

PRESS RELEASE

First semester results

Infarmed approved 14 news medicines and finished 30 evaluation processes

The Infarmed approved 14 new drugs in the first six months of 2017, overtaking the approvals of the same period of 2016 (9). This result clearly meets the target for 2017 of maintaining or overcoming the number of publicly financed molecules in 2016. Last year marked a new record, with 51 new medicines approved.

Most of the new medicines are meant to be used in hospital care, such as several molecules used in cancer treatment (three for the melanoma), hepatitis C (two) and Hemophilia (two), but there are also new treatments for asthma or Parkinson disease (see Annex 1,2 and 3, below).

In the first half of the year the Infarmed completed 30 distinct assessment processes, 16 of which were dismissed or closed in response to companies requests.

There are about 30 processes already in the final stages of negotiation and about to be completed in the next few weeks.

Almost 200 approved drugs: 138 are generics

Among the 234 examined applications were 187 approved drugs. Most of them were generics (138) and one was a biosimilar.

The acceleration of the evaluation processes has been a priority for the Infarmed, but there is also a great effort to reduce the most delayed files. In the last 12 months it was possible to reduce them by half.

These approvals have allowed the treatment of thousands of patients every year and have reduced the use of exceptional use authorisations. Some legislative amendments are expected within the next weeks, taking Portugal closer to the European framework.

The evaluation timings will be more balanced and adjusted to the processes complexity (generic medicines, new presentations and new active substances).

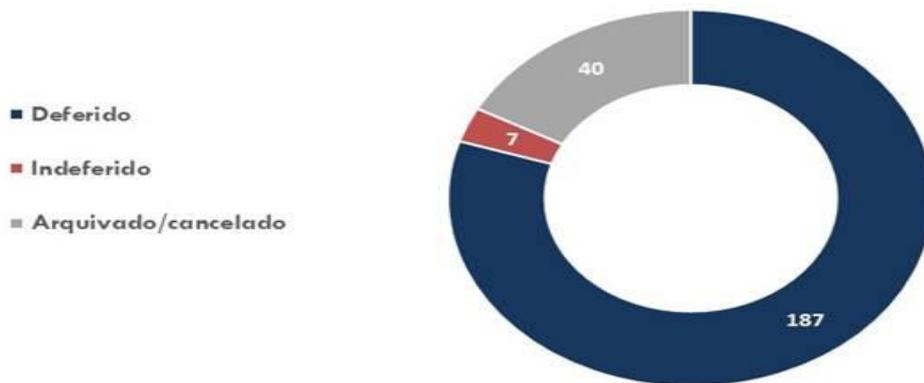
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ANNEX 1 – NUMBER OF NEW MEDICINES

Financiamento - Acesso à Inovação | 2007 - 2017

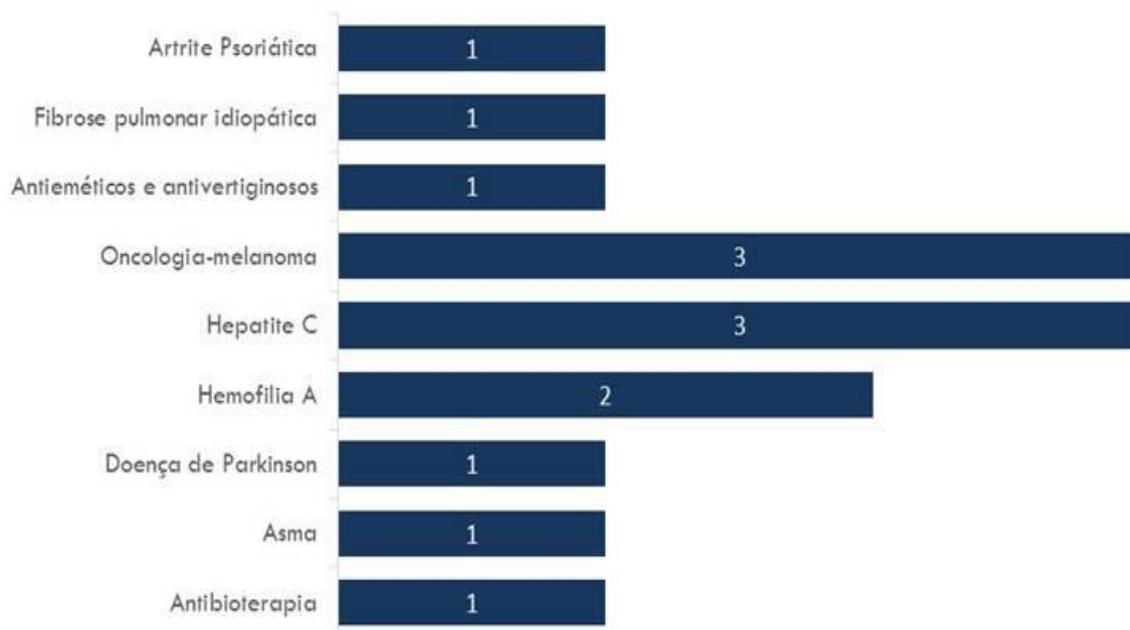


ANNEX 2 – FILES EVALUATED IN 2017 (Positive, negative and canceled)



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ANNEX 3 – APPROVALS BY THERAPEUTIC AREA (such as oncology, hemofilia or hepatitis C)



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