

DAP MP protests unchecked powers in new medical Act
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KUALA LUMPUR, Oct 3 — The Dewan Rakyat today passed the Medical Device Authority Act, which grants absolute power to authorised enforcement officers to conduct raids and seizures over unregistered medical devices without producing a warrant.

The Act also stipulates the authorities will not be bound to pay damages or relief costs or be liable to court action for such seizures, unless a raid was conducted “without reasonable cause”.

During debate in Parliament today, Lim Lip Eng (DAP-Segambut) urged Putrajaya to withdraw and review provisions in the bill, arguing that it grants too much enforcement power to the Health Ministry and its agents.

“Section 57 gives blanket immunity to officials to raid or seize any medical devices. And no one can initiate any legal proceedings before any court,” he told the House.

The bill was tabled by Health Minister Datuk Seri Liow Tiong Lai for the second and third readings today, before being passed by majority vote.

Under the Act, “medical device” refers to “any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related material intended by the manufacturer to be used on human beings” for various purposes such as “diagnosis, prevention, monitoring, treatment or alleviation of disease” and other reasons.

The law compels all manufacturers, importers or distributors to register their medical devices with the newly formed Medical Advice Authority (MAA), following safety standards set by the Conformity Assessment Body, an independent regulatory agency formed under the Act.

Unregistered devices are also banned from being advertised and any person who violates this provision will be liable to a fine not exceeding RM3,000 or a maximum three-year jail term, or both.

Speaking to The Malaysian Insider later, Lim said he was not opposed to the requirement for all medical devices to be registered in order to meet safety standards.

“But the wide scope of powers granted to health officials could be open to abuse and the manufacturers or retailers are offered no protection,” he said.

He pointed out that any negligence by health officials would be overlooked as no court action could be initiated to question their decisions.

According to Section 48 of the Act, the health minister may, in writing, authorise any public servant to exercise enforcement powers.

Section 50 states that the authorised officer “shall have all or any of the powers of a police officer of whatever rank in relation to police investigations in seizable cases as provided for under the Criminal Procedure Code”.

While Section 51 stipulates the officer should obtain a search warrant from a Magistrate, Section 52 states the said officer could also conduct the raid without a warrant if he has reason to believe that any delay in obtaining the warrant could adversely affect the evidence.

The Act also allows any “aggrieved” persons to appeal to the minister, who has the power to confirm, reverse or vary the decision of the MAA.

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