

BEFORE THE  
DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION  
STATE OF CALIFORNIA

In the Matter of the Penalty Issued to:

**VISTAPHARM INC.**

Appellant.

HCAI No. 21-030-Q1

**PROPOSED DECISION**

This matter was heard before Michelle Church-Reeves, Hearing Officer, Department of Health Care Access and Information (“HCAI”), successor to the Office of Statewide Health Planning and Development (“OSHPD”),<sup>1</sup> State of California, on Wednesday, March 16, 2022, beginning at 10:32 a.m. PDT.

HCAI was represented by Geoffrey Trautman, Attorney. Dionne Evans-Dean, Staff Services Manager II, Cost Transparency in Prescription Drug Pricing (“CTR<sub>x</sub>”) Section, Jacob Rivera, Staff Services Manager I, CTR<sub>x</sub>, and Rodney Garcia, Associate Governmental Program Analyst for CTR<sub>x</sub>, were also present on behalf of HCAI.

VistaPharm Inc., “Appellant,” was represented by Samantha Kirkland, Sate License Servicing, Inc., contractor for Appellant, Ivan Cartagena, VistaPharm Vice President for Technical Operations, Noel Greenburger, Vertice Chief Commercial Officer, and James Farley, Vertice Senior Business Analyst. VistaPharm was acquired by Vertice Pharma in 2015.

Both documentary and testamentary evidence was received. The matter was submitted

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<sup>1</sup> Stat. 2021, Ch. 143 (A.B. 133), §§ 30, 31.

for decision and the record was closed on Wednesday, March 16, 2022, at 11:26 a.m. PDT.

### PROCEDURAL FINDINGS

1. On October 4, 2021, HCAI assessed a penalty against Appellant in the amount of \$18,000 for the late filing of its quarterly Wholesale Acquisition Cost (“WAC”) Increase Report.
2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated October 18, 2021 and received via email by the Hearing Office on October 18, 2021.
3. Appellant submitted its appeal within the required thirty days from the date of the penalty notice.<sup>2</sup>
4. The hearing was held electronically using videoconferencing at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.
5. HCAI submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 14 were found to be authentic and relevant; and admitted to the record.
6. Appellant submitted a written statement to the Hearing Office and HCAI at the time of appeal. The written statement was found to be authentic and relevant; and admitted to the record.

### FACTUAL FINDINGS

1. Prior to the CTRx program implementation, Appellant was mailed the Notice of Proposed Rulemaking.<sup>3</sup> Appellant did not dispute its receipt.
2. On or about January 7, 2021, a representative for