EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

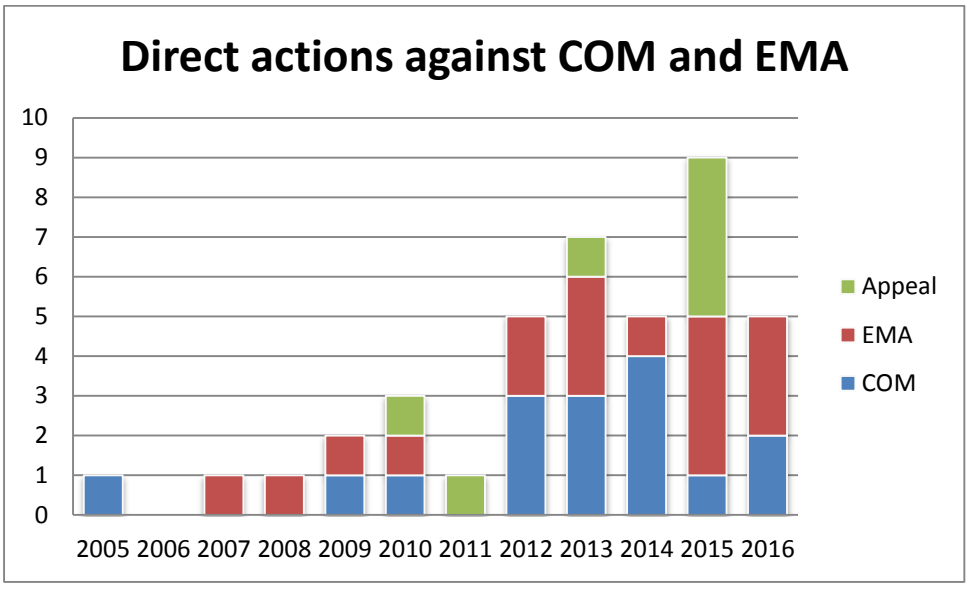
PHARM 716

PHARMACEUTICAL COMMITTEE
18 October 2016

Subject: **Update on Court cases**

Agenda item 1i

- **Litigation initiated by pharmaceutical companies in the period 2005-2016**



- **Case C-276/15 – Hecht Pharma – Opinion of AG Szpunar of 30 June 2016**

Hecht Pharma, the applicant in the national court case, sells incense capsules as a food supplement in Germany. The defendant operates a pharmacy in Germany and sells in his pharmacy incense extract capsules as a medicinal product. The defendant does not have a marketing authorisation for those capsules, but relies on a specific derogation in German pharmaceutical law, which allows pharmacists the manufacture and sale of ready-made medicines under certain conditions. The derogation applies, if the essential manufacturing steps for such product are carried out in a pharmacy as part of normal business producing a limited quantity per day and intended for clients of the pharmacy only.

The national court case concerns mainly the question, whether the defendant is allowed to advertise and promote the incense capsules or whether this would be contrary to the prohibition on advertising medicinal products that are not authorised. For that question to answer, the national court wants to know from the Court of Justice whether the specific derogation in German pharmaceutical law complies with Directive 2001/83. If the derogation is compliant, the incense capsules manufactured by the pharmacy will be covered by the derogation and fall outside the scope of pharmaceutical law applicable to industrially manufactured products and thus are not bound by the advertising prohibition in the German pharmaceutical law (and in Directive 2001/83).

More concretely, the national court asks whether the specific derogation in German law complies with one of the two 'pharmacy'-exemptions provided by Article 3(1) and (2) of Directive 2001/83.

