



National Contact Point

OECD Guidelines for Multinational Enterprises

Final Statement

Bart Stapert, attorney vs. Mylan

11 April, 2016

ArgentinaAustraliaAustriaBelgiumBrazilCanadaChileColombiaCzechRepublicDenmarkEgyptEstoniaFinlandFranceGermanyGreeceHungaryIcelandIrelandIsraelItalyJapan

Final statement by the Dutch National Contact Point (NCP) for the OECD Guidelines for Multinational Enterprises (the Guidelines) further to a specific instance submitted by Bart Stapert concerning an alleged breach of the Guidelines by Mylan.

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1. Introduction

This final statement describes the process and outcomes of the dialogue facilitated by the NCP after receipt of notification regarding the specific instance from Bart Stapert on 3 March 2015.

The statement is based on the information from the parties and the outcomes of the dialogue. Confidential information disclosed to the NCP in the course of the dialogue was not used in the preparation of this final statement.

This final statement marks the completion of the procedure by the NCP.

2. The NCP procedure

The Dutch NCP procedure in this specific instance

On 3 March 2015, the NCP received notification of a specific instance from Bart Stapert concerning an alleged breach of the Guidelines by Mylan. On 9 March 2015, the NCP acknowledged receipt of this notification and forwarded it to Mylan.

In April 2015, the NCP held separate meetings with Bart Stapert and Mylan about the procedure for consideration of the specific instance.

In June 2015, the NCP sent the parties a draft version of the initial assessment, requesting that they submit any comments within two weeks. In its initial assessment, the NCP concluded that at least part of this specific instance merits further consideration and offered its good offices to resolve the issue at hand by facilitating a dialogue between the parties.

Both parties accepted the NCP's offer and made agreements concerning confidentiality and transparency in line with the NCP procedure.

On 17 July, the NCP published its initial assessment on the website <http://www.oecdguidelines.nl/notifications/documents/publication/2015/07/17/initial-assessment-stapert-mylan>.

In November 2015, the NCP convened the first joint meeting of both parties to discuss the specific instance. A second meeting was held in February 2016. As a result of these meetings, the NCP and the parties agreed to wind up the mediation process and draft a final statement, given the steps agreed to and taken by Mylan.

Details of the parties submitting the specific instance

Mr Bart Stapert¹ has long-standing 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 defence of capital cases and recognised as such by the Dutch Ministry of Foreign Affairs. In 1996, he was a witness to the execution by lethal injection of Ronald Lee Hoke in the Commonwealth of Virginia, United States.

Details of the enterprise

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 operations 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

3. The NCP's assessment of the specific instance

Scope of the assessment

In its initial assessment of 17 July 2015, the NCP concluded that part of this specific instance merited further consideration. In accordance with the NCP specific instance procedure, the NCP therefore offered its good offices to assist the parties in reaching agreement on the non-primary functional use of medicine in general and rocuronium bromide in particular in capital punishment. The NCP was of the opinion that doing so could 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's offer to engage in a dialogue.

Applicability of the Guidelines to the pharmaceutical sector

The 2011 update of the Guidelines confirmed that they apply to all sectors. The Guidelines do not provide more detailed guidance on their application to any specific sector, but they do state that enterprises should:

'seek to prevent or mitigate an adverse impact where they have not contributed to that impact, when the impact is nevertheless directly linked to their operations, products or services by a business relationship.'

¹ <http://www.stapertlaw.com/nl/>.

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

Relevant OECD Guidelines for Multinational Enterprises

The chapters on General Policies (Chapter II) and Human Rights (Chapter IV) of the Guidelines are relevant to this dialogue.

The use of medicines in lethal injections

Lethal injection is the primary method of execution in all 31 US states which have the death penalty. Approximately 1,402 lethal injections have been carried out since 1976. Most executions by lethal injection are carried out using commercially manufactured medicines. These medicines were designed to improve and save the lives of patients, not to end the lives of prisoners. Manufacturers have objected to the misuse of these medicines in executions. In addition to making public statements opposing the use of medicines in executions, a large number of manufacturers have taken concrete action in recent years to try to end this misuse, including establishing comprehensive distribution controls to prevent sales of their medicines to prisons for use in executions. In the past few years, there has also been a series of changes in execution protocols across US states, in part in response to the effective action taken by manufacturers to prevent the use of their medicines in lethal injections. A number of states have adopted experimental new protocols using untested combinations of medicines. The result has been a series of high profile 'botched' executions.

In a number of states rocuronium bromide was added to their lethal injection execution protocols. It was used in an execution in Oklahoma in January 2015.

The position of the pharmaceutical sector on the use of medicines in lethal injections

In October 2014 Mylan released the following public statement on the issue:

'Mylan is committed to setting new standards in healthcare and providing access to affordable medicines for the world's 7 billion people. We are dedicated to upholding the highest standards of quality and integrity in everything we do. Mylan only distributes its products through legally compliant channels. All of its products are intended for prescription by healthcare providers consistent with approved labeling and applicable medical standards of care.'

