

Drugs with discontinued production: a descriptive analysis of the Brazilian scenarium

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Introduction

- Drugs with discontinued production by the manufacturers can cause drug shortage, a global problem that also affects the Brazilian healthcare system. (1–3)
- Since 2014, Brazilian Health Regulatory Agency (ANVISA) obliges manufacturers to communicate temporary or definitive discontinued production of drugs. (4)
- Information on discontinued production is available as a database at ANVISA's webpage and can be applied to predict potential drug shortages. (5)

Objective

- This study aims to describe the profile of drugs with discontinued production by manufacturers in 2018, in Brazil.

Methods

- A descriptive analysis was conducted considering data on drugs with discontinued production in 2018, available at ANVISA's webpage. (5) Data collection was carried out until March/2019.
- The following variables were collected from public database for further analysis: type of discontinuation (definitive or temporary); reason for discontinuation; and therapeutic classification.
- Reasons for discontinuation were classified as follows: market interest (lack of commercialization interest from manufacturer); active ingredient (raw material unavailability); manufacturing process (changes on manufacturing process due to manufacturer decision or sanitary requirements); logistic issues (increase on demand, importation issues and priority of sales to public sector); industrial park (manufacturing site changes or change of a step of the manufacturing process to another place).
- Descriptive analyses were performed through the calculation of each group of interest proportion.

