Journal of Social Research

P-ISSN: 2827-9832
E-ISSN: 2828-335x
http://ijsr.internationaljournallabs.com/index.php/ijsr

TIMELINE ANALYSIS OF CORRECTIVE AND PREVENTIVE ACTION OF COMPLETION BY PHARMACEUTICAL WHOLESALERS IN THE FRAMEWORK OF GOOD DISTRIBUTION PRACTICES CERTIFICATION YEAR 2020-2022

Lili Damayanti[1], Dumilah Ayuningtyas[1], Teti Hastati[2]
[1]*Department of Health Policy and Administration, Faculty of Public Health, Universitas Indonesia*
[2]*Indonesian Food and Drug Authority, Jakarta, Indonesia*
lili.damayanti@ui.ac.id

ABSTRACT

The mandatory implementation of Good Distribution Practices (GDP) for Pharmaceutical Wholesalers can secure drug distribution channels from counterfeiting and misuse of drugs by the public. One of the important things in accelerating the GDP Certification process is the stage of completing Corrective and Preventive Action (CAPA) by Pharmaceutical Wholesalers. The purpose of this study is to analyze the timeline for the completion of CAPA by Pharmaceutical Wholesalers in the framework of GDP Certification in 2020 – 2022 so that an overview of Pharmaceutical Wholesalers' ability and readiness to implement the GDP Certification policy as a business licensing standard is obtained. This study used a quantitative approach with descriptive analysis methods, using GDP Certification data from the Indonesian FDA. The results showed that the fastest average time to complete CAPA by Pharmaceutical Wholesalers was in 2022, which was 31 working days with 3 submissions, followed in 2021 by 41 working days with 4 submissions, while the longest CAPA completion time was in 2020 for 71 working days with 5 submissions. In general, this has met the provisions of the Indonesian FDA Regulation Number 25 of 2017, but if you refer to the latest regulations, namely Government Regulation Number 5 of 2021 and the Indonesian FDA Regulation Number 10 of 2021, the average time for CAPA completion by Pharmaceutical Wholesalers in 2020-2022 still does not meet the requirements. The recommendation from this study is that it is necessary to carry out training, technical guidance, or assistance to improve the ability and readiness of Pharmaceutical Wholesalers so that the implementation of GDP certification according to the latest regulations can be fulfilled immediately.

Keywords: *timeline, CAPA, pharmaceutical wholesaler, GDP certification*

INTRODUCTION

The circulation of counterfeit drugs is increasing worldwide (Jeong & Ji, 2018). the World Health Organization (WHO) estimates that 1 in 10 medical products in low and medium countries are substandard or counterfeit products, including drugs, vaccines and in vitro diagnostics (WHO, 2018). Substandard or counterfeit medical products that enter global distribution channels or supply chains will not only have an impact on public health because they can increase disease prevalence, antimicrobial resistance and produce adverse health effects but can also have an impact on socio-economics because they can contribute to decreased productivity and increase productivity of medical costs (WHO, 2020a).

According to the World Health Organization (WHO), distribution is an important activity in the integrity of supply chain management of pharmaceutical products. Good Distribution Practices (GDP) is part of the quality assurance of pharmaceutical products through control during the distribution process and to secure the distribution system of pharmaceutical products from counterfeiting, stealing, abuse, substandard, and/or misbranded (WHO, 2020b).

Based on Indonesia FDA Regulation No. 9 of 2019 regarding Technical Guidelines for Good Distribution Practices, "GDP is a method of distribution of drugs and/or medical products that aims to ensure quality along the distribution channel according to the requirements and purposes of use" (BPOM RI, 2019). The consistent mandatory application of GDP by Pharmaceutical Wholesalers can secure drug distribution channels from the rampant circulation of illegal drugs including counterfeit, minimize drug distribution to illegal facilities, irregularities in the distribution of other drugs, and drug abuse by the public. GDP certificate is given as proof that Pharmaceutical Wholesalers have met GDP's requirements in distributing drugs and/or medical products (BPOM, 2020).

