BEFORE THE

OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT

STATE OF CALIFORNIA

In the Matter of the Penalty Issued to: **ALEMBIC PHARMACEUTICALS, INC.** Appellant.	OSHPD No. 20-023C-Q16

DECISION OF THE DIRECTOR

This matter came before Elizabeth A. Landsberg, the Director of the California Office of Statewide Health Planning and Development ("Director"), for decision following the Director's review and rejection of the proposed decision prepared by the Hearing Officer. The Director independently reviewed the hearing record, including the video recording of the hearing and the exhibits. For the reasons provided below, the Director concludes that Appellant, Alembic Pharmaceuticals, Inc., established good cause for reduction of the penalty assessment.

HEARING AND RECORD

This matter was originally heard before Michelle Church-Reeves, Hearing Officer, Office of Statewide Health Planning and Development ("OSHPD"), State of California, on Thursday, October 22, 2020 beginning at 10:32 a.m. PDT.

Ty Christensen, Health Program Audit Manager II, Accounting and Reporting Systems Section, and Chaz Chung, Staff Services Manager I, Cost Transparency in Prescription Drug

Pricing, represented OSHPD.

Alembic Pharmaceuticals, Inc. ("Appellant") was represented by Albert Manwaring, Director and Senior Counsel, Eric Hacker, Counsel, Craig Salmon, President of U.S. Operations for Alembic Pharmaceuticals, Inc., Armando Kellum, Director of Logistics for Alembic Pharmaceuticals, Inc.

Both documentary and testamentary evidence was received. The matter was submitted for decision and the record was closed on Thursday, October 22, 2020 at 12:31 p.m. PDT.

PROCEDURAL HISTORY

The following findings of procedural facts were made by the Hearing Officer and are adopted by the Director.

1. On August 14, 2020, OSHPD assessed penalties against Appellant in the amounts of $4,140,000 and $1,012,000 for delinquent quarterly Wholesale Acquisition Cost ("WAC") Increase Reports.

2. Appellant appealed the penalties by submitting a Request for Administrative Hearing form dated August 14, 2020 and received by the OSHPD Hearing Office on September 2, 2020.

3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.[1]

4. The hearing was not scheduled within 60 days of receipt of the appeal due to the Hearing Officer being on military leave. No party objected to the scheduling of the hearing.

5. The hearing was held electronically at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.

6. OSHPD representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 15 were found to be authentic and relevant and admitted to the record.

[1] Cal. Health & Saf. Code § 127681(f).

7. Appellant submitted written exhibits to the Hearing Office and OSHPD representatives in advance of the hearing. Exhibits A through J were found to be authentic and relevant and admitted to the record.

FACTUAL FINDINGS

The following findings of fact were made by the Hearing Officer and are adopted by the Director:

1. On or around July of 2018, OSHPD mailed the Notice of Proposed Rulemaking to "Alembic Pharmaceuticals, Inc." via regular U.S. mail.

2. On or about December 20, 2019, OSHPD mailed a courtesy reminder letter to Appellant addressed to "Armando Kellum" reminding Appellant of the statutory reporting requirements.

3. On or about May 4, 2020, OSHPD staff reached out to Appellant to discuss three WAC Increase Reports that had been inputted into SIERA but not submitted.

4. Appellant was required under Health and Safety Code section 127679 to file twelve WAC Increase Quarterly Reports for the drugs Irbesartan and Irbesartan HCTZ in twelve dosages (the "Irbesartan products") by July 31, 2019.[2] Penalties accrued from August 1, 2019 until July 10, 2020 when the reports were filed.

5. In accordance with Health and Safety Code section 127679, subsection (e), OSHPD assessed penalties in the amount of $1,000 per day for 345 days for each of the twelve reports due by July 31, 2019, resulting in a total penalty amount of $4,140,000.[3] These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.

6. On or about July 10, 2020, Appellant submitted four reports for quarter 3 of 2019.

[2] *See* Cal. Code Regs. tit. 22, § 96071.
[3] Cal. Health & Saf. Code § 127679. *See also* Cal. Code Regs. tit. 22, § 96080.

7. Appellant was required under Health and Safety Code section 127679 to file four WAC Increase Quarterly Reports for the drugs Losartan and Losartan HCTZ in four dosages (the "Losartan products) by October 31, 2019.[4]

8. In accordance with Health and Safety Code section 127679, subsection (e), OSHPD assessed penalties in the amount of $1,000 per day for 253 days for each of the four reports due by October 31, 2019, resulting in a total penalty amount of $1,012,000.[5] These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.