Results

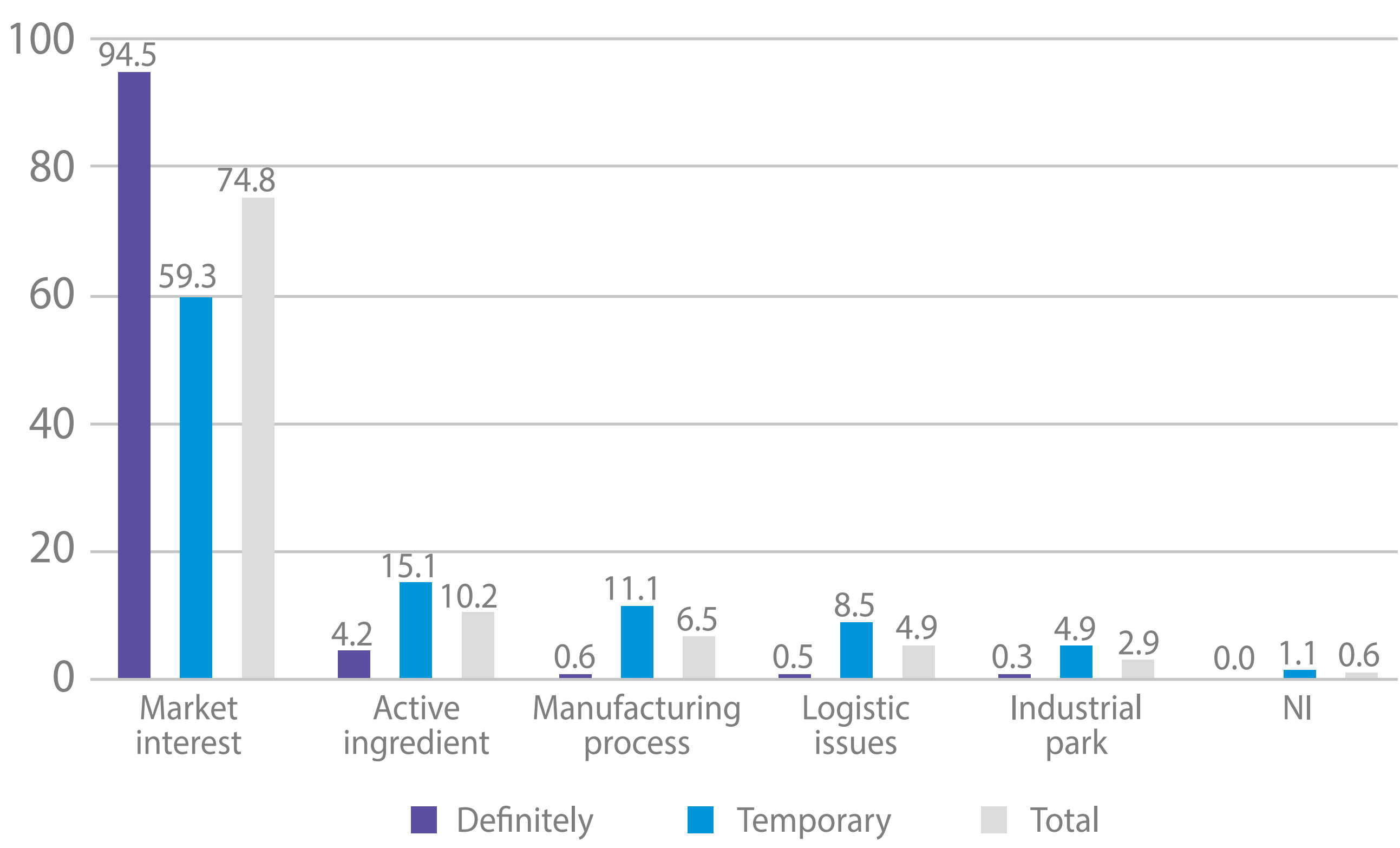
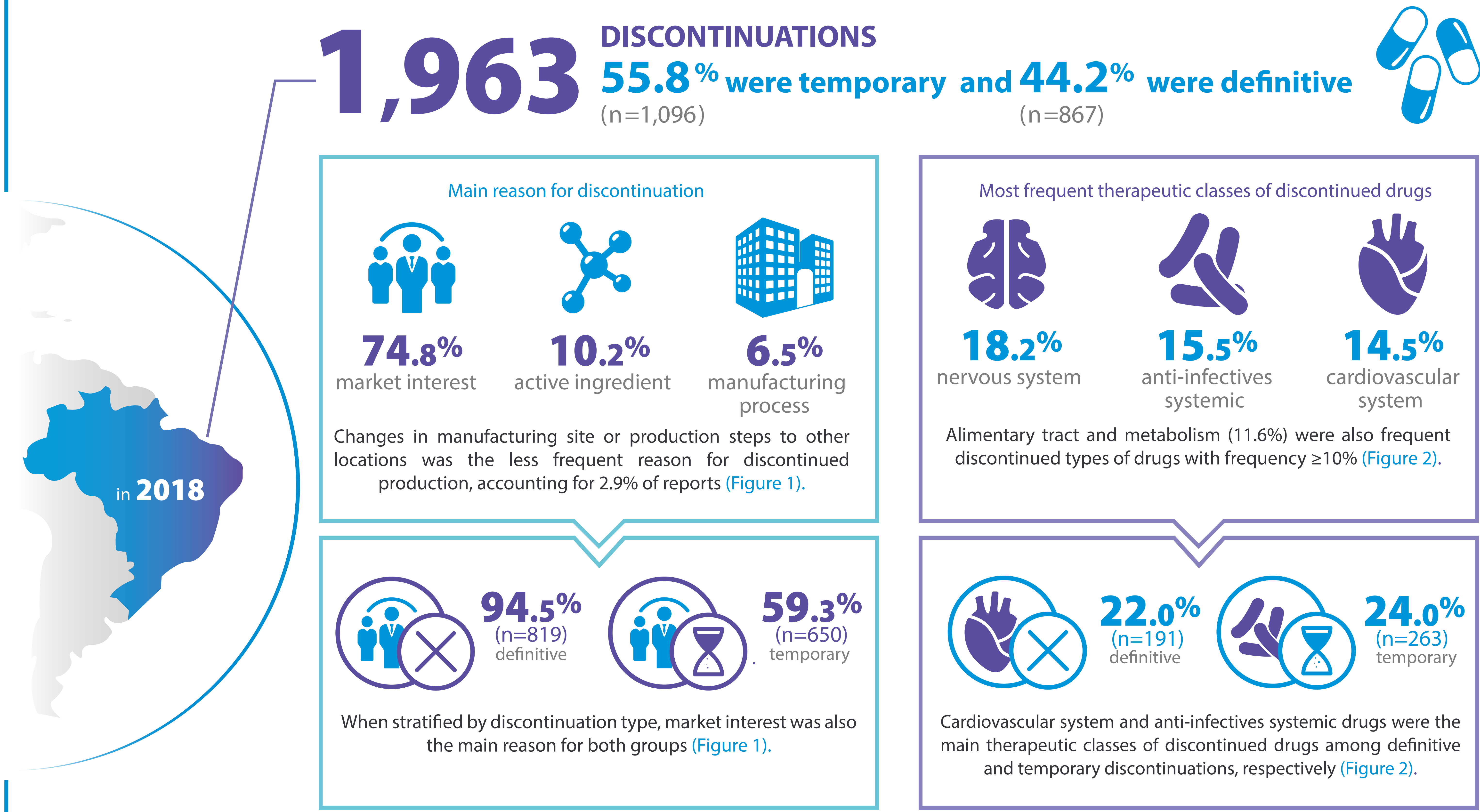


Figure 1- Reasons for discontinuation stratified by type in Brazil, 2018.