Currently, GDP Certificate is issued by the Indonesian FDA, and GDP Certification is one of the public services in the Indonesian FDA. Based on data from the Indonesian FDA as of December 31, 2022, there are around 2,544 pharmaceutical wholesalers throughout Indonesia, of which 2,319 (91.15%) Pharmaceutical Wholesalers already have GDP certificates, 106 (4.16%) pharmaceutical wholesalers are still in the GDP certification process and 119 (4.67%) pharmaceutical wholesalers have not applied for GDP certification (BPOM, 2022).

In the GDP Certification process, the fulfillment of Corrective and Preventive Action (CAPA) examination results by pharmaceutical wholesalers is one of the important things to accelerate the GDP certification process (Kumari et al., 2021). Based on Indonesian FDA Regulation No. 25 of 2017 regarding GDP Certification Procedures, the duration of CAPA completion by pharmaceutical wholesalers is a maximum of 13 (thirteen) months, where the first CAPA must be carried out no later than 1 (one) month from the issuance of the CAPA request by the Indonesian FDA, and the next CAPA must be carried out within a maximum period of 1 (one) year from the time the results of the first CAPA evaluation are received by pharmaceutical wholesalers. This regulation is not limited to the maximum number of times pharmaceutical wholesalers submits their CAPA during that period (BPOM RI, 2017).

Based on the GDP Implementation Guidelines, CAPA (Corrective and Preventive Action) is a corrective and preventive action (Ambarwati et al., 2022). Corrective action is the act of eliminating the cause of a found nonconformity or an undesirable situation. Aims to prevent the recurrence of a discrepancy that has already occurred. While preventive action is measures to eliminate potential causes of nonconformity or potentially undesirable situations. Aims to prevent non-conformities that currently have not occurred (BPOM RI, 2015).

Since 2021, based on the Government Regulation No. 5 of 2021 regarding the Implementation of Risk-Based Business Licensing, GDP Certificate has become one of the standards for Business Licensing to Support Business Activities (PB UMKU) for pharmaceutical wholesalers. "PB UMKU is a license required for business activities and/or products during the operational and/or commercial stages" (RI, 2021). For the implementation of Government Regulation in the drug and food sector, Indonesian FDA Regulation No. 10 of 2021 regarding Business Activity and Product Standards in the Implementation of Risk-Based Business Licensing in the Drug and Food Sector was issued. There are several changes in the requirements in the GDP Certification process as a business licensing standard based on Government Regulation No. 5 of 2021 and Indonesian FDA Regulation No. 10 of 2021, one of the significant changes is related to changes in the timeline for completing CAPA examination results that were originally completed no later than 13 (thirteen) months from the examination to a maximum of 40 working days with a maximum of 2 CAPA submissions (2

times 40 working days). However, until the end of December 2022, the implementation of changes to the CAPA settlement timeline by pharmaceutical wholesalers has not been implemented (BPOM, 2021).

Based on the foregoing, it is necessary to analyze the timeline for the completion of CAPA examination results by pharmaceutical wholesalers (Lijun & Yue, 2017). The purpose of this study is to provide an overview of the completion time of CAPA by pharmaceutical wholesalers in the framework of GDP Certification for the last 3 years (2020 to 2022). It is expected that this research can obtain an overview of pharmaceutical wholesalers' ability and readiness in implementing the GDP certification policy as a business licensing standard based on the latest regulations.

METHOD

This research is descriptive research with a quantitative approach (Sugiyono, 2013). A quantitative approach is used to get an idea of the completion time of CAPA GDP certification examination results by pharmaceutical wholesalers. The data used in this study is secondary data from the Indonesian FDA, namely GDP Certification data from 2020 to 2022. The population in this study is all pharmaceutical wholesaler's application data in the framework of GDP Certification, GDP Recertification, and pharmaceutical wholesaler's warehouse addendum for 4 types of applications, namely Narcotics, Cold Chain Products (CCP), Other Drugs (other than Narcotics and CCP) and Starting materials. While the sample in this study was taken by exhaustive sampling technique where all populations were used as research samples.