9. Appellant submitted a written statement with its appeal and made oral statements of facts it believes show good cause why its reports were not submitted in a timely manner.

10. Appellant testified that it did not receive either the notice of rulemaking or the courtesy reminder due to problems with the addressing. The notice of rulemaking was not addressed to any specific employee or title, although it did have the correct street address. The December 20, 2019 letter addressed to Mr. Kellum did not contain the company name or suite information and was not delivered to Appellant. On or about April 16, 2020, Appellant was served with investigative interrogatories and subpoena by the Office of the Attorney General ("OAG") which asserted that Appellant had delinquent reports under California's Prescription Drug Pricing Program[6] (the "CTRx program"). The deadlines for the investigative interrogatories and subpoena were extended by 30 and 60 days respectively. As shown in Exhibit B, the deadlines for written responses were extended to June 17, 2020, and document production to July 17, 2020. Appellant took 85 days to gather information and documents and respond to the OAG.

[4] *See* Cal. Code Regs. tit. 22, § 96071.
[5] Cal. Health & Saf. Code § 127679. *See also* Cal. Code Regs. tit. 22, § 96080.
[6] Cal. Health & Saf. Code § 127675 et seq.

11. Concurrent with working to comply with the OAG investigative interrogatories and subpoena, Appellant registered with the CTRx program on or about April 23, 2020. Extensions were not available for CTRx program reports.

12. Appellant is a subsidiary of a subsidiary of Alembic Pharmaceuticals, Ltd., an Indian corporation. Appellant sells generic drugs manufactured by Alembic Pharmaceuticals, Ltd. located in India. Appellant is a small business with 11 employees and sells primarily to wholesalers and resellers.

13. Upon receipt of the investigative subpoena, Appellant's priority was to comply. However, Appellant had numerous concerns about revealing proprietary information. Discussions occurred between Appellant and OAG related to the confidentiality of documents produced for the subpoena including discussions of aconfidentiality agreement.

14. Appellant testified that the price margins on generic drugs are very narrow. Gross sales for the Irbesartan products during second quarter of 2019 in California totaled $768,649, and net sales revenues were $245,436. During the third quarter of 2019, California gross sales of Losartan products were $160,875 and the net sales were a loss of $31,045. These facts were substantiated by oral statements made under oath by Mr. Salmon and Mr. Kellum at the hearing.

15. The initial statements of both parties were not rebutted.

16. OSHPD's representative confirmed that Appellant had no previous report filings.

The Director makes the following additional findings of fact:

1. Appellant offered testimony that it was unaware that the statutes, which it read as applying only to manufacturers as distinguished from distributors like itself, and the regulations implementing the CTRx program applied to Appellant until it received the OAG investigative subpoena.

2. The WAC increases reported for the second quarter of 2019 for the Irbesartan products ranged from 211% to nearly 700%, with 6 of the 12 increases in excess of 600%.

3. The WAC increases reported for the third quarter of 2019 for the Losartan products ranged from 790% to over 931%.

4. Seven of the 12 WAC price increases for the Irbesartan products occurring during the second quarter of 2019 took effect on April 17, 2019, four took effect on April 8, 2019, and one on May 1, 2019.

5. All four of the WAC price increases for the Losartan products occurring during the third quarter of 2019 took effect on July 15, 2019.

DISCUSSION AND LEGAL CONCLUSIONS

1. The issue here is whether Appellant had good cause, as required by Health and Safety Code section 127679, for failing to file sixteen quarterly WAC Increase Reports (consisting of twelve reports for the Irbesartan products by July 31, 2019, and four reports for the Losartan products by October 31, 2019), or other good cause for reduction of the penalties, such that the penalties should be waived in whole or in part.

2. In *Waters v. Superior Court*, the California Supreme Court stated that, "good cause may be equated to a good reason for a party's failure to perform that specific requirement from which he seeks to be excused."[7] Good cause must be directly related to the specific legal requirement which the party failed to perform and should be outside the reasonable control of the party.[8]

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[7] *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal.2d 885, 893 (hereafter *Waters*).

