

# An Investigation on Drug Shortage in Canada

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## Introduction

Drug shortages creates significant risks to the Canadian health care system and patients. Currently, there is a high number of shortages in Canada (Videau, Lebel, & Bussi res, 2019). It is imperative to decrease this shortage and any further actions should be guided by data. This report aims to address this concern by providing suggestions for the top three companies in the drug shortage report to be inspected by management, inspector, and compliance and enforcement specialists.

## Drug shortages in Canada

In the drug shortage report, there are 7 key reasons for drug shortages (**Table 1**). The top 3 reasons, disruption of the manufacturing, demand increase, and delay in shipping drugs, amounted to 86% of the total shortages. Manufacture disruption is the primary reason for drug shortages, accounting for 56% (3010 out of 5356) cases of national drug shortages (**Figure 1**). TEVA Canada has also discontinued the most drugs, with 105 out of 734 drug discontinuations.

## Companies with the most drug shortages

The companies that experience the most shortages is shown in **Figure 2**, with TEVA Canada, Apotex Inc., Sandoz Canada, Taro Pharmaceuticals, and Auro Pharma being the top 5 companies. Compared to the national distribution, these top 5 companies experience fewer delays in the shipping of the drug (**Table 1**). These companies also have a 16% higher proportion of drug shortages due to manufacturing disruptions compared to the national proportion.

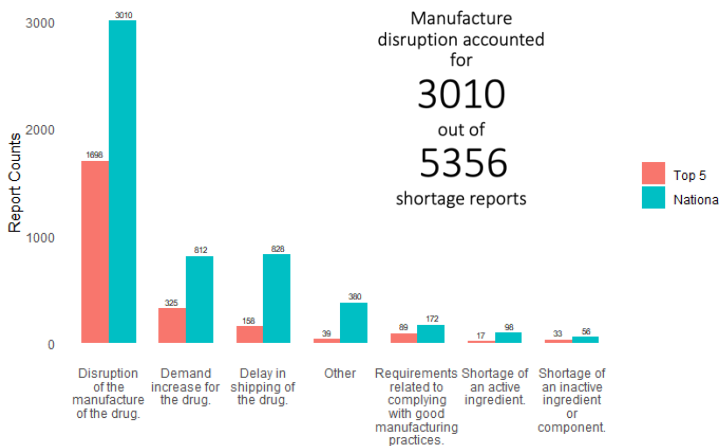


Figure 1 The comparison of reasons for drug shortage between national and top 5 companies' distribution

Reasons	National	Top 5 Companies
Disruption of the manufacture of the drug	56%	72%
Demand increase for the drug	15%	14%
Delay in shipping of the drug	15%	7%
Requirements related to complying with good manufacturing practices	3%	4%
Others	7%	2%
Shortage of an inactive ingredient or component	2%	1%
Shortage of an active ingredients	1%	1%

Table 1 Proportion comparison for drug shortage reasons between national and top 5 companies' distribution

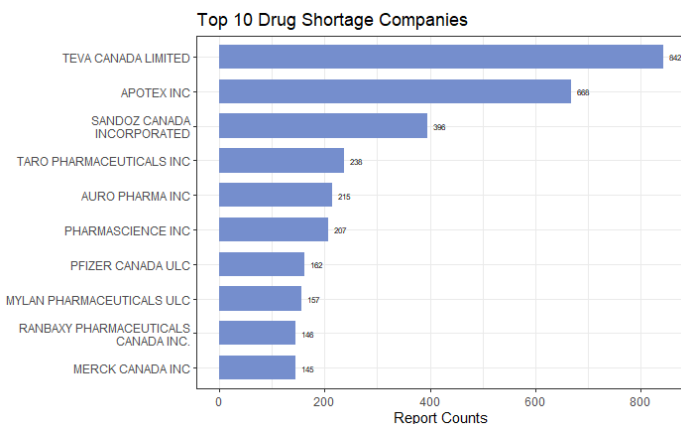


Figure 2 A ranking of companies who experience the most drug shortage

Top 5 companies that failed to provide anticipated start dates for drug shortages

Out of 144 companies, TEVA Canada, Apotex Inc, Sandoz Canada, Taro Pharmaceuticals, and Auro Pharma are the top 5 companies that failed to provide anticipated start dates for drug shortages. TEVA Canada failed the most to provide start dates, accounting for 36% (822 out of 2295) of the total failures to provide anticipated drug shortage start dates (Figure 3).

