

## Q&A regarding contributions

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### Who has to pay the contribution?

According to Annex I of the law of 20 July 2006 on the establishment and operation of the FAMHP, economic operators who have supplied medical devices (including IVDs) to an end user or retailer in Belgium needs to pay the contribution.

### What is an economic operator?

According to article 33 of the law of 15 December 2013 on medical devices, an economic operator is a manufacturer, an importer or a distributor:

- manufacturer: the natural or legal person responsible for the design, manufacture, packaging and labelling of a device with a view to placing it on the market under its own name, whether these operations are performed by the same person or on their behalf by a third party. The natural or legal person who assembles, packages, processes, renews and/or labels one or more prefabricated products and/or assigns them as devices for placing them on the market under their own name are also considered as a manufacturer. This rule does not apply to persons who, without being a manufacturer within the meaning of the first sentence, assemble or adapt devices already on the market for an individual patient in accordance with their intended purpose.
- importer: any natural or legal person established in the European Union who places a product from a third country on the market in the European Union
- distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market in the European Union.

### What is meant by end user?

End user means any natural or legal person, other than a distributor, who uses a medical device in the context of their professional activities

E.g.: health professionals, hospitals, medical-social institutions and retailers.

### What is meant by retail or retailer?

Retail means the trade in which a trader primarily provides services to the general public. In other words, their customers are primarily members of the general public. For example, supermarkets, pharmacies that offer parapharmaceutical products, sports shops, etc.

### Who needs to register as an economic operator in our online applications?

As a Belgian distributor or an operator active in Belgium, and in accordance with the Royal Decree of 15 November 2017 on the notification of a contact person for materiovigilance and the registration of distributors and exporters of medical devices, you are required to register on our online applications.

As a manufacturer and importer: according to the above-mentioned Royal Decree, you do not have to register on our online applications. However, other legislation requires you to perform this registration, namely in the case of long-term implantable or invasive medical devices for reimbursement from the NIHDI.

If you do not have to register and you are liable to pay the contribution, we advise you to register in order to simplify the administrative procedures.

### I do not distribute medical devices and do not sell to end users or retailers. Do I still need to declare my turnover and pay the minimum of €500?

Yes, all economic operators have to file a declaration, but the contribution is only due by the economic operators who distributed medical devices to end users or retailers. You then need to tick the box: "I do not distribute medical devices or accessories to retailers or end users, so I do not have to pay the contribution", under Contribution via <https://www.vas.ehealth.fgov.be/webmedseip/nl>

### I do not file a declaration to the FAMHP, what can I risk?

If no declaration is filed, the FAMHP will determine itself the contribution to be paid, based on the distributor's total turnover as known to the FPS Finance.

Moreover, if the economic operator fails to meet its obligations with regard to contributions, it runs the risk of a fine of 1% of its total turnover as known to the FPS Finance.

### My company started its activities in December of the year N-1. In other words, it started distributing medical devices to end users or retailers at that time. Do I have to pay the minimum 'economic operators' contribution of €500 in year N?

Yes, the contribution must be paid in year N by all companies that generated turnover in year N-1 (regardless of the date on which they started their activity).

### I registered as a distributor in January of year N-1, but my company's activities only actually started in January of year N. Do I have to pay the minimum contribution on turnover of €500 in year N?

Yes, according to Article 14/3, if no turnover was generated in the previous year, the minimum fixed fee is due.

### The declaration of turnover relates to deliveries on the Belgian market to end users and retailers. I am active as a distributor on the European market, but not in Belgium. Do I need to pay the indexable minimum contribution on turnover of €500, while declaring a turnover of €0 on the Belgian market?

No, the contribution has to be paid by economic operators who distributed medical devices to end users and retailers in Belgium. Economic operators who did not supply medical devices to end users or retailers in Belgium therefore do not have to pay the contribution.

### My company not only sells medical devices, but also provides maintenance and repair services. Does the turnover from these activities also need to be taken into account when calculating the contribution?

No, the calculation of turnover is based solely on sales of medical devices.

### My company sells medical devices, but also rents them out. Does the turnover from this activity need to be taken into account when calculating the contribution?

Yes, a product is placed on the market when it is supplied for distribution, consumption or use in the market. The transfer of a product is therefore deemed to have taken place, in particular in the context of a sale, loan, lease or donation transaction. The transfer of ownership implies that the product is intended to be made available to another natural or legal person.

### As a manufacturer of custom-made products, do I have to pay a contribution?

Economic operators who have supplied medical devices to an end user or retailers in Belgium need to pay the contribution.

On the other hand, if the manufacturer works through a wholesaler, and therefore does not supply medical devices to retailers or end-users, that manufacturer does not have to pay any contribution.

Example: I am a dental technician and provide a service to end users, such as a dentist or dental practice. I therefore have to pay contributions on account of my activity.

### Can a third party (e.g. one of my suppliers) pay the contribution on my behalf?

Yes, a third party can pay the contribution on your behalf, but it must be calculated on the basis of the turnover that your company generated via your customers (end users and retailers). You remain solely responsible for paying your contribution.