By that time, all other US, Indian and European manufacturers of FDA-approved medicines that could potentially be misused in executions had been taking action to prevent the sale of their medicines to US prisons for use in lethal injections.

Bart Stapert's objections to Mylan's initial position on the use of medicines in lethal injections

In his notification of the specific instance, Bart Stapert argues that the statement cited above does not address the human rights implications of the sale of its medicines to prisons for use in lethal injection executions in the US. He states that while judicial executions in the US are not illegal, this does not mean it is appropriate for a multinational pharmaceutical company

dedicated to health care to willingly allow its medicines to be sold to prisons for use in what may be torturous executions, particularly when there are simple steps the company could take to prevent this from happening and the company is headquartered in a European state that categorically opposes the death penalty.

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 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.'

4. The NCP's good offices

The course of the dialogue

Both parties accepted the NCP's offer to engage in mediation. A joint meeting was scheduled for the beginning of November 2015. The purpose of the meeting was for the parties to start a dialogue facilitated by the NCP aimed at resolving the issue at hand.

The NCP's observations

The NCP appreciated Mylan's willingness to enter into dialogue with the objective of reaching agreement on the non-primary functional use of medicine in general and rocuronium bromide in particular in capital punishment.

In the run-up to the notification of the specific instance and the dialogue between the parties several events took place.

Parliamentary questions

In March, April and August 2015, members of the Dutch parliament posed questions to Minister for Foreign Trade and Development Cooperation Lillianne Ploumen about the possible supply of rocuronium bromide produced by Mylan to US prisons for use in executions.

The minister responded that the Ministry of Foreign Affairs had discussed this issue several times with Mylan itself, and with investor APG, human rights NGO Reprieve and the Dutch attorney Bart Stapert.

The ministry addressed the following matters with a delegation from Mylan on 18 August:

- As a Dutch company, Mylan has a duty to comply with Dutch CSR policy. This means, among other things, that the company is obliged to avoid involvement in human rights violations anywhere in the world. The Netherlands considers the death penalty to be a serious human rights violation.
- For this reason Mylan is advised to make contractual agreements with its distributors to limit the risk of its products being used in executions.
- The ministry shared with Mylan documentation provided by Reprieve showing that prisons in the US state of Virginia have medicines produced by Mylan in their possession.

On 30 August, Mylan issued a statement about the latter issue.

The government has indicated that it expects Mylan to take additional proactive steps to exercise corporate social responsibility and to stay in communication with the Ministry of Foreign Affairs on this matter.

Shareholders

Several investors have entered into dialogue with Mylan to persuade the company to ensure that its products are not used to carry out lethal injection executions.

On 28 August 2015 ABP, the pension fund for the government and education sectors, announced that it had sold all its shares in Mylan and no longer wished to invest in the company because its products could be used to carry out death sentences in the United States. ABP had been in talks with Mylan since October 2014 about the use of muscle relaxants in executions in US prisons. Because its requests that Mylan alter its distribution systems met with an inadequate response, ABP decided to sell its shares in the company.

At the end of August, other shareholders, such as ROBECO, PGGM-Pensioenfondos Zorg & Welzijn and NNGroup N.V., indicated their intention to continue the dialogue. They issued the following responses to ABP's withdrawal from Mylan in an article posted by *Nieuwsuur*:

ROBECO

'... Robeco is of the opinion that more can be achieved through dialogue than by ruling out investments. This is why Robeco regards excluding investments to be a last resort that should be used only when all other forms of active shareholding have not led to the desired result.'

NNGroup N.V.

'We have continued our dialogue with Mylan. Since some of our questions have not yet been answered, prior to the shareholders meeting we addressed our questions to the board as well. (...)'

PGGM/Pensioenfonds Zorg & Welzijn

'... We have offered to assist the company in drafting protocols aimed at preventing its products from being used to carry out the death penalty. Although Mylan products have to date not been used for executions, Pensioenfonds Zorg en Welzijn would like Mylan to incorporate this into its terms and conditions of delivery and use.'

'...We urged the company to do everything in its power to prevent its products being used to carry out executions in Virginia... We have also called upon Mylan to enter into discussion on this matter with the authorities in Virginia. (...)'

Mylan's statement on use of rocuronium bromide in lethal injections³

On 30 September 2015, Mylan published the following statement on the use of rocuronium bromide in lethal injections:

'Mylan is committed to setting new standards in healthcare and providing access to more affordable medicines for the world's 7 billion people. We are dedicated to upholding the highest standards of quality and integrity in everything we do.'

'Mylan only distributes its products through legally compliant channels. All of its products are intended for prescription by healthcare providers consistent with approved labeling and applicable medical standards of care.'

'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.'

'As with any Mylan product, this product only is intended for use consistent with approved labeling and applicable medical standards of care.'