RESULTS AND DISCUSSION

Overview

Based on the analysis of GDP Certification data, in the period 2020 to 2022, there were around 1,753 GDP Certification applications submitted through GDP e-certification applications at the Indonesian FDA, consisting of 683 applications in 2020, 457 applications in 2021 and 613 applications in 2023, as stated in table 1 below:

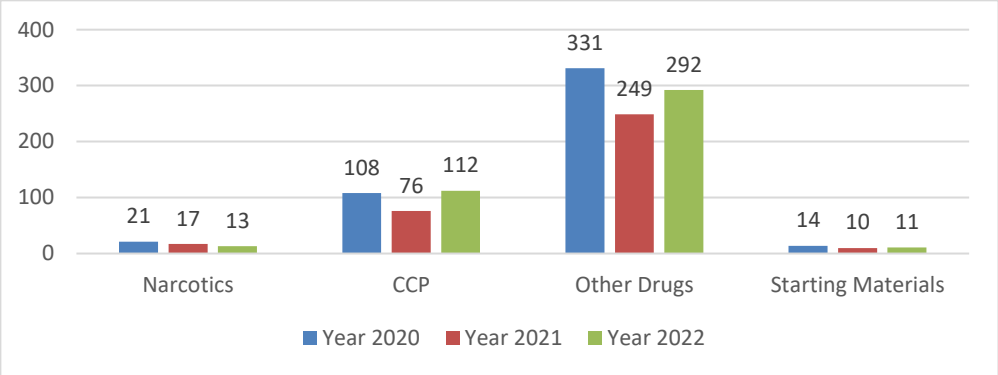
Table 1.
Number of GDP Certification applications in 2020 – 2022

Year	Number of applications GDP Certification
2020	683
2021	457
2022	613
Total	1,753

Based on the type of application, the highest number of GDP certification applications are for other drug certification applications, followed by CCP certification applications and narcotics certification applications, while the least is for starting materials certification applications. This is illustrated in the following graph 1:

Graph 1.

Number of GDP Certification applications based on application type



Based on Graph 1, the number of GDP Certification applications from 2020 to 2022 for each type of application fluctuates. The highest number of applications was for other drug certification applications, where in 2020 there were 331 applications, but decreased in 2021 to 249 applications, then in 2022 it increased again to 292 applications. The same trend occurs in applications for CCP certification and starting materials certification, where for CCP certification in 2020 there were 108 applications, in 2021 it decreased to 76 applications and increased again in 2022 to 112 applications; And for applications for certification of starting materials in 2020 as many as 14 applications, decreased in 2021 to 10 applications and in 2022 slightly increased to 11 applications. Meanwhile, the trend for applications for narcotics certification each year has decreased, where in 2020 there were 21 applications, decreasing to 17 applications in 2021 and again decreasing to 13 applications in 2022.

CAPA Completion Timeline GDP Certification Examination Results by pharmaceutical wholesalers

Based on the analysis of GDP Certification data from 2020 to 2022, the average CAPA turnaround time in 2020 was 71 working days, longer than in 2021 with an average of 41 working days and in 2022 with an average of 31 working days, this can be seen in Table 2 below:

Table 2.