Additional trends, risks, or issues

By comparing the estimate and actual delay duration for the top 5 companies have the most shortages, the data seems to suggest these companies do not overestimate their length of their drug shortages (Figure 4). Another trend of interest is the ratio of pediatric drugs to non-pediatric drugs. Pediatric drugs rarely report shortages (Table 2). Thus the estimated delay duration and pediatric drug shortages are not issues worth pursuing and they are not used in the criteria in choosing a company to investigate.

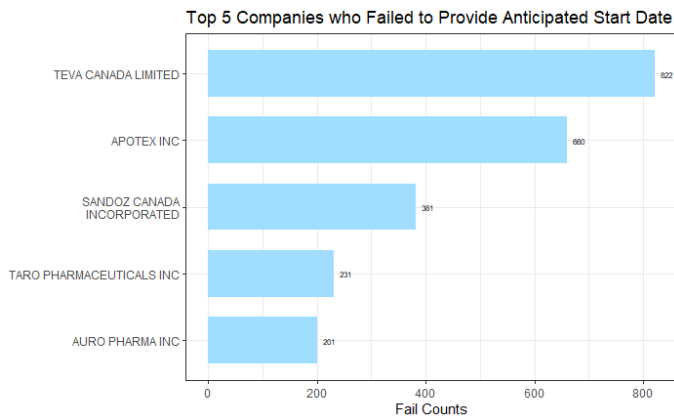


Figure 2 ranking of top 5 companies who failed to provide anticipated start date for drug delays

Pediatric Drug	Not Pediatric Drug
3	5081

Table 2 The count of cases of pediatric drugs that is both identified in the drug product database and the drug shortage report

Conclusion

Since the disruption of drug manufacturing attributes to the largest proportion in the shortage report, this should be the primary focus for investigators. In fact, the proportion goes even higher at 76% if only looking at the top 5 companies with shortage reports. Therefore, the top 3 companies management should investigate are TEVA Canada, Apotex Inc, and Sandoz Canada. All of these companies also ranked the highest in failing to provide anticipated drug shortage start date and has the highest number of drug shortage reports. TEVA has also issued 14% of drug discontinuation of out all the discontinued drug reports. This could also be another indication for companies with inferior resource management which could cause more drug shortages although more investigation is needed to validate such a hypothesis.

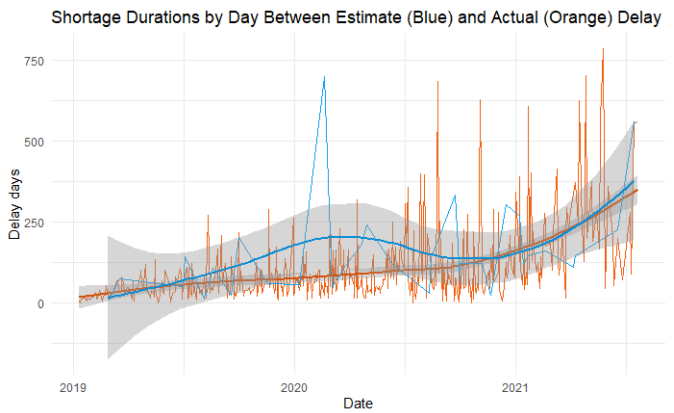


Figure 3 A timeseries of shortage duration comparing to prediction and actual delays for the top 5 companies reporting drug shortages

1. Videau, M., Lebel, D., & Bussi res, J.-F. (2019). Drug shortages in Canada: Data for 2016 2017 and perspectives on the problem. In Annales Pharmaceutiques Fran aises (Vol. 77, Issue 3, pp. 205 211). Elsevier BV. <https://doi.org/10.1016/j.pharma.2018.11.007>