GARCIA LOPEZ BERGES Victor (TRADE)

Subject: TTIP Pharma - Meeting with Eli Lilly

From: KAIZELER Ivone (TRADE)
Sent: Thursday, November 21, 2013 6:42 PM
To: GARCIA BERCERO Ignacio (TRADE); PERREAU DE PINNINCK Fernando (TRADE)
Cc: LEVIE Damien (TRADE); VELASCO MARTINS Pedro (TRADE); EMBERGER Geraldine (TRADE); TRADE TTIP TRANSPARENCY; LOPIAN Arthur (TRADE); JUUL-JOERGENSEN Ditte (TRADE); DUPUIS Philipp (TRADE); BENGTSSON Claes (CAB-DE GUCHT)
Subject: TTIP Pharma - Meeting with Eli Lilly

Dear Ignacio,
CAB met today with Eli Lilly. Damien asked me to join the meeting. Pedro was out today so he could not join. Short summary below.

Participants Eli Lilly
[**ART. 4.1b**]
[**ART. 4.1b**]
[**ART. 4.1b**]

Participants EU
BENGTSSON Claes (CAB-DE GUCHT) + stagiaire;
DUPUIS Philipp (TRADE)
KAIZELER Ivone (TRADE)

- Lilly is a US based company with strong footprint in EU. Manufactures in France, Ireland, Italy, Spain and the UK. Has research and development in UK and Spain (see details below)
- Strong expectations on TTIP which is seen as a major opportunity
- 3 Priorities: Regulatory Convergence, IPR and Pricing and Reimbursement

Regulatory Convergence:

- Very interested in Parallel Scientific Advice (this is one of the issues being discussed). If Parallel Scientific Advice is fully implemented significant gains (millions) are expected as divergences on clinical trials would be removed (ideally one clinical trial should suffice both jurisdictions and that is currently not the case). NB: Parallel Scientific Advice is cooperation between EMA, FDA and manufacturer (sponsor) at the pre-production phase whereby regulators give indicators to the companies on what type of clinical trials have to be conducted. Currently there is a pilot project going on. Both FDA and EMA say it works very well. We have asked industry to better explain what is their aim (institutionalise the pilot? Increase the scope to all types of medicines?, are there any caveats, is the pilot not delivering the aim? etc)

- Very interested GMP audits recognition. Industry is still assessing financial gains. They have mentioned 140.000 € per inspection (3 times every 3 years). They have noted that savings will be smaller than parallel scientific advice

➢ **All in all regulatory convergence very important [NOT RELEASABLE]**

Pricing and Reimbursement:

Asked provisions at least as the ones we have with Korea. Industry noted concerns on certain decisions to regulate prices to the bottom. They wish better predictability. Long statement on risk for future investments – if pricing and reimbursement decisions and IPR protection are not favourable to an industrial base in the EU. They produce in Europe and US and export to the rest of the world. Noting impeaches that future investments go elsewhere.
We have noted that this (pricing and reimbursement) is a very difficult issue and will be a very sensitive issue for EU MS + different situation than the one we had with Korea (size, risk, economic context, population coverage, balance of interests). They asked if we are in contact with MS on this and said they will provide some more ideas on this issue.

IPR
Not discussed at length, but they have asked that IPR is harmonized with US upwards. Mentioned the recent change in US legislation that increased protection for biologicals from 10 to 12 y. Would like to have the same in the EU.
We have noted that regardless of TTIP the balance is difficult to find within Europe (generics vs innovators).

Best regards,

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From: [ART. 4.1b]@lilly.com]
Sent: Wednesday, November 13, 2013 12:12 PM
To: VANHEUKELEN Marc (CAB-DE GUCHT)
Subject: Meeting with Eli Lilly and Company

Dear Mr Vanheukelen

I would like to check if you would be available for a meeting with [ART. 4.1b]. Mr [ART. 4.1b] will be in Brussels on Wednesday 21 November.

We would be particularly interested in discussing TTIP and the level of ambition that is being envisaged for the pharmaceutical sector in the negotiations. We would also like to take the opportunity to review the recent conclusion of the CETA agreement, which marks a major step forward for IP protection in Canada, and discuss some of the implementation challenges that lie ahead.

The TTIP negotiations are a major priority for Lilly, given our transatlantic footprint. Over the last decade Lilly's annual research and development investment in Europe has doubled to over EUR 450 million and we employ 9,000 people in the EU. Lilly conducts research and development at centres in the UK and Spain and manufactures in France, Ireland, Italy, Spain and the UK, exporting to over 100 countries worldwide. Approximately one third of our worldwide clinical trials take place in Europe, a total investment of nearly EUR 125 million per year.

We welcome the focus of TTIP negotiators on regulatory harmonisation and believe there are tangible gains to be made here. However in our view TTIP must also set a high level of ambition for intellectual property protection and enforcement, and market access. This is critical to ensure rapid access for patients to new

medicines, the support of an industry that directly provides over 1.2 million highly skilled jobs in the transatlantic economy, and an appropriate benchmark for future trade agreements with other countries.

For background, [**ART. 4.1b**] has previously held roles as [**ART. 4.1b**].

I will contact your office in the coming days to check your availability for a meeting.

Best wishes

[**ART. 4.1b**]
[**ART. 4.1b**]
Eli Lilly and Company
Tel. [**ART. 4.1b**]
Mob. [**ART. 4.1b**]