Average CAPA completion time by pharmaceutical wholesalers in the framework of GDP Certification 2020 – 2022 based on its completion time

Year	Number of Applications GDP Certification	CAPA Time to Turnaround (business days)				
		Min	Max	Median	Average	Standard Deviation
2020	683	1	481	37,5	71	81,1
2021	457	1	350	25	41	49,0
2022	613	1	211	23	31	28,4

Based on Table 2, the average time to complete CAPA by pharmaceutical wholesalers in the last 3 years is getting faster, this shows that the ability and readiness of pharmaceutical wholesalers have increased every year, but it is also necessary to see how many times the average pharmaceutical wholesalers submit CAPA to the Indonesian FDA because, in the latest regulation, there is a restriction that pharmaceutical wholesalers can only apply for a maximum of 2 CAPA times. The data can be seen in Table 3 below.

Table 3.

Average time to complete CAPA by pharmaceutical wholesalers in the framework of GDP Certification 2020 – 2022 based on the number of times

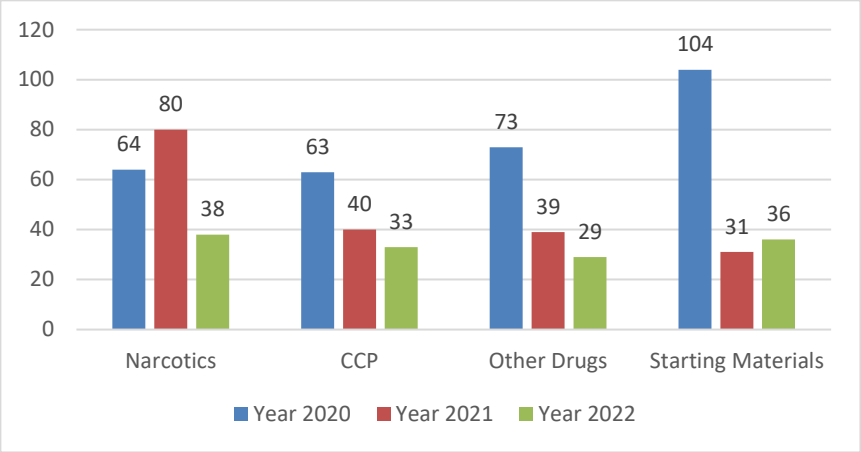
Year	Number of Applications GDP Certification	CAPA Turnaround Time (times)				
		Min	Max	Median	Average	Standard Deviation
2020	683	1	35	4	5	3,3
2021	457	1	17	3	4	2,2
2022	613	1	10	2	3	1,6

In Table 3, it can be seen that on average pharmaceutical wholesalers submitted CAPA applications to the Indonesian FDA in 2020 5 times, while in 2021 it was 4 times and in 2022 it was 3 times. It also shows that pharmaceutical wholesalers' speed in completing its CAPA from year to year has increased.

Based on Table 2 and Table 3, in 2020 the average CAPA completion time by pharmaceutical wholesalers was 71 working days with 5 CAPA submissions to the Indonesian FDA, in 2021 the average CAPA completion time was 41 working days with 4 CAPA submissions while in 2022 the average CAPA completion time was 31 working days with 3 CAPA submissions. From the results of this data analysis, if referring to the provisions in the Indonesian FDA Regulation No. 25 of 2017, the average CAPA completion time by pharmaceutical wholesalers from 2020 to 2022 has met the provisions, but if you refer to the latest regulations, namely Government Regulation No. 5 of 2021 and the Indonesian FDA Regulation No. 10 of 2021 where CAPA can be completed within a maximum of 40 working days with a maximum of 2 CAPA submissions, then the average completion time of CAPA in 2020 to 2022 has not met the requirements.

Graph 2.

Average time to complete CAPA by pharmaceutical wholesalers in 2020 – 2022 in the framework of GDP certification based on the type of application (working days)



In Graph 2, it can be seen that the average CAPA completion time by pharmaceutical wholesalers in 2020 to 2022 in the framework of GDP certification based on the type of application, in general, the average CAPA completion time for CCP certification and other drug certifications every year is getting faster. In 2020, the average CAPA turnaround time for CCP certification was 63 working days, then 40 working days in 2021 and 33 working days in 2021. For certification of other drugs in 2020 for 73 working days to 39 working days in 2021 and 29 working days in 2022. Meanwhile, narcotics certification from 2020 to 2021 has become longer, from 64 working days to 80 working days, then in 2022 it will be faster, from 38 working days. As for starting materials certification, in 2020 the average completion of CAPA for starting materials certification was the longest compared to narcotics, CCP and other drug certifications, which was 104 working days; But in 2021 it accelerated to 31 working days and in 2022 to 36 working days.

