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MSD

Transparency, Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

[redacted]

Dear Madam/Sir,

RE: Consultation: Whether the TGA should publish that a prescription medicine is under evaluation

MSD welcomes the opportunity to provide a submission to this important TGA consultation on transparency reforms, and strongly supports the TGA's commitment to increasing the transparency of regulatory processes.

MSD is an innovative biopharmaceutical company that has a wide range of medicines including patented branded medicines, non-branded generic medicines and biosimilar medicines. As a result we are in a good position to comment on the proposed changes.

As a member of Medicines Australia, MSD fully supports and endorses the position of this industry representative body, and would like to reinforce a number of Medicines Australia's positions as outlined below.

MSD supports changes to the current system to increase transparency, and therefore opposes *Option 1: maintain TGA's current publication arrangements*, as maintaining the status quo will not improve transparency, and will not meet community expectations regarding transparency of government agency processes.

MSD strongly supports *Option 2: list all applications accepted for evaluation*

- MSD is passionate about improving the health of Australians. Increased transparency will allow for greater patient and HCP (Healthcare Professional) awareness of medicines under evaluation.
- Increased transparency will also provide additional time for resolving intellectual property disputes.

MSD opposes *Option 3: list all applications at two different time points*, and *Option 4: list all applications of innovator medicines of highest public interest, but not generic or biosimilar medicines*

- These options would create an inequitable two-tier system.
- Transparency should not be applied selectively based on an assumption that innovator medicines are of greater public interest than generic/biosimilar medicines. There needs to be full transparency across all medicines so that patients and HCPs can be fully informed about the particular medicines that are of interest to them.

We look forward to working with the TGA to ensure that our regulatory system is fit for purpose and addresses community expectations regarding transparency.

Please do not hesitate to contact me should you have questions about any aspect of this submission.

Yours sincerely,

Anne-Maree Englund
Policy Manager
MSD Merck Sharp & Dohme (Australia) Pty Ltd