



National Contact Point

OECD Guidelines for Multinational Enterprises

Initial Assessment

Specific instance Mr. Bart Stapert, attorney - Mylan

17 July 2015

ArgentinaAustraliaAustriaBelgiumBrazilCanadaChileColombiaCzechRepublicDenmarkEgyptEstoniaFinlandFranceGermanyGreeceHungaryIcelandIrelandIsraelItalyJapan

Notification to the Dutch National Contact Point of Mr. Bart Stapert, attorney, concerning an alleged violation of the OECD Guidelines for Multinational Enterprises by Mylan (3 March 2015).

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- the issues raised by Mr. Stapert are material and prima vista substantiated;
- there seems to be a link between Mylan's activities and the issues raised in the specific instance;
- the consideration of this specific instance may contribute to the Guidelines' objectives and effectiveness.

Executive summary

On 3 March 2015 Bart Stapert notified a specific instance with the Dutch National Contact Point with regard to an alleged violation of the OECD Guidelines for Multinational Enterprises (hereafter: the Guidelines) by Mylan.

As part of the initial assessment of the specific instance, the NCP had separate, confidential meetings with both the party raising the issue and the business involved concerning the specific instance and related considerations.

The Dutch NCP concludes that part of the notification merits further consideration based on the following criteria:

- the notifying party is a concerned party with a legitimate interest in the issues raised in the notification;
- Mylan is a multinational enterprise in the sense of the Guidelines;

The decision to further examine part of this specific instance does not entail substantive research or fact finding, nor does it entail a judgment on whether or not Mylan has violated the Guidelines.

In this initial assessment, the NCP explains its decision to offer parties 'its good offices' to come to a solution through dialogue. With reference to the Dutch NCP Specific Instance Procedure for handling notifications¹ in the appendix.

In conformity with the Dutch NCP's procedure, the draft initial assessment has been sent to the parties involved, inviting them to respond to the assessment in writing within a two weeks' notice, after which the initial assessment has been finalized, taking into account the parties' comments. This initial assessment was subsequently published on the NCP's website:

www.oecdguidelines.nl.

¹ <http://www.oecdguidelines.nl/notifications/documents/publication/2015/3/5/specific-instance-procedure-ncp-v-15-3>

Summary of the notification

On 3 March 2015 the Dutch NCP received a notification of Mr. Stapert, attorney against Mylan. In this initial assessment the NCP will not express an opinion on the correctness of the statements of Mr. Stapert.

In the notification Mr. Stapert stated that “Mylan manufactures a medicine called rocuronium bromide. Rocuronium bromide has recently been adopted into the lethal injection execution protocols of a number of U.S. States and was used in an execution in Oklahoma in January of this year. In contrast to all other American and European manufacturers of FDA-approved medicines which have the potential for misuse in executions, Mylan has refused to take any meaningful action to prevent the sale of its medicine to US prisons for use in lethal injections. Mylan has failed to assess the impact of its inaction on this issue, to acknowledge its involvement, to develop a (public or internal) policy on the issue or to engage in a meaningful way with its stakeholders or interested parties. This puts Mylan in a breach of a number of requirements set out in Chapters II and IV of the OECD Guidelines for Multinational Enterprises (the Guidelines).”

The notification specifically concerned the alleged non-observance of OECD Guidelines under the section on General Policies (Chapter II) and the commentary on Human Rights (Chapter IV).

In the notification of the specific instance under the OECD Guidelines for Multinational Enterprises, Mr. Stapert stated the following:

“Mylan’s failure to restrict the sale of its products to US prisons risks enabling the executions of prisoners using rocuronium bromide, in violation of their right to life and, potentially, their right not to be subjected to cruel, inhuman and degrading treatment.”

“Mylan is in breach of Chapter II, paragraph A2 and of Chapter IV, paragraph 1, by virtue of its failure to “respect human rights” as defined under Dutch, European and International law – specifically through its failure to take simple steps to prevent its medicines from being sold and used in executions which violate the right to life of prisoners in the USA.”

“Mylan is in breach of Chapter II, paragraph A11, and of Chapter IV, paragraph 2, by failing to “avoid contributing to an adverse human rights impact”- specifically the execution of prisoners in experimental and potentially torturous executions by lethal injection.”

“Mylan is in breach of Chapter II, paragraph A12, and of Chapter IV, paragraph 3, as a result of its refusal to “seek ways to prevent or mitigate the human rights impacts “of its medicines being sold to prisons for use in executions. Unlike other manufacturers of potential execution drugs, Mylan has declined to introduce industry standard supply chain controls restricting the sale of its medicines to execution chambers.”

“Mylan is in breach of Chapter II, paragraph A10, and of Chapter IV, paragraph 5, in respect of its failure to carry out effective due diligence processes (appropriate to its size as a \$20.9bn multinational enterprise and in line with the actions of other similarly sized companies) to assess whether

Mylan medicines might be purchased by prisons for use in the execution of prisoners by lethal injection; or indeed if Mylan medicines have already been used in such procedures.”