'It is important to note that rocuronium bromide is not approved for, labeled for, or marketed for use in lethal injections. Mylan does not distribute this product to prisons, nor does the company condone its product being distributed by any third party for use outside of the approved labeling or applicable standards of care.'

'Recently Mylan received information indicating that a department of corrections in the U.S. purchased Mylan's rocuronium bromide product from a wholesaler for possible use outside of the labeling or applicable standard of care. Mylan takes very seriously the possibility its product may have been diverted for a use that is inconsistent with its approved labeling or

applicable standards of care. As such, Mylan conducted its own investigation into the matter and took direct action by sending several letters to the department of corrections seeking prompt assurances that it has not purchased any Mylan product for use outside the bounds of its approved therapeutic purpose, approved labeling and applicable standards of care. When Mylan received no response to its inquiries and therefore was unable to ensure appropriate use of its product, Mylan took further action by demanding the return of the Mylan product.'

'Mylan has taken steps to prevent similar future issues. Specifically, Mylan is contractually restricting its distributors from distributing Mylan products, including rocuronium bromide, for use in lethal injection or for any other use outside of the approved labeling or applicable standards of care.'

'Mylan takes this matter seriously and will continue to work with distributors and other interested parties to ensure that its products are used appropriately.'

The outcomes of the dialogue

The goal and scope of the dialogue were:

- to resolve the issue at hand by means of a dialogue between the parties facilitated by the NCP;
- to bring parties to agreement on the non-primary functional use of medicine in general and rocuronium bromide in particular in capital punishment.
- to 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.
- In the joint meeting of the parties, Bart Stapert warned that the success of Mylan's efforts to prevent the use of rocuronium bromide in executions would depend on the company's swift and effective implementation of the distribution restrictions announced in its public statement. Mr Stapert also highlighted the need for specific detail to be provided on the exact nature of the controls proposed by Mylan, and for the company to commit to regular monitoring and auditing of the system to ensure its efficacy.

The parties agreed to continue a constructive dialogue on this matter. As Mylan indicated in its statement, the company takes the matter seriously and will continue working with distributors and other interested parties to ensure that its products are used properly all over the world.

Mylan's rocuronium bromide was used in the execution of Alfredo Prieto on September 30 2015. Further supplies of Mylan medicines were sold to Virginia Department of Corrections in October 2015. However, since this time, Mylan has taken active steps to prevent the rocuronium bromide that might be in the

³ <http://newsroom.mylan.com/index.php?s=2429&item=123361>

possession of a department of corrections from being used for purposes that are inconsistent with its approved labeling or applicable standards of care and to tighten up its control systems so that further sales of Mylan medicines are not sold to US prisons for use in executions. The NCP has made some recommendations in addition to the due diligence recommendations in the Guidelines.

Recommendations of the NCP

The OECD Guidelines

The NCP observes that all Dutch companies that conduct business abroad are expected to comply with the OECD Guidelines. The Dutch government also regards the Guidelines as the normative framework for responsible business conduct in the international context. In accordance with previous recommendations, the NCP would point out that enterprises should address any adverse impacts on matters covered by the Guidelines, even where they have not directly contributed to those impacts, if the impacts are nevertheless linked to their operations, products or services by a business relationship. The NCP is of the opinion that distributors and purchasers of, in this case, medicines distributed or purchased for purposes that are inconsistent with approved labelling and applicable medical standards of care fall under a business relationship. It can be concluded that the Guidelines are applicable to both the supply chain and the distribution chain.

The NCP encourages Dutch companies to incorporate the Guidelines into their policy and annual reports.

Multi-stakeholder approach

In the NCP's view, a multi-stakeholder approach like the one to which Mylan subscribes in its statement fosters the wider application of due diligence in a sector. The NCP urges pharmaceutical companies to work with distributors, human rights organisations and others to prevent rocuronium bromide and other medicines being used in lethal injections. It is important for Mylan to share the outcome of this matter and its due diligence steps with other companies in the sector.

Shareholders

The NCP is pleased to observe that in this matter various shareholders have applied the OECD Guidelines and used their influence as investors and their investment policy to counter adverse impacts. It is encouraging to see shareholders exercising their influence to hold companies accountable for responsible business conduct. In this case, dialogue as well as disengagement by some appear to have contributed to improvements in Mylan's conduct.

Monitoring

The NCP recommends that in March 2017 an evaluation be conducted of the outcomes of the dialogue, to ensure that Mylan's products are being used properly and prevent use of medicine in lethal injections. 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 soon expected to be fully implemented with all remaining customers. Mylan has further agreed to periodically review 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. The evaluation will be published on the NCP's website.

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

Published by:
National Contact Point OECD Guidelines for
Multinational Enterprises

Ministry of Foreign Affairs
P.O. Box 20061 | 2500 EB The Hague | The Netherlands
www.oecdguidelines.nl
© Ministry of Foreign Affairs | April 2016