MEETING DALLI/GERMAN AUTHORITIES
PETITION [redacted] /EFFECTO
BRUSSELS, 24 MARCH 2011
Responsible official: [redacted] Tel: [redacted]

STEERING NOTE

1. SCENE SETTER

This meeting follows a meeting Commissioner Dalli had with [redacted] /atmed on 9 February 2011. The main purpose of the meeting with the German authorities is to obtain clear indications from them how the effecto could get market access in Germany.

The next step after this meeting will be a second meeting with [redacted] /atmed on 29 March 2011, to which the German authorities are equally invited. However, the German authorities are apparently not available to participate in such a meeting, given several legal proceedings [redacted] started against them over the last years in Germany. In the meeting their participation on the 29 March 2011 should be requested.

2. GERMAN AUTHORITIES INVOLVED

In Germany the Ministry of Health (BMG) has the responsibility for ensuring the respective legal framework for medical devices. The assessment of the safety of medical devices is the task of the Federal Institute for Drugs and Medical Devices (BfArM), an independent higher federal authority under the Federal Ministry of Health. The enforcement of the legislation is with the Länder authorities, this means that a device prohibition will not be issued by BfArM, but by the responsible authorities at Länder level. The Länder authorities are scientifically advised by the BfArM.

In 1996 BfArM became aware of the device now called effecto and shared its concerns originally with the Bavarian authorities, where the then distributor was located. The Bavarian authorities contacted the Sachsen-Anhalt authorities, as the then manufacturer was located there. The authorities in Sachsen-Anhalt in the first instance did not see sufficient reasons for a prohibition, but following further information provided to them by the BfArM in 1997 prohibited the device in September 1997. The responsible person in Sachsen-Anhalt at the time was [redacted] now seems to claim that in his view there were never sufficient reasons for this prohibition.

In the following years the manufacturer changed and is now located in Bavaria. Therefore, the prohibition of the placing on the market of the effecto in 2005 was issued by the Bavarian authorities. At the present time, Sachsen-Anhalt has no further responsibility in this case.

3. POSSIBLE WAYS FORWARD

3.1. Procedural Steps

The Commission should not declare the German measure unjustified according to Article 8 of 93/42/EEC as requested by [redacted] The safeguard clause of Article 8 applies where a risk is established after a product has been legally put on the market.

Instead, the Commission considered since 2007 that the device has never been legally placed on the market and should not have been affixed with the CE marking because the manufacturer has not sufficiently demonstrated conformity with the essential requirements of Directive 93/42/EEC. This is a case of Article 18 of Directive 93/42/EEC, not Article 8. The Commission considered the measure justified in the framework of Article 18 in its analysis of July 2007.

Germany has considered the device as a medical device (not as a pharmaceutical as [redacted] argues) and has applied the medical device framework to the device in the 1997 procedure, as well as in the 2005 prohibition and in the further communication.

3.2 Clinical Data Needed

The Commission services analyzed the German prohibition and the data provided by [redacted]/atmed, including most of the data and expert reports referred to now, in detail in 2007. On this basis they concluded that the German authorities position was correct, according to which two questions still needed to be addressed by atmed:

- Is the deposition in the lungs the same or higher when using the effecto than with the original mouthpiece?

- Are there potentially increased side effects resulting from the higher deposition in the lungs/the use of effect?

These questions were discussed in a meeting between the German authorities and [redacted]/atmed in February 2008. The protocol of this meeting describes what is practically required to address these questions sufficiently, ie. a physical study to determine the particle size with effecto and a pharmacokinetic follow-up study with 20 to 24 patients for each medicinal product the effecto is intended to be used with. The patient study is intended to provide information on pulmonary deposition and systemic safety. In addition, the BfArM also pointed out that it must be ensured that the patient information that comes with the effecto is understandable to the patients.

The estimated cost of the physical study is about 30.000 to 40.000 €, the clinical studies with the patients involve the use of the respective medicinal product with the effecto and blood tests for a short term following the administration to observe the development of the concentration in the blood.

While the information and experts reports provided by atmed, as well as the information on in-use experiences, might be valuable indicators, they can not replace proper clinical studies with the respective patient follow-up. The German authorities also may have ideas how to best exploit such practical experiences. The fact that the German monitoring system (DIMDI) did not report incidents with the Effecto does not sufficientl prove the safety either, as argued by [redacted]

[redacted]/atmed clearly negates the need of these studies (see main arguments made in meeting of 9 February 2011 in Annex hereto).

4. LINE TO TAKE

- Reassure the German authorities that you do not intend to take any decision declaring the national decisions in Germany to be illegal

- Explain that you see the meeting on 29 March as last offer of help to [redacted] to explore via which kind of data he could get market access for his Effecto, based on the advice of the German authorities as discussed with [redacted] in February 2008

- Invite the German authorities to participate in the meeting on 29 March

Briefing prepared by [redacted] *: Unit B2, Tel:* [redacted]
Sanco officials who will attend the meeting:
[redacted], *Unit B2*
End

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3. MÖGLICHE VORGEHENSWEISEN

3.1. Verfahrensschritte

Die Kommission sollte die deutsche Maßnahme nicht gemäß Artikel 8 der Richtlinie 93/42/EWG für ungerechtfertigt erklären, wie von (Name geschwärzt) beantragt. Die Schutzklausel des Artikel 8 gilt, wenn ein Risiko festgestellt wird, nachdem ein Produkt legal in Verkehr gebracht wurde.

Stattdessen hat die Kommission seit 2007 die Auffassung vertreten, dass das Gerät bisher noch nicht legal in Verkehr gebracht worden sei und keine CE-Kennzeichnung tragen dürfe, da der Hersteller die Konformität mit den grundlegenden Anforderungen der Richtlinie 93/42/EWG nicht ausreichend nachgewiesen hat. Dies ist ein Fall von Artikel 18 der Richtlinie 93/42/EWG, nicht von Artikel 8. Die Kommission hielt die Maßnahme im Rahmen von Artikel 18 in ihrer Analyse vom Juli 2007 für gerechtfertigt.

Deutschland hat das Gerät als medizinisches Gerät angesehen (nicht als Arzneimittel wie argumentiert wurde) und wandte im Verfahren von 1997 wie auch im Verbot von 2005 und den weiterführenden Mitteilungen die Rahmenbedingungen für medizinische Geräte an.

3.2 Clinical Data Needed

The Commission services analyzed the German prohibition and the data provided by /atmed, including most of the data and expert reports referred to now, in detail in 2007. On this basis they concluded that the German authorities position was correct, according to which two questions still needed to be addressed by atmed:

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/atmed clearly negates the need of these studies (see main arguments made in meeting of 9 February 2011 in Annex hereto).

4. ZU VERTRETENDER STANDPUNKT

- Versichern Sie den deutschen Behörden, dass Sie nicht beabsichtigen, eine Entscheidung zu treffen, die die nationalen Entscheidungen Deutschlands für illegal erklärt
- Explain that you see the meeting on 29 March as last offer of help toto explore via which kind of data he could get market access for his Effecto, based on the

advice of the German authorities as discussed within February 2008

- Invite the German authorities to participate in the meeting on 29 March

Briefing prepared by: Unit B2, Tel:

Sanco officials who will attend the meeting:

, Unit B2 **End**