# The Pharma Legal Handbook

# Europe

## Marketing, Manufacturing, Packaging and Labeling Advertising

PHARMA BOARDROOM

# Marketing, Manufacturing, Packaging and Labeling Advertising

**This Pharma Legal Handbook answers essential questions about the legal and regulatory environment in 23 European countries.**

**Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.**



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TGS BALTIC
VARUL GRUNTE SUTKIENE

# Belgium

**This chapter about Marketing, Manufacturing, Packaging and Labeling Advertising in Belgium was published in association with:**


ALTIUS is one of the largest Belgian independent law firms, consisting of approximately 65 lawyers. Established in Brussels, we advise Belgian and international companies on the legal aspects of transactions, projects and disputes.

We help our clients navigate through often-complex legislation and regulatory environments and provide clear solutions to a wide range of legal issues. In addition to our specialist legal knowledge, we focus on thinking creatively with our clients to offer tailor-made solutions. Our aim is to turn, through careful listening and awareness, strategic questions into clear, straightforward answers.

For tax-related issues, ALTIUS works closely with Tiberghien, a leading independent Belgian firm that specialises in tax law.

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# Belgium

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# MARKETING, MANUFACTURING, PACKAGING AND LABELING ADVERTISING

**1. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?**

First of all, the medicines must be the subject of clinical trials. These clinical trials must be submitted to the FAMHP and an ethics committee for review and approval (see also Chapter II (available in **The Pharma Legal Handbook Belgium**))

If these clinical trials have been successful, the applicant can submit an application for a MA. Obtaining a MA is a sine qua non condition for the marketing of the medicines on the Belgian market. Such application can be submitted applying one of the following procedures:

### i. Centralised procedure:

Medicines can be authorised by means of a single application procedure at the European Medicines Agency ('EMA'). It is important to note that some products, such as biological medicines, must be centrally authorised.

The application is assessed by the EMA's Committee for Medicinal Products for Human Use ('CHMP') during a period of maximum 210 days. The CMHP's scientific opinion is sent to the European Commission for a final decision.

Once granted, the centralised MA is granted with a European authorisation number that is valid in all EU states, Iceland, Liechtenstein and Norway.

### ii. Decentralised procedure and mutual recognition procedure:

The decentralised procedure ('DCP') aims to obtain a MA simultaneously in several Member States for a not yet authorised medicine. The applicant can choose the Member States where obtaining a MA is envisaged. Each Member State chosen by the applicant is called a "Concerned Member State" ('CMS') and, among those Member States, the applicant has to choose one state that will be responsible for the evaluation of the application and that is called "Reference Member State" ('RMS').

The mutual recognition procedure ('MRP') enables an applicant to have a MA already obtained in one Member State (=RMS) recognised in one or more other Member States (=CMS).

Following approval, the applicant receives national MAs with national authorisation numbers for each of the Member States involved in the proceeding.

It is mandatory to use one of these two procedures if a MA application has already been submitted in another Member State. These procedures allow also obtaining authorisation for generic medicines of medicines that have already been authorised under the centralised procedure.

### iii. National procedure:

In Belgium, the request for a national MA must be submitted with the FAMHP. The Commission for Medicines for Human Use decides on the benefit/risk

balance of a medicine on the basis of three criteria: the efficacy, safety and quality of the medicine. After an assessment, the applicant receives the decision from the Minister or the FAMHP. If positive, the applicant receives a national MA that is only valid on Belgian territory.

**2. What is the authorization process for the marketing of generic versions of these products?**

Please refer to **Chapter I, Question 6**: "*How does the authorisation process differ between brand-name products and generic products?*". (available in **The Pharma Legal Handbook Belgium**)

**3. What are the typical fees for marketing approval?**

Please refer to **Chapter I, Question 4**: "*What are the approximate fees for each authorisation?*". (available in **The Pharma Legal Handbook Belgium**)

**4. What is the period of authorization and the renewal process?**

Please refer to **Chapter I, Question 5**: "F*or how long are marketing authorisations/registrations valid? How are mare marketing authorisations/registrations renewed?*". (available in **The Pharma Legal Handbook Belgium**)

**5. What are the requirements, if any, for post-approval pharmacovigilance?**

The **bodies within the administrative authorities** responsible for assessing and monitoring the safety of human medicines are the Belgian Pharmacovigilance Centre for medicines for human use ('BPC') established at the FAMHP, and the Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA.

The MA holder must also set up a pharmacovigilance system (*sensu lato*), consisting of **(i)** a pharmacovigilance system that is company specific and **(ii)** a risk management system that is product specific. The MA holders should keep detailed reports of all possible side effects that have occurred in or outside the European Union, and report to the relevant authorities serious adverse reactions within a maximum period of fifteen days. Additionally, they should also at regular intervals submit actualised periodical reports regarding the safety to the competent authorities.

The **MA holder** must also appoint a pharmacovigilance manager, called the qualified person responsible for pharmacovigilance ('QPPV'), who is responsible for the above actions. If the QPPV is not physically present in Belgium, a local contact person should be appointed as well.

Following the evaluation of the pharmacovigilance data, the FAMHP may decide to suspend, withdraw or amend the MA. It must then communicate this decision to the EMA, the other Member States and the MA holder.

**6. Are foreign marketing authorizations recognized?**

Foreign marketing authorisations can only be recognised provided that they are rendered by a Member state of the European Union and not by a third country. In such case, the so-called mutual-recognition procedure should still be followed (see also **Question 1**).

**7. Are parallel imports of medicines or devices allowed?**

Yes, parallel import or parallel distribution of **medicines** is allowed within the European Economic Area.

When it concerns centrally authorized medicines (i.e. one authorisation for the entire EU), reference is not made to '**parallel import**', but to 'parallel distribution'. In such case, a notification of the EMA of the intended parallel distribution is required.

In case of nationally granted MAs, parallel import is allowed, provided that the following conditions are met:

- A MA has been granted in the Member State of origin (part of the EU or of the European Economic Area) for the medicine to be imported;
- A MA has been granted in the Member State of import for the reference medicine;
- The imported and the reference medicine should at least:
  - o have the same qualitative and quantitative composition in active ingredients;
  - o have the same therapeutic indications;
  - o be therapeutically equivalent;
  - o have the same pharmaceutical form;
- No further differences may exist between the imported and reference medicinal product that could be therapeutically relevant and/or could pose a danger to public health.

The applicant for a **parallel import** authorisation is required to compile a file and submit it to the FAMHP in order to obtain this authorisation and the setting of the maximum price.

Finally, parallel distribution and import should respect intellectual property rights, such as trade mark rights, and should in this regard comply with the principles that have in this regard been set by the Court of Justice of the European Union.

As for **medical devices**, once a device has been CE-marked, it can be marketed anywhere in the EU, as long as the general requirements for medical devices are complied with.

**8. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?**

Belgian law prohibits the requesting, offering, accepting, or providing of "gifts, monetary advantages or benefits in kind" to wholesalers, persons qualified to prescribe, deliver or administer medicines or medical devices and institutions where prescribing, delivering or administering medicines or medical devices take place.

The above prohibition does not apply to:

**(i)** gifts or benefits of limited value that concern medical, dental or veterinarian practices (such as EUR 50 per gift and up to a maximum of EUR 125 per year),

**(ii)** invitations and payment of costs for participation in scientific events, including the hospitality of healthcare professionals if certain conditions are met; and