[8] *Waters, supra*, 58 Cal.2d 885, 893 and Secretary of State, "Good Cause" Reasons for Waiving Late Campaign & Lobbying Filing Fees https://www.sos.ca.gov/campaign-lobbying/good-cause-reasons-waiving-late-campaign-lobbying-filing-fees/ [as of December 4, 2019].

Good cause is sometimes defined as circumstances beyond the party's control, and not related to the party's own negligent act or failure to act. On an individual basis, courts and administrative bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.[9] However, good cause is not limited to the listed reasons. The determination of good cause in a particular context should utilize common sense based upon the totality of the circumstances, including the purpose of the underlying statutory scheme.[10]

3. Appellant first argues that it has good cause for a reduction or waiver of the penalties because it is not a manufacturer under a layperson's definition and had no reason to believe that the statute applied to Appellant. However, Appellant's narrow focus on a strict definition of manufacturer, ignoring the context in which the term is used in the statute, is misplaced. The meaning of words used in statutes "must be construed in context, keeping in mind the nature and obvious purpose of the statute where they appear."[11] While the CTRx statutes refer only to reporting by a manufacturer of a prescription drug, the focus of the chapter is pricing and the term manufacturer is used entirely in the context of pricing and the determination of WAC price increases.[12] The statues are not concerned with how or where the drugs are produced, but rather how the drugs are priced and sold to purchasers, specifically those drugs purchased by state purchasers, pharmacy benefit managers, health insurers and health care service plans.[13] While Appellant may not consider itself a manufacturer, the statute is clearly addressing Appellant's prescription drug products, WAC prices set by Appellant, and the negotiation and sale of those

[9] Fair Political Practices Commission, Guidelines for Waiving Late Fines (Nov. 2017) http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/FilingOfficer/700FO-Folder/Late%20Fine%20Guidelines.pdf [as of December 4, 2019]. See also *Waters, supra,* 58 Cal.2d 885, 893.

[10] *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

[11] *Johnstone v. Richardson* (1951) 103 Cal.App.2d 41, 46. See also *Twining v. Taylor* (1959) 170 Cal.App.2d Supp. 842, 844.

[12] Cal. Health & Saf. Code §127675 *et seq*.

[13] Cal. Health & Saf. Code §127675.

products to Appellant's customers. The regulations dispense with any potential ambiguity. The regulations appropriately and explicitly define manufacturer as the holder of the national drug code number and the entity responsible for setting the WAC for the drug.[14] In the case of the Irbesartan and Losartan products, that is the Appellant. Under Appellant's reading of the statutes, any drug product could escape the reporting requirements of the CTRx program so long as it was distributed by a subsidiary of the company that produced the drug product. This would be an absurd result considering the intent of the CTRx program.[15] Ultimately, Appellant does not argue that the reporting mandates of the statute are limited to a narrow reading of the term manufacturer, and it concedes that the associated regulations do apply to Appellant and the drug products it sells.

4. As additional grounds for good cause for its late reports, Appellant alleges it never received OSHPD's notice of proposed rulemaking or its December 20, 2019, courtesy notice. However, Appellant does not allege that OSHPD's notice of rulemaking, addressed to Appellant, was legally deficient. As to the courtesy notice, there is nothing in the statutes codifying the CTRx program, or the accompanying regulations, that requires a courtesy notice or any affirmative action by OSHPD to a drug manufacturer before it is responsible for filing a WAC quarterly increase report. Any delay in a courtesy notice from OSHPD, receipt of an incomplete courtesy notice, or failure to receive such a courtesy notice at all, whatever the cause, cannot be relied upon to excuse a failure to file a timely report.

5. Likewise, although cited by Appellant as a basis for its delay, Appellant's interactions with the OAG are entirely independent of its obligation to report WAC pricing to OSHPD, and irrelevant to the determination of any good cause for delay in such reporting. Appellant chose to commence the processes to produce subpoena responses to the OAG and report to OSHPD

[14] Cal. Code Regs. tit. 22, § 96060 *et seq*.
[15] Cal. Health & Saf. Code §127676.

concurrently though did not report to OSHPD until it had responded to the subpeona. The substantiated facts show that Appellant was concerned with the disclosure of confidential or proprietary information. Appellant asserted that it did not produce the reports to OSHPD first because of is confidentiality concern and because it considered the subpoena a priority due to the possibility of legal sanctions. However, the confidentiality concerns did not apply to the delinquent reports because OSHPD's regulations clearly state that a "manufacturer may limit the information provided…to that which is otherwise in the public domain…."[16]

