sold to generic drug manufacturers, either directly or via distributors (2).

Following the Commission's investigation, which covered the entire European Economic Area, these companies were fined a total of €13.9 million (2,4). The investigation identified the initial in-person meetings between company representatives to discuss the *Duboisia* harvest, which began in 2005 and took place once or twice a year. From 2011 onwards, they mainly communicated by email. The frequency of contact decreased when the price of the active pharmaceutical ingredient rose due to a shortage of Duboisia leaves, and increased when the price was expected to fall due to oversupply, or when a new player entered the market. Contact between the companies also decreased after 2014 when Boehringer Ingelheim, which was both a supplier of the ingredient and used it to produce its own proprietary product Buscopan®, decided to discontinue this product. The €10.4 million fine received by this company, largely calculated based on the value of its sales, reflects its substantial involvement in the infringement (2).

This is the first time the Commission has fined economic operators (producers and distributors) upstream of market entry, and signals its intention to tackle more covert agreements than those made once a drug enters the market (4).

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References 1- "Scopolamine à 20 mg/ml: le retour" *Rev Prescrire* 2001; 21 (220): 590. **2-** European Commission "Case AT.40636-SNBB" 19 October 2023: 31 pages. **3-** Eur-Lex "Summary of Commission Decision of 19 October 2023 (...) (Case AT.40636-SNBB) (C/2024/6961)" 18 November 2024. **4-** European Commission "Commission fines Alchem for participating in a pharmaceutical cartel" 4 July 2025: 2 pages.

The EMA can still do more to improve official drug information documents

● In August 2025, Prescrire responded to a public consultation by the European Medicines Agency (EMA) concerning summaries of product characteristics (SmPCs) and package leaflets.

The EMA's suggested changes to the package leaflet largely concerned its content and structure, and were intended to make it easier to understand and more relevant to users (1).

The SmPC and package leaflet are used to provide information to healthcare professionals and to patients or their caregivers, respectively. The content of these documents plays a crucial role in medication safety, along with the information included on the packaging.

In its response to the consultation, Prescrire suggested a number of ways in which these documents could be improved:

– Adding a boxed summary at the very start of the SmPC to help healthcare professionals quickly identify the key points to bear in mind for proper use of the drug, including a warning statement about the serious adverse effects to be taken into account, the outcomes assessed in the clinical trials, and what remains unknown about the drug's efficacy and adverse effects. This information should also be provided, in patient-friendly language, at the start of the package leaflet;

– Systematically using the international nonproprietary name (INN), with or without the proprietary product name, in the SmPC and package leaflet, since these documents are insufficiently informative if the drug is referred to solely by the brand name, as is often the case;

– Providing more detailed information relating to pregnant or breastfeeding women, in order to reduce inappropriate use in situations where the foreseeable risks outweigh the anticipated benefits;

– Making packaging mock-ups publicly available on the EMA website as soon as a drug has been granted marketing authorisation, since these provide important information for proper use of the drug. These mock-ups should be included as an annex to the SmPC from its first version;

– Avoiding instructions to refer to other parts of the document in the package leaflet, since they make it harder to read, and therefore harder for patients or their caregivers to understand (2).

As of September 2026, the findings of this consultation had not yet been published.

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