Document 18

From: CAB ANDRIUKAITIS WEBPAGE
To: [redacted] (CAB-ANDRIUKAITIS)
Subject: FW: Medicines for Europe - meeting request
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Commissioner ANDRIUKAITIS_Meeting request.pdf
Importance: High

Please register, thank you.
[redacted]

From: Secretariat - Medicines for Europe [mailto:xxxx@xxxxxxxxxxxxxxxxxx.xxx]
Sent: Monday, January 15, 2018 2:51 PM
To: ANDRIUKAITIS Vytenis (CAB-ANDRIUKAITIS); CAB ANDRIUKAITIS WEBPAGE
Cc: [redacted] - Medicines for Europe; [redacted] - Medicines for Europe
Subject: Medicines for Europe - meeting request
Importance: High

Dear Commissioner,

Please find enclosed a letter from [redacted], [redacted] of Medicines for Europe, the European Association representing generic, biosimilar and value added medicines.

Your sincerely,
Medicines for Europe Secretariat

Rue d'Arlon 50 - 1000 Brussels - Belgium
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Mr. Vytenis ANDRIUKAITIS
Commissioner for Health and Food Safety
European Commission
Rue de la Loi 200
1040 Bruxelles

Brussels, 15 January 2018

Dear Commissioner Andriukaitis,

Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Our vision is to provide sustainable access to high quality medicines for Europe, based on five important pillars: patients, quality, value, sustainability and partnership. Its members employ 160.000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation. Our members, pharmaceutical companies with headquarters throughout Europe and National Associations, provide the essential medicines that European patients, healthcare professionals and healthcare systems rely on to treat the most acute ailments and chronic diseases ranging from cardiovascular, to diabetes and cancer.

In October 2017, Medicines for Europe nominated [redacted] as its new [redacted] he is the Executive Vice President for Generic Drugs at Fresenius Kabi, a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. [redacted] will be in Brussels on both Thursday 8th March and Monday 26th March and he would be honoured to meet you to exchange views on the key priorities for the generic and biosimilar sector. We have been working closely and fruitfully with the European Commission for many years and we would like to continue this crucial collaboration.

In particular, we are closely following the **European One Health Action Plan against Antimicrobial Resistance (AMR)** that the European Commission has recently published. We fully support this important initiative and we would like to discuss further with you how the generic and biosimilar medicines industries could contribute in supporting this crucial initiative. Medicines for Europe believes that, while it is important that we continue to research new effective antibiotics, it is also important to ensure that patients of all ages have access to existing effective treatments. In addition, we are witnessing more and more cases of the absence of antibiotics from the market and also repeated and prolonged shortages of supply for these antibiotics worldwide in different settings. The main reasons are very often unsustainable price levels and drastic cost-containment measures, as well as strict regulatory requirements. This lack of availability may have a serious impact on antibiotic prescribing. Physicians may be forced to use less optimal, often broad-spectrum antibiotics instead. Such alternatives may be less effective, they may have more adverse effects, and may also drive the selection of resistance.

Furthermore, Medicines for Europe believes in the importance of providing patients with timely access to medicines and is committed to the provision of a safe and continuous supply of medicines as a key public health objective. With this in view, Medicines for Europe aims to ensure a patient-centric proactive dialogue on the availability and access of medicines involving all the stakeholders: payers, regulators and supply chain actors. In

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order to tackle **medicines shortages** in a multi-source context, Medicines for Europe believes in an approach that addresses both the root causes of medicines shortages (preventing medicines shortages) and mitigates them once they occur (mitigating medicines shortages).

Lastly, we would like to discuss with you the urgent introduction of a **Supplementary Protection Certificate (SPC) manufacturing waiver** in the EU legislation, before the expiry of the Juncker Commission. This is a crucial initiative for the generic and biosimilar medicines industries.
In the EU, a Supplementary Protection Certificate (SPC) extends the protection of patented medicines for up to five years to compensate for the time lost in obtaining regulatory approval of the medicine. During this period, European manufacturers of generic and biosimilar medicines cannot produce their medicines in the EU. The SPC manufacturing waiver would be an important tool to fix the unintended side effects of the SPC, as stated in the Charles River Associates study commissioned and published by the European Commission. In fact, it will allow the generic and biosimilar medicines industries to produce and stockpile in the EU during the extra IP period granted by the SPC to the originator industry. In this way, the EU legislation could increase highly qualified scientific jobs in the EU, boost European competitiveness at global level and support the European, biosimilar and generic, SMEs without changing the existing European IP system.
We would very much welcome the opportunity to set up a meeting with you and President Mahl on 8th March or 26th March for in-depth discussions around our priority issues, given our sector's technicality and complexity.

We look forward to hearing from you,

Yours faithfully,

Medicines for Europe

Medicines for Europe

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