



National Contact Point

OECD Guidelines for Multinational Enterprises

Evaluation of the Final Statement of 11 April 2016

Bart Stapert, attorney vs. Mylan

27 September 2017

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Recommendations of the NCP (Final Statement)

The NCP recommends in its Final Statement an evaluation of the outcomes of the dialogue, to ensure that Mylan's products are being used properly and prevent use of medicine in lethal injections.

The NCP recommended the following in its Final Statement:

- It is important in this regard for Mylan to maintain a constructive dialogue on this issue with all relevant stakeholders, as it pledged to do in its statement of 30 September 2015.
- While the practical implications are understood, Mylan agreed that the implementation and monitoring of the distribution policy deserves Mylan's undivided attention.
- To this end, Mylan has continued its efforts to formalize restrictions on the distribution of products that could be used for lethal injections, and such arrangements are expected to be fully implemented with all remaining customers in February 2016.
- Mylan has further agreed to review periodically the distribution of such products in order to monitor compliance with the controls.
- The NCP is of the opinion that compliance in the distribution chain should be monitored both through Mylan's own sales data and through sales data requested from Mylan's customers.
- In line with industry best practise, Mylan is recommended to do after sales checks on a monthly or bimonthly basis.
- The NCP anticipates a positive outcome of the steps taken by Mylan in the distribution chain.

Evaluation 18 of July 2017

On 18 of July, both parties and the NCP evaluated the outcomes of the dialogue.

Mylan has given full attention to the implementation and monitoring of its distribution policy. The restrictions on the distribution of products that could be used for lethal injections are formalized in Mylan's distribution policy and are fully implemented with all the customers. Mylan has put in place a continuous monitoring process based in part on the sales data available to Mylan (i.e., chargeback data for indirect sales and SAP/ value track data of direct sales), which also includes a review of purchase orders for restricted products, to verify that sales are only made to eligible customers.

The NCP in its Final statement stressed the importance for Mylan to share the outcome of this matter and its due diligence steps with other companies in the sector.

Mylan has done so by updating Mylan's public statement that is on the Mylan corporate website. Mylan will consider including an expanded list of known execution drugs and a reference to active ingredients in its statement. Furthermore, Mylan is finalizing a formal, internal written policy that details the operational steps that have been (and will be) taken to implement and ensure compliance with its restricted-distribution program. It is advisable that Mylan engages with industry associations and at the wholesale level.

The parties concluded that the landscape of the pharmaceutical sector changes all the time. New developments, product innovations and market approvals of new medicines, make it necessary for pharmaceutical companies to be alert to prevent use of their finished products or active ingredients in lethal injections.

Mylan is aware of this constantly changing landscape and has taken steps to respond to it.

On this basis, when the risk arose that Mylan's etomidate, midazolam and atracurium besylate products could be diverted for use in executions, Mylan decided proactively to add these drugs to its list of products under restricted distribution. Mylan checks all new market approvals to assess whether additional products should be included in the distribution policy.

Mylan has also been in direct contact with/sent letters to US State officials in a couple of states reminding them or informing them of Mylan's position and the controls in place concerning the use of their products. It is recommended that Mylan write to officials in all executing states informing them of the company's position on the misuse of medicines and the controls that are in place to prevent this.

Pharmaceutical companies such as Mylan should remain vigilant in this changing landscape. Where companies become aware of developments that could undermine their controls, proactive steps should be taken to address the issue.

For example, in the face of increased efforts by states to shield where and how they have procured medicines for executions, companies should adopt a clear and unequivocal position opposing such secrecy and take active steps to ensure their contracts and position are respected.

Looking back, the Parties conclude this dialogue facilitated by the NCP has been a productive process, with tangible benefits for both parties. Parties agree to maintain a constructive dialogue, as the NCP recommended. The NCP appreciates the open and constructive attitude of Mylan in this case.

The NCP urges pharmaceutical companies to be alert in this changing landscape, take new steps if necessary and check on a regular basis if controls put in place are really working.

The role of National Contact Points (NCPs) is to further the effectiveness of the OECD Guidelines. The Dutch government has chosen to establish an independent NCP which is responsible for its own procedures and decision making, in accordance with the Procedural Guidelines section of the Guidelines. In line with this, the Netherlands NCP consists of four independent members, supported by four advisory government officials from the most relevant ministries. The NCP Secretariat is hosted by the Ministry of Foreign Affairs. The Minister for Foreign Trade and Development Cooperation is politically responsible for the functioning of the Dutch NCP.

More information on the OECD Guidelines and the NCP can be found on www.oecdguidelines.nl

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