EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries
Food and Healthcare Industries, Biotechnology

MEETING BETWEEN MEMBERS OF CABINET OF COMMISSIONER ELŻBIETA BIEŃKOWSKA AND EGA REPRESENTATIVES
BRUSSELS, 06 MARCH 2015

MEETING MINUTES

Participants:

EGA: Adrian van den Hoven (EGA), [redacted] (Teva), [redacted] (Fresenius Kabi)

Commission: Kristian Hedberg (Deputy Head of Cabinet), Carsten Bermig (Member of Cabinet), [redacted] (DG GROW)

Topics addressed:

- Importance of pharmaceutical sector and role of generics/biosimilars.
- Industrial policy as a Commission's priority and pharma-specific comprehensive strategy in light of multiple issues relevant to the pharmaceutical industry.
- Concerns regarding i.a. pricing/reimbursement practices in MS, regulatory changes like falsified medicines, and problems concerning the availability of certain products.
- Comprehensive approach due to the range of issues (at MS and Commission level) and their interplay.
- Pharma-regulatory/intellectual property issues and EGA's request for changes.

EGA's key messages:

- Underlined the importance of the generics industry for the EU's economy and public health.
- Acknowledged the outcome of the work done under the Process of Corporate Responsibility in the Field of Pharmaceuticals and the Staff Working Document (summer 2014) as important and underlined the need for future steps.
- Explored the possibility of addressing the specifics of the pharmaceutical industry in a COM sector-specific industrial policy and urged the COM services to assume an active role in line with what has been done in the field of pharmaceuticals (including the recent multi-stakeholders' workshops).
- Pointed out the need for a long-term approach to health/pharmaceuticals in the context of the European Semester and the negative implications of quick fixes which put MS budgetary considerations at the forefront.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BREY[redacted]. Telephone: direct line (32-2) 29[redacted]. Fax: (32-2) 29 21365.

e-mail: [redacted]@ec.europa.eu

- Inter alia the following specific issues were raised:
    a. the international dimension of generics/biosimilars including the need to have international adherence to approaches taken in the EU (GMP, ICH, etc.) in order to create a level field in the international marketplace (through e.g. bilateral regulatory dialogues and FTAs, including TTIP);
    b. the need to capitalise on the full potential of biosimilars in the EU (higher market uptake) and internationally (proposed changes in the Supplementary Protection Certificate);
    c. the need to find practical solutions in implementing European legislation (e.g. falsified medicines legislation).
    d. MS pricing/reimbursement decisions whose extremely low prices make it economically unviable to have certain generics in various MS, thus undermining the availability of needed medicines

Commission's key messages:

- Referred to the ongoing work with regard to formalising the increased cooperation between DGs GROW and SANTE on pharma/medical devices related files (MoU between the two services).
- Signalled that the COM is still in its first days and currently exploring/identifying the next concrete steps concerning sector-specific activities.
- Explained that the ongoing pharma-related activities would be continued (e.g. the multi-stakeholders' workshop).

[redacted]

Copies: K. Hedberg, C. Bermig (CAB)
[redacted], G. Cozigou, [redacted], [redacted] (DG GROW)