Legal Considerations of the Advocate-General (AG):

- The AG considers that the questions of the national court are to narrow and should be extended to include Article 2 of Directive 2001/83, i.e. whether the product in questions is 'prepared industrially or manufactured by a method involving an industrial process'. This extension has to be seen against the backdrop of the much debated ECJ ruling in the Abcur cases (C-544/13 and C-545/13) from last year, where the ECJ ruled that the pharmacy exemptions in Article 3 are only applicable, if the product satisfies the conditions of Article 2, i.e. if it is an industrially prepared product.
- For the AG, the products in questions are not: because first, they are "the result of an exercise of individual craftsmanship, which is not akin to 'standardised production'" (para. 22), and secondly German law limits the production per day, to a quantity which is considered by the AG as being not significant (para. 23).
- On Article 3(2), the AG considers that this provision is potentially applicable, supposed it is guaranteed that the products in questions are manufactured 'in accordance with the prescriptions of a pharmacopeia'. While this requirement is not specifically referred to in the German provision under consideration, the AG follows the argument of Germany that this requirement would apply anyhow in view of other German requirements related to pharmacy business (para. 38).
- Additionally, the AG concludes that the wording in Article 3(2) 'in accordance with the prescriptions of a pharmacopeia' implies that if such prescriptions exist they imperatively need to be followed. If they do not exist, Article 3(2) is not applicable. They cannot be simply dispensed with (para. 40).

➢ Case C-277/15, Judgement of 13 October 2016, Servoprax

Background: A manufacturer subjects test strips for use with an *in vitro* diagnostic medical device to a conformity assessment in one Member State. The labelling and instructions for use are in the language of that Member State. The test strips are approved and receive CE marking. Its distribution company in another Member State markets the same test strips there, with a label and instructions for use in the language of that second Member State. A parallel distributor buys the test strips in the first Member State with labelling and instructions for use in the language of that Member State, but adds product information on the outer packaging and encloses instructions for use that correspond word-for-word to the instructions enclosed with the test strips distributed by the

manufacturer's distribution company in the second Member State. It then distributes the test strips on the market of that second Member State. The distribution company challenges the lawfulness of its competitor's activity, arguing that the parallel distributor is acting as a 'manufacturer' within the meaning of Article 9 of the Directive on *in vitro* diagnostic medical devices (Directive 98/79/EC and that a new or supplementary conformity assessment procedure is therefore required for that distribution activity.

Main considerations of the Court:

An oral update of the outcome of the case will be provided during the meeting.

- **Watch list - Interesting pending cases**

Case **T-672/14** (A. Wolff v Commission), direct action seeking the partial annulment of the Commission decision in an Article 31 referral re: estradiol containing medicines;

Case **T-269/15** (Novartis v Commission), direct action seeking the annulment of the Commission decision to grant marketing authorisation to the medicinal product Vantobra;

Cases **T-235/15, T-718/15 and T-729/15**, series of access to document cases against EMA concerning the confidentiality of scientific opinions on similarity/clinical superiority under the Orphan Regulation and the confidentiality of clinical study reports;

Case **T-80/16** (Shire v EMA), direct action seeking the annulment of EMA's decision to refuse validation for an application for orphan designation;

Case **T-295/16** (Symbioflor v EMA), direct action against the initiation of a referral procedure under Article 31 of Directive 2001/83/EC;

Case **T-303/16** (Novartis v Commission), direct action against the Commission decision in an Article 29 referral on tobramycin-containing products;

Case **T-329/16** (BMS v Commission/EMA), direct action against the Commission/EMA challenging the decision to withdraw the orphan status of a product at the time of marketing authorisation;

Case **C-629/15P (**and **C-630/15P)**, appeal of a pharmaceutical company against the General Court ruling in case T-472/12 and T-67/13 (Global marketing authorisation concept);

Case **C-114/15**, preliminary reference concerning the possibility of livestock farmers to (parallel) import veterinary medicinal products from other Member States;

Case **C-148/15**, preliminary reference concerning the applicability of the German system of fixed prices to products bought from non-German internet pharmacies;

Case **C-296/15**, preliminary reference concerning tendering practices of Slovenian hospitals with regard to the procurement of plasma products;

Case **C-621/15**, preliminary reference concerning the liability for medicinal products (Article 4 of Directive 85/374 - standard of proof).

Case **C-179/16**, preliminary reference – anticompetitive behaviour of a pharmaceutical company on the Italian market – Avastin.

Action to be taken:
For information