



Making Medicines Affordable

## PRESS RELEASE

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### REMOVE BARRIERS TO COMPETITION & FREE TRADE TO BOOST THE GENERIC MEDICINES INDUSTRY

Today the EGA held its 10th Legal Affairs Forum calling on the EU to remove barriers to competition and free trade by introducing common sense reforms to European pharmaceutical intellectual property rules.

#### Improve the efficiency of the Patent system

To ensure that generic and biosimilar medicines can enter markets at patent expiry, the conference highlighted EGA efforts to improve the quality of patent assessments and particularly to strengthen the application of the 'inventive step' criteria. This problem is clearly identified in the numerous pharmaceutical patents that are subject to invalidity decisions.

Lidia Mallo, EGA Government Affairs and IP Manager, stated: "The EGA is engaged in a constructive dialogue with the European Patent Office to address deficiencies in the granting of pharmaceutical patents that, if abused, can delay competition in the Single Market".

Regarding the Unified Patent Court, the EGA reiterated concerns that enforcement measures that may be abused to delay generic entry -such as injunctions- should only be authorised after the Court has assessed the validity of the patent.

#### Introduce an Export Provision to boost growth and jobs in Europe

A special session called on the EU to amend the Supplementary Protection Certificate (SPC) Regulation, to allow generic and biosimilar medicine producers to export to emerging markets where SPCs do not apply. According to Adrian van den Hoven, the EGA's Director General, "Europe is a competitive location for high-tech medicine manufacturers. The SPC unfairly blocks our industry from exporting to the rest of world and encourages the delocalisation of our production. The Commission needs to act now!"

#### Clarify Policy on Patent Settlements

The EGA expressed concerns over the effect of the European Commission's policy on patent settlements which could limit the possibility for generic medicines producers to challenge weak patents. Given the high risk and unclear patent landscape in Europe, our industry needs more guidance from the Commission on what is authorised in a patent settlement.

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