To the Speaker of the Lower House of the States General
P. O. Box 20018
2500 EA The Hague

September, 6, 2009

Subject: Undertakings made on 23 June 2009 concerning the interception and seizure of consignments of pharmaceutical products by Dutch customs.

Dear Mr Speaker,

On 23 June 2009, questions from Member Vendrik prompted a discussion about the interception and seizure by Dutch customs of pharmaceutical products ('medicines') destined for developing countries. In this letter, I wish to return to the four undertakings I made on this occasion, *viz*:

1. to prepare and submit a report of the discussions with the European Commission and the Indian and Brazilian ambassadors to the European Union, and to do so before the end of the summer recess;
2. to prepare and submit an account of the seventeen instances of consignments which were intercepted by Dutch customs in 2008 (with details of the companies concerned);
3. to ascertain whether German customs has indeed published a list of those companies which have submitted an application under Article 5 of Council Regulation (EC) No. 1383/2003 and, if so, whether a similar approach can be adopted in the Netherlands;
4. to provide further information about the ongoing ACTA discussions.

Before addressing these points, I wish to offer a brief summary of the current situation. In doing so, it is appropriate to refer you to the responses which I gave to the questions raised by Members Irrgang and Bashir, concerning the interception of pharmaceutical products bound for Africa[1]. On this occasion, I was also speaking on behalf of the Minister for Development Cooperation and the State Secretary of Finance.

In 2008, Dutch customs intercepted seventeen consignments of medicines (or the raw materials used to manufacture such products) further to the 'MEDI-FAKE' operation. This was a large-scale campaign coordinated at European level, intended to step up the customs control of counterfeit medicines entering the European Union. The operation resulted in the interception of more than 34 million counterfeit pills and tablets. All 17 consignments were 'in transit', i.e. bound for a final destination outside the EU itself.

The Dutch customs department acted in accordance with extant EU legislation, and in particular Council Regulation (EC) No. 1383/2003. This regulation stipulates that the holders of intellectual property rights, such as patents or registered trademarks are entitled to request customs officials to take action in the event of a possible infringement of those rights, should counterfeit products be discovered during the inspection of goods entering, leaving or in transit through an EU country. Where customs intercepts goods further to such a request, the holders of the intellectual property rights are informed accordingly. Should the rightsholder believe that there has indeed been an infringement of its rights, it is required (under the Regulation cited) to contact the owner of the consignment and to take legal action in the civil courts or reach some other form of settlement. In five of the seventeen cases recorded in 2008, there was some dispute regarding the legitimacy of interception itself, or in the case of (raw materials for) generic medicines in transit to developing countries, whether there could be reasonable grounds to claim an infringement of intellectual property rights.

All but one of the 17 intercepted consignments have since been released. The exception remains impounded because the consignor and the patent-holder have been unable to reach a settlement.

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1 Appendix, Proceedings of the Lower House 2008–2009, no. 2412.

It may be added that customs officials at Schiphol Airport recently intercepted and detained two consignments of medicines further to a suspected infringement of intellectual property rights. Both originated in Pakistan and were destined for Nigeria. The holder of the intellectual property rights, in this case a registered brand name, decided not to take further action whereupon the consignments were released and allowed to proceed.

1. Report of discussions with the European Commission and the Indian and Brazilian ambassadors to the EU

As I stressed during the session of 23 June, it is undesirable to impede the transport of generic medicines to developing countries. However, it is also important to take affirmative action against infringements of intellectual property rights (including the practice of counterfeiting) and to protect the interests of the legal rightsholders. An appropriate balance must be struck, but that is not the case at present. It remains unclear precisely what is permitted and what is prohibited, which is clearly an undesirable situation.