When viewed based on the Province, there are still around 14 Provinces in Indonesia whose CAPA completion time is more than 40 working days, this can be seen in Table 4 below:

Table 4.

Average time to complete CAPA examination results by pharmaceutical wholesalers in 2020 – 2022 based on the Province

No	Region	Number of Applications GDP Certification	Average CAPA Completion time (weekdays)
1.	West Sumatra	21	9
2.	Bengkulu	7	13
3.	Gorontalo	8	14
4.	Aceh	9	17
5.	Southeast Sulawesi	20	17
6.	Lampung	27	18

7.	North Sulawesi	23	21
9.	Yogyakarta	32	23
10.	Bangka Belitung	6	24
11.	South Sumatra	26	24
12.	West Papua	8	28
13.	Maluku	6	30
14.	South Kalimantan	27	31
15.	Riau Islands	26	32
16.	Riau	25	34
17.	Central Kalimantan	4	34
18.	Central Sulawesi	14	38
19.	West Kalimantan	25	39
20.	East Kalimantan	30	41
21.	Papua	21	42
22.	Bali	36	49
23.	Batam	70	49
24.	Jambi	22	51
25.	Central Java	151	53
26.	West Java	194	54
27.	South Sulawesi	42	55
28.	East Nusa Tenggara	22	57
29.	Jakarta	168	58
30.	West Nusa Tenggara	10	60
31.	East Java	127	66
32.	North Sumatra	45	82
33.	West Sulawesi	2	116

In Table 4, we can see 5 provinces with the fastest average CAPA completion time including West Sumatra with 9 working days, Bengkulu with 13 working days, Gorontalo with 14 working days, Aceh with 17 working days, and Southeast Sulawesi with 17 working days. While the 5 provinces with the longest average CAPA completion time include West Sulawesi with 116 working days, North Sumatra with 82 working days, East Java with 66 working days, West Nusa Tenggara with 60 working days, and DKI Jakarta with 58 working days.

CONCLUSION

From the results of the study, it can be concluded that the average CAPA completion time for the fastest examination results by pharmaceutical wholesalers is in 2022, which is 31 working days with 3 submissions, followed in 2021 by 41 working days with 4 submissions, while the longest CAPA completion time is in 2020 for 71 working days with 5 submissions. In general, this has complied with the provisions of Indonesian FDA Regulation No. 25 of 2017, in this regulation the time for completion of CAPA by pharmaceutical wholesalers is no longer than 13 (thirteen) months from the inspection. However, if you refer to the latest regulations, namely Government Regulation No. 5 of 2021 and Indonesian FDA Regulation

No. 10 of 2021 (in this regulation, CAPA can be completed no later than 40 working days with a maximum of 2 CAPA submissions), then the average time for completing CAPA in 2020 – 2022 does not meet the requirements. From the results of this study, it can also be concluded that the ability of pharmaceutical wholesalers in solving CAPA still needs to be improved.

In order to accelerate the implementation of GDP certification as a business license, especially in accelerating the time to completion of CAPA by pharmaceutical wholesalers, it is necessary to intervene in the form of training activities, technical guidance, or assistance to pharmaceutical wholesalers. These activities can be prioritized, especially for areas with the longest average CAPA completion time.

ACKNOWLEDGEMENTS

We would like to thank the Indonesian Food and Drug Authority, especially Directorate of Distribution and Service of Drug, Narcotics, Psychotropics and Precursor Control for their support in providing data in this study.

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