6. Lastly, Appellant contends that the penalties are too high and that its profit from the drug products in the quarters where it failed to provide the required reports should be the limit of any penalty. Generally, a penalty must have some reasonable relation to the harm, and a penalty well in excess of the harm could be considered prohibitively high.[17] How any manufacturer accounts for net profit or loss on the sales of its products over a short period is not a reliable measure of harm and therefore not a reasonable basis for a good cause reduction of penalties as to this program. Expenses and revenues can be accounted for in different ways that can shift the profit or loss shown over subsets of time. Where, as in this case, only a narrow period of net profit and loss information is available, it cannot serve as the basis for a reduction in the penalty for good cause.

7. In contrast, the gross sales produced by a drug's sales into California during Appellant's period of non-compliance does offer a more reliable quantitative measure of the upper limits of the harm that may be cause by a failure to report. Except in limited circumstances, such as where a price increase causes a collapse of the market, the quantitative harm of an undisclosed WAC price increase will not exceed the gross sales generated by the drug's sales. The record as to Appellant's sales of Irbesartan and Losartan products into California during the period it failed

[16] Cal. Code Regs. tit. 22, § 96070(c).
[17] *Simon v. San Paolo U.S. Holding Co., Inc.* (2005) 35 Cal.4th 1159, 1179-1180.

to provide the required reports is limited and incomplete in this case. However, there is some evidence that the $1,000 per day penalty mandated by code may have exceeded the gross sales of these drug products into California.

8. Appellant provided testimony and documentation showing the gross sales total of the Irbesartan products into California was $768,649 for the second quarter of 2019. With the exception of one WAC price increase on May 1st, all of the WAC price increases for the Irbesartan products took effect in early to mid-April, and therefore would have been in place for most of the second quarter of 2019. That amounts to average daily sales of approximately $8,540.54 during the quarter. Given that Appellant generally sells to wholesalers and resellers, and that WAC price increases on the Irbesartan products ranged from 211% to nearly 700%, with 6 of the 12 increases in excess of 600%, the $8,540.54 value almost certainly understates the daily gross sales following the WAC increases. However, greater detail and sales volume information for later quarters is not available in the record. Using this conservative value, the daily gross sales for the Irbesartan products amounts to 71% of the statutory daily penalty of $12,000 per day for the late reports on 12 Irbesartan products.

9. Appellant provided testimony and documentation showing the gross sales total of the Losartan products was $160,875 for the third quarter of 2019. All of the WAC price increases for the Losartan products took effect on July 15th, and therefore would have been in place for most of the third quarter of 2019. That amounts to average daily sales of approximately $1,787.50 during the quarter. Given that the WAC price increases on Losartan products ranged from 790% to over 931%, the $1,787.50 value again almost certainly understates the daily gross sales following the WAC increases. Again, greater detail and sales volume information on the Losartan products for later quarters is not available in the record. Using this conservative value, the daily gross sales for the Losartan products amounts to 45% of the statutory daily penalty of $4,000 per day for the late reports on 4 Losartan products.

10. The civil penalties assessed against Appellant are as required by the CTRx statutes and are not grossly disproportional to the quantifiable harm.[18] However, good cause may exist considering common sense and the underlying purpose of the statutory scheme,[19] even if the penalties are not prohibitive. Here the penalties appear to exceed Appellant's sales into the state, and as such would be more than sufficient to incentivize reporting compliance under the CTRx program. Appellant has also recognized and does not contest its reporting obligations under the CTRx program in this instance and in the future. Given these facts, good cause exists for a modest reduction of the penalties.

CONCLUSION

For the reasons set forth above, Appellant has established good cause for reduction of the assessed penalty on the failure to report WAC increases on the Irbesartan products to 71% of the original penalty, for a total penalty of $2,939,400. Appellant has also established good cause for reduction of the assessed penalty on the failure to report WAC increase on the Losartan products to 45% of the original penalty, for a total of $455,400.

[18] *City and County of San Francisco v. Sainez* (2000) 77 Cal.App.4th 1302, 1322.
[19] *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

ORDER

The assessed penalties are reduced to $2,939,400 and $455,400, respectively, for good cause.

Dated: September 29, 2021

//original signed//

ELIZABETH A. LANDSBERG
Director
Office of Statewide Health Planning and Development