Because Dutch customs takes action on the basis of an EC regulation, it is necessary to approach the issue at the European level, given that the interception of the medicines further to the stated Regulation may result in a fundamental difference of opinion between the European Commission and a some developing countries with regard to the compatibility of the applicable European legislation with WTO law, including the Trade Related Intellectual Property Rights (TRIPS) and the Doha Declaration on the TRIPS Agreement and Public Health of November 2001.
The basis of a solution must therefore be sought within European legislation itself. Accordingly, I have expressly requested the European Commission to analyse the situation and to arrive at a workable solution. The Netherlands has also broached the issue in the context of the 'Committee 133' (EU committee on trade affairs) and has gained the support of several other member states. In the autumn of 2008, the Council of Europe requested the European Commission to review and evaluate current customs regulations. In my opinion, the issue currently under consideration must form an intrinsic part of this evaluation.

This fundamental discussion aside, I wish to arrive at a practical solution which is acceptable to all parties, and to do so as quickly as possible. Accordingly, a meeting was held on 16 June between the European Commission's Director-General for Trade and Director-General for Taxation and Customs, and a number of officials representing both my ministry and the Ministry of Finance. The European Commission shares the Netherlands' opinion that generic medicines should be allowed unimpeded passage to developing countries, and is keen to find a solution to the current problems. In this context, the Commission is now working on an ‘explanatory memorandum’ which will establish the opportunities offered by Council Regulation (EC) No. 1383/2003 to guarantee unhindered movement of generic medicines. The Commission has stated that this memorandum will be published on the internet within the foreseeable future. The Commission also wishes to enter into a dialogue with the holders of intellectual property rights as soon as possible, whereby this discussion will consider the actual implementation of the transit regulations and the responsibilities of the rightsholders. Because rightsholders are important actors in the relevant procedures, the manner in which they choose to exercise their entitlements will form a crucial component of any alternative arrangements. In the first instance, the Commission's efforts will therefore focus on finding an appropriate solution within the existing legislative framework, but there remains an open attitude towards the amendment of the current legislation should this prove necessary.

This approach is very much in keeping with the Netherlands' intention of applying the provisions of by Council Regulation (EC) No. 1383/2003 in such a way as to allow generic medicines to be shipped to developing countries as expeditiously as possible. Full use will be made of the possibilities allowed by existing European legislation, since this will ensure quick results. Those possibilities are now being explored and defined by my ministry in association with the Ministry of Finance in a process which will also take into account the contents of the aforementioned ‘explanatory memorandum’. In addition, we intend to consult aid organisations to determine whether, with the cooperation of the rightsholders and customs, it will be possible to arrive at more flexible arrangements for consignments of medicines destined for developing countries.

Following the discussions between the European Commission and the Netherlands, talks were also held with the Indian and Brazilian ambassadors to the European Union. The Commission has stated that it takes the medicines issue very seriously, and will work earnestly towards a solution with regard to those generic medicines which do not infringe intellectual property rights and cannot justly be regarded as 'counterfeit' products. Brazil and India are to be involved in the further quest for solutions to the current problems. The Netherlands endorses the approach adopted and has reiterated its commitment to the 2001 Doha Declaration.

2. List of consignments intercepted and detained by Dutch customs in 2008
As promised, I attach a summary of the seventeen consignments of (raw materials for) medicines intercepted by Dutch customs while in transit during 2008. This summary represents the situation at 1 August 2009. Following updating and clarification, the list is identical to that which accompanied the State Secretary of Finance's response of 7 May 2009 to a request for information made by HAI Europe under the *Wet openbaarheid van bestuur* (Freedom of Information Act; WOB).

HAI Europe requested the release of documents relating to customs' seizures of medicines in transit, to include the notifications sent by customs to (the representatives of) the registered rightsholders. This request could not be honoured in full due to the confidentiality which must be accorded to certain information provided by market parties under the relevant articles of the Community Customs Code (CCC) and the exemptions to the Freedom of Information Act, as stipulated in Article 10 of that Act (preamble; paras 1b, 1c, 2b and 2g). In view of the Minister of Finance's decision in this matter, I consider that the submission of a full and detailed list to accompany this letter would not be in keeping with the aforementioned provisions.

