

“Call for action” of the Israeli Ministry of Health: Marketing exclusivity to biological drugs

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BREAKING NEWS: The Israeli Ministry of Health is considering amending the Israeli law and possibly introducing marketing exclusivity to biological drugs registered in Israel; therefore, it has recently published a “call for action” inviting the public to take a stand.

On 31 July 2018, the Israeli Ministry of Health (MoH) published a “call for action”, inviting the public to participate in the process of examining the need to amend Section 47D of the Pharmacists’ Ordinance, so it will also cover the protection of confidential data submitted in connection with the registration of biological drugs.

Section 47D of the Pharmacists’ Ordinance already provides marketing exclusivity. However, the MoH took the position, in its letter, that the current regime applies to new chemical entities only.

As indicated in the MoH letter, a team has been assembled, which includes representatives from several government offices, that will conduct a regulatory impact analysis (RIA) procedure, all in accordance with a formal Government decision (no. 2118).

The public was requested to provide its written position in the matter at hand, by **September 16th, 2018 to the following email address:** regulation@moh.health.gov.il^[1]. Interested parties who wish, additionally, to orally present their position to the team, should indicate such in their submission, and will be invited to a meeting in due course.

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^[1] The subject line of the email should read: “RIA – Protection of Confidential Information in connection with the registration of biological drugs – consultation with the public”.