“Mylan is in breach of Chapter II, paragraph A13, b virtue of its failure to encourage the direct and third party distributors of its medicines to “apply principles of responsible business conduct compatible with the Guidelines”, and specifically to refrain from selling its medicines on to prisons for use in executions.”

“Mylan is in breach of Chapter II, paragraph B2, as a result of its refusal to “engage in or support...private or multi-stakeholder initiatives and social dialogue on responsible supply chain management”, demonstrated by its failure to substantively respond to outreach on this issue from numerous investors and civil society groups.”

“Mylan is in breach of Chapter IV paragraph 4 as a result of its refusal to “have a policy commitment to respect human rights”, and specifically one which reflects that the company has considered the human rights of prisoners who may be executed using its medicines.”

“The complainant submits that Mylan should:

1. Follow the vast majority of its competitors and acknowledge the risk that without distribution controls in place its medicines may be purchased by US prisons and used to execute prisoners;
2. Actively and seriously investigate what distribution controls it may impose to prevent the sale of its medicines to prisons for use in executions while maintaining access for legitimate medical users (where appropriate consulting third party experts and peer companies which have already done so successfully);
3. Take swift action to implement comprehensive distribution controls to prevent Mylan medicines from being purchased for use in lethal injection executions;
4. Take active steps to try to prevent the use of any Mylan medicines which may already have been being sold to prisons in executions;
5. Publish a policy statement confirming Mylan’s commitment to human rights, in particular in relation to the human rights abuses associated with the use of medicines in lethal injection executions.”

Summary of the initial response of Mylan

On 21 April 2015 the Dutch NCP received an initial response of Mylan on the notification of Mr. Stapert. In this initial assessment the NCP will not express an opinion on the correctness of response of Mylan:

About Mylan

“Mylan distribute its products through legally compliant channels, intended for prescription by healthcare providers consistent with the approved labelling or applicable standard(s) of medical care.”

About rocuronium bromide

"In the U.S. rocuronium bromide is approved by the U.S. Food and Drug Administration as an adjunct in general anaesthesia for surgical procedures (...)"

Production of rocuronium bromide for Mylan and distribution in the U.S.

"Mylan's rocuronium bromide product is a generic version of Zemuron®. Rocuronium bromide is manufactured, labelled and packed exclusively for Mylan by a third party in India."

"Batches of rocuronium bromide are shipped directly from the facilities of the manufacturer in India to Mylan's subsidiary in the U.S."

"Rocuronium bromide is not manufactured by Mylan or at Mylan's order in the Netherlands, nor anywhere else in the EU, and there are no EU based Mylan-group entities that provide "technical assistance" (as defined in Section 2(f) of EC 1236/2005) in connection with the manufacturing, labelling, packaging or distribution of rocuronium bromide."

"Rocuronium bromide is only distributed in the U.S. to wholesale customers and hospitals in the U.S. via Mylan's U.S. subsidiary for use consistent with approved labelling and applicable medical standards of care. The distribution channel for pharmaceuticals is monitored by the U.S. Drug Enforcement Administration and state authorities for diversion. Mylan has never delivered, marketed, or distributed rocuronium bromide for use in lethal injections, nor has Mylan ever received or filled an order from any prison or any other entity for the use of rocuronium bromide in connection with a lethal injection."

No jurisdiction of the Netherlands NCP

"According to the Stapert Complaint, Stapert Advocaten complain about an alleged breach of the Chapters II and IV of the OECD Guidelines. All aspects of the Stapert Complaint are inextricably linked to the factual allegation that rocuronium bromide produced by or at the order of Mylan is distributed for the use as a component in lethal injections in the U.S. by a separate U.S. legal entity. More specifically, Stapert Advocaten complain about a failure to investigate the distribution chain in the U.S. and to put distribution controls in place, which would help mitigate or prevent the use of rocuronium bromide as a component of lethal injections in the U.S. Although Mylan contests these allegations, it is indisputable that all circumstances leading to the complaint occurred in the U.S. Hence, it is respectfully submitted that under the guidelines, the U.S. NCP is the proper jurisdiction to hear this specific instance."

Demanded measures are beyond Mylan's control

"In short, the Stapert Complaint calls for Mylan to investigate and implement "distribution controls" to prevent the sale of rocuronium bromide to U.S. prisons. Contrary to what Stapert Advocaten contend (...), distribution controls which prevent "Mylan medicines from being purchased for use in lethal injections executions" are not available. Moreover, even if such measures were available to Mylan, they would be futile, as several other companies sell the same product in the U.S. (...). Moreover, the Stapert Complaint seems to assume that rocuronium bromide produced by or at the order of Mylan was or will be used in lethal injections in prisons, but there is no evidence for this."

Mylan will not be drawn into an ethical and public policy debate

"Capital punishment, limited to capital offenses, is legal in certain states of the U.S. (...). Capital punishment per se is not a violation of the OECD Guidelines. This is evident from the fact that the U.S. is an OECD member state, as well is Japan. For that reason alone, it is difficult to see how the mere fact that a multinational does not seek to prevent the potential diversion of rocuronium bromide for capital punishment is a violation of the OECD Guidelines. It isn't."