3. Publication of information in Germany relating to companies which have lodged an application further to Article 5 of Council Regulation (EC) No. 1383/2003, and possible emulation in the Netherlands
During the session of 23 June, Member Gill'ard drew my attention to the fact that applications made by pharmaceutical companies to the German customs authorities have been made public, and asked whether it would be possible to emulate this practice in the Netherlands. I undertook to make the necessary enquiries, and have since learned that German customs has indeed listed the names of companies which have requested action under Article 5 of Council Regulation (EC) No. 1383/2003 on its website[2]. The information provided is limited to the names and addresses of the applicants, and the nature of the intellectual property rights which they wish to enforce. Following consultation with the Ministry of Finance, I see no reason not to publish similar information concerning the applications made to Dutch customs. Accordingly, the necessary arrangements will be made and the list will be published on the website as soon as practicable. However, because it will take time to gather and digitise the necessary information, it is not possible to indicate any firm date of publication at this time. In the interests of equal treatment, the Dutch list, like its German counterpart, will include all 'Article 5 applicants' rather than only the pharmaceutical companies.

4. Further information regarding the ACTA discussions
The Anti-Counterfeit Trade Agreement (ACTA) is an initiative of Japan and the United States. Its objective is to arrive at international standards for the enforcement of intellectual property rights, doing so with the input and cooperation of other countries, and hence to provide an effective means of combating piracy and counterfeiting. The founder members have now been joined by Canada, Mexico, South Korea, Singapore, Australia, New Zealand, Switzerland and the European Union in the ongoing discussions and negotiations.

The European Commission coordinates and negotiates all matters on behalf of the European Union, insofar as such matters fall within the competence and authority of the Community as a whole. The Council of the European Union issued a mandate authorising the Commission to act in this capacity in March 2008. The Commission takes part in the negotiations following due consultation with the member states (by means of the 133 Committee and other relevant committees). In the case of

[2] www.zoll.de/e0_downloads/f0_dont_show/liste_antragsteller.pdf

matters which fall under the direct sovereign responsibility of the individual member states, such as penalties under criminal law and cooperation between national enforcement agencies, the Presidency takes part in the discussions on behalf of the member states, again following due consultation. In the discussions to date, the Netherlands' focus has been on means to counter the production and distribution of counterfeit and illegally copied goods. Such 'piracy' is a phenomenon of international proportions and can have serious consequences, both economic and social, which threaten the effective working of the internal market. It is also essential to counter the illegal practices in the interests of consumer protection, public health and public safety.

ACTA is to focus on three main aspects:
1) enhanced international cooperation in enforcement activities;
2) the sharing of 'best practices', and
3) the implementation of a more effective legislative framework with regard to counterfeiting and piracy.

To date there have been five rounds of discussions and negotiations, during which the following matters were considered:
- 1st round (June 2008, Geneva, Switzerland): structure of ACTA, customs measures and instruments;
- 2nd round (July 2008, Washington DC, USA): customs measures and instruments, enforcement under civil law, transparency;
- 3rd round (October 2008, Tokyo, Japan): enforcement under civil law, enforcement under criminal law;
- 4th round (December 2008, Paris, France): institutional aspects, international cooperation, practical aspects of enforcement, internet, customs measures and instruments, definitions;
- 5th round (July 2009, Rabat, Morocco): international cooperation, practical aspects of enforcement, institutional aspects, transparency.

The next round is scheduled for November 2009 and will be held in Seoul, South Korea. The participants have stated the intention of completing their negotiations in (the first half of) 2010.

