Status of New Drug Product Approvals in 2018

In the EU & US

- **Hematology**: 7
- **Neurology**: 8
- **Other Disease Areas**: 26
- **Oncology**: 31
- **Immunology/Rheumatology**: 12
- **Infection**: 19

**Total**: 103

- **89 Products** were classified as novel drugs (NAS, NME, BLA)
  - Only EU: 11
  - In both: 34
  - Only US: 44

- **44 Products** received expedited approval pathways (fast track, breakthrough, conditional etc)
  - Only EU: 0
  - In both: 2
  - Only US: 51

- **44% Big Pharma**
- **56% Small and Medium size Pharma**

**Disease Areas**
- Oncology: 49
- Immunology/Rheumatology: 12
- Infection: 19
- Hematology: 7
- Neurology: 8
- Other Disease Areas: 26

**Do you want your product approved in the EU?**

NDA supported over 40% of the new medicinal products that were approved in the EU during 2013-2018.

Contact us today.

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Data excludes generic applications. Data pooled from the FDA and EMA websites on the new approved products during 2018.

List of top pharma companies in 2018 was obtained from: EvaluatePharma 2018 Evaluate Ltd www.evaluate.com

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New drug product approvals: new active substance (chemical, biological, biotechnology or radiopharmaceutical substance), new biological entity, new drug combination, biosimilars, new active ingredient, vaccines.