"Obviously, capital punishment is a highly debated social and moral issue. However, it is beyond the powers and the responsibility of multinational enterprises such as Mylan to side with those who advocate or oppose the capital punishment in the United States. This is not an appropriate commercial practices debate, but rather a political question."

"In short, Mylan understands that the Stapert Complaint seeks to further a seriously held moral and political belief but asserts that a complaint against Mylan with the NCP is not a proper means to achieve this goal."

Initial assessment

In accordance with the OECD Guidelines and the Dutch NCP Specific Instance Procedure, the Dutch NCP concludes that, in light of the following considerations, the notification merits further examination:

Is the Dutch NCP the right entity to assess the alleged violation?

In principle a notification should be filed at the NCP of the country where the alleged problems, caused by the company, are occurring. Therefore the Dutch NCP has consulted the US NCP on this specific instance in regards to which NCP should handle the case and it was agreed that the Dutch NCP will assess the alleged violations [handle this specific instance]. The goal of the notification aims to affect change at the highest corporate entity; the Dutch entity Mylan N.V.

What is the identity of the reporting party and its interest in the case?

Mr. Bart Stapert has a longstanding experience as an attorney in the representation of defendants in complex criminal cases in the Netherlands and the United States. He is known as an expert in the defense of capital cases, recognized as such by the Ministry of Foreign Affairs of the Netherlands. In 1996, he was a witness to the execution of Ronald Lee Hoke in the Commonwealth of Virginia, United States. This execution took place by lethal injection.

Is Mylan N.V. a multinational enterprise according to the Guidelines?

Mylan is a multinational enterprise according to the Guidelines. Mylan N.V. is a publicly traded company on the NASDAQ Global Select Market and incorporated under the laws of the Netherlands. The business and affairs of Mylan N.V. are managed and controlled under the oversight of the company's board of directors in the United Kingdom, where the board generally meets. The Chief Executive Officer and other executive officers

carry out the day-to-day conduct of the Company's business at the Company's principal offices in Canonsburg, Pennsylvania.²

Are the issues raised by Bart Stapert material and substantiated?

The issues raised are **prima vista** material and substantiated by documents and the notification refers to relevant provisions of the Guidelines. The notification concerns the alleged non-observance of OECD Guidelines Chapter II, paragraph A.2, A.10-13, B.2 and Chapter IV, commentary 1-5.

Does there seem to be a link between Mylan's activities and the issues raised in the specific instance?

There seems to be a link between Mylan's activities and the issues raised in the specific instance. Rocuronium bromide, a product used in general anesthesia, is manufactured for Mylan by a third party in India and distributed to wholesale customers and hospitals in the U.S. via Mylan's U.S. subsidiary. This product is intended for use consistent with approved labeling and applicable medical standards of care. Rocuronium bromide is not approved for, labeled for, or marketed for use in legal injections. Mylan states it does not distribute this product to prisons, nor is the company aware of its product being distributed by any third party for use in lethal injection or for any other use outside of the approved labeling.³

The notification concerns Mylan's responsibility to prevent or mitigate alleged adverse human rights impacts.

What is the relevance of applicable legislation and procedures, including court rulings?

Rocuronium bromide has recently been adopted into the lethal injection execution protocols of a number of US States and was used in an execution in Oklahoma in January 2015. The Oklahoma protocol (which includes rocuronium bromide) has now been taken up by the United States Supreme Court.⁴ The death penalty is prohibited under Dutch and European law (Dutch Constitution, European Convention on Human Rights and the Charter of Fundamental Rights).⁵

Would the consideration of this specific problem contribute to Guideline objectives and effectiveness?

The Netherlands NCP believes that dealing with this notification will contribute to the purpose and effectiveness of the Guidelines in the sense that it will help clarify the due diligence recommendations for the pharmaceutical sector in relation to the possible human rights abuses associated with the use of medicines in lethal injection executions.

² <http://www.mylan.com/en/company/leadership>

³ <http://www.mylan.com/news/press-releases/item?id=123295>

⁴ http://www.supremecourt.gov/opinions/14pdf/14-7955_aplc.pdf

⁵ <http://www.government.nl/issues/constitution/documents-and-publications/regulations/2012/10/18/the-constitution-of-the-kingdom-of-the-netherlands-2008.html>, <http://conventions.coe.int/Treaty/en/Treaties/Html/114.htm>

Conclusion

The NCP is of the opinion that this specific instance merits further consideration and will therefore, in accordance with the Netherlands NCP specific instance procedure, offer its good offices to facilitate a dialogue between the parties. The objective is to bring parties to agreement on the non-primary functional use of medicine in general and rocuronium bromide in particular, in capital punishment.

In the opinion of the NCP this may help clarify the OECD due diligence recommendations for the pharmaceutical sector in relation to the possible human rights abuses associated with the use of medicines in lethal injections.

Both parties accepted the NCP offer to engage in mediation. In accordance with the NCP procedure, mediation or further examination will be confidential while in progress. The NCP will complete the procedure by issuing a final statement on the results of the procedure. The final statement will be published on the website of the NCP.

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