New drugs not always safe, adviser warns

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NEW medicines approved by the pharmaceutical regulator are not always entirely safe, the federal government's own adviser on medicine safety has warned.

Emily Banks, who chairs the government's advisory committee on the safety of medicines, has recommended a "black triangle" logo be placed on newly approved pharmaceuticals to alert the public that the drugs could cause unknown side-effects.

In a critique of Australia's regulatory system, Professor Banks says drug companies have little incentive to carry out ongoing safety studies after their products have been approved for public use by Australia's industry-funded regulator, the Therapeutic Goods Administration.

She also supports demands from the West Australian and Victorian health departments that the TGA give the public access to its secret database of 15,000 "adverse events" reported by doctors, patients and pharmaceutical companies in the past year.

Professor Banks's criticisms go to the heart of Australia's flu vaccine debacle last year, when a new and untrialled seasonal flu shot approved by the TGA caused febrile fits in young children and had to be withdrawn for the under-5s.

The US Food and Drug Administration issued a formal warning letter last week to CSL, the Australian manufacturer of the Fluvax vaccine, over its production methods and its in-house investigation into the Fluvax fits.

The TGA yesterday played down the FDA action, saying its own five audits of CSL's facilities in the past year had revealed "similar issues".

"Neither the TGA nor the FDA have identified manufacturing deficiencies that would warrant product recall or a change to the vaccine production process," the TGA said.

In her submission to the TGA's "public transparency" review, Professor Banks says that the TGA bases its registration of new products on only "limited" evidence.

Some side-effects become apparent only after a new drug has been on the market for some time, she says: "Evidence suggests that the community is largely unaware of the uncertainties surrounding drug safety post-regulation and works on the assumption that drugs, once registered by the TGA, are 'safe'."

"It is widely accepted by those involved in drug regulation, and in clinical practice, that preregistration drug trials are necessarily limited in size and narrow in terms of the population involved.

"This means that evidence about safety is limited at the point of registration and certain less common adverse events will only be detectable during the post-registration period."

Professor Banks, a prominent epidemiologist who has advised the World Health Organisation, recommends that the public be told which medicines are associated with "uncertainty or risk".

A black triangle could be placed on medicine packets and advertising material in a British-style scheme to alert doctors and patients that a drug is new or potentially risky.