to provide a comprehensive service, appropriate to controlling the various hazards encountered in the pharmaceutical industry. The state needs to pass appropriate legislation, and to enforce acceptable workplace conditions more vigorously. Workers and their trade unions must push for internationally acceptable standards which are safe, monitor employers' adherence to laws intended to ensure the health and safety of all workers and challenging unsafe conditions wherever they may arise.

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