Because several of the ACTA participants are precluded (by national legislation or parliamentary protocol) from divulging the contents of certain documents, the members agreed at the outset that all documents are to be treated in the strictest confidence and will only be made available to government officials, to other persons who actually take part in the internal discussions, or those who are asked to advise during such discussions. Nevertheless, the matter of greater transparency (including the full or partial publication of documents) has been raised and discussed on several occasions. A number of countries, including the Netherlands, regard the lack of transparency as problematic. During the discussion round held in Rabat in July, transparency was the subject of extensive debate. It was subsequently agreed that the draft agendas of all future discussion rounds will be published in advance. The topic of transparency has also been included on the agenda of the forthcoming meeting in Seoul.

The closed nature of the discussions has prompted some speculation. The Netherlands supports an international development such as ACTA, but is of the opinion that greater transparency should be introduced to the negotiation process. This standpoint has been openly expressed in the context of the 133 Committee. Recently, the Netherlands and a number of other member states issued a statement to this effect. Nevertheless, and contrary to opinion in some quarters, ACTA is not a (completely) secret organisation. A press release is issued after each discussion round, and a number of press conferences have been held. The European Commission has included information about ACTA on its website[3] and two 'ACTA Stakeholders Consultation Meetings' have been organised, at which the European Commission gave a full account of the discussions to date and all attendees were invited to express their opinions of ACTA.

The Netherlands intends to apply similar transparency. In the short term, the agendas of all past discussion rounds will be published on the Ministry of Economic Affairs' website, together with other public information and links to the websites of relevant organisations elsewhere. Moreover, it

[3] http://ec.europa.eu/trade/issues/sectoral/intell_property/acta_en.htm

has been agreed with the other ministries most closely involved in ACTA (Justice, Finance and Development Cooperation) that all stakeholders are to be given an opportunity to express their views with regard to ACTA. This intention has already been publicised, albeit on a relatively small scale to date. The intention is that this consultation will take place as soon as the minutes of the discussions have been made public. Should it become clear during the next discussion round in November that such publication is not imminent, I shall make every effort to ensure that the consultation takes place as soon as practicable, based on the information available in the public domain at that time.

In response to the question raised by Member Irrgang, who asked whether the ACTA negotiations will render it even more difficult for the very poorest developing countries to acquire drugs to treat or prevent HIV/Aids, I wish to reiterate that the objective of ACTA is to combat the counterfeiting of all products, including drugs. Insofar as the effects of ACTA will be felt beyond the signatory countries themselves, it is clearly in the best interests of the developing countries that they have access to genuine medicines of proven efficacy.

The State Secretary of Economic Affairs and Minister for Foreign Trade,
Frank Heemskerk

Appendix to the written reply concerning the interception and seizure of consignments of medicines destined for developing countries by Dutch customs: summary of seizures of consignments in transit during 2008. (This summary presents the situation at 31 December 2008.)

Origin
A total of 17 consignments were intercepted and impounded further to Council Regulation (EC) No. 1383/2003. Of these, 16 originated in India and one in China.

Destination
5 to Peru
4 to Colombia
2 to Ecuador
2 to Mexico
1 to Portugal
1 to Spain
1 to Brazil
1 to Nigeria.

Contents
The consignments were found to contain the following goods:
- 8 x cardiological medicines: blood pressure suppressants and thrombosis inhibitors (with a total weight of 1,750 kg)
- 5 x 'lifestyle' medicines: erection pills and cholesterol lowering supplements (100,000 pills with a total weight of 515 kg)
- 2 x HIV/AIDS inhibitors (30,000 pills with a total weight of 24 kg)
- 1 x medicines to treat dementia (94,000 pills)
- 1 x medicines to treat schizophrenia (500,000 pills).

Action
- In six instances, the simplified customs procedure (per Article 11 of Council Regulation (EC) No. 1383/2003) was applied, whereby the goods were released for destruction by the rightsholder. This action is taken only when the consignor, consignee or owner of the goods fails to come forward.
- In six instances, the rightsholder waived further action, whereupon the goods were released.
- In four instances, the parties reached amicable agreement whereupon the goods were released. In two of these four instances, the owner relinquished any further claim to the goods.
- One case is subject to ongoing legal action in the civil courts.