NI: Not informed

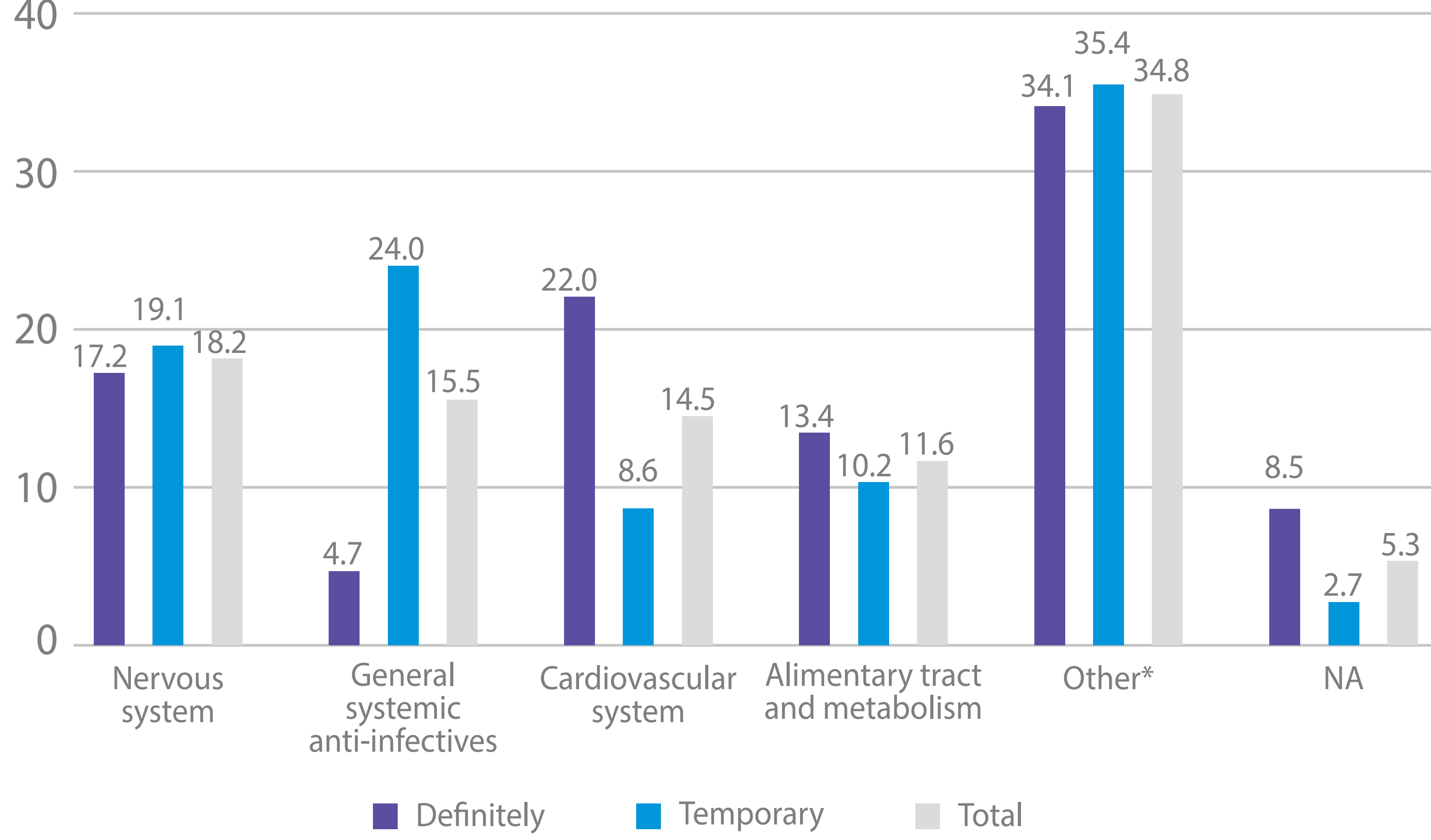


Figure 2- Therapeutic classes distribution stratified by type in Brazil, 2018.

* Other (frequency <10%): Respiratory system, dermatologicals, musculoskeletal system, sensory organs, hospital solutions, genitourinary system and sexual hormones, antineoplastic and immunomodulating agents, parasitology, blood and blood forming organs, systemic hormonal preparations (excluding sex hormones), various and diagnostic agents.
NA: Not available

Conclusions

- The process of drug production discontinuation in Brazil is most frequently temporary. Market interest is the main motivating reason.
- This procedure does not consider the availability of a similar technology to attend patients' need.
- Although the World Health Organization defines that regulatory agencies cannot obligate a manufacturer to produce a drug, these data highlight the need of creating strategies to avoid impact on patients' healthcare due to drug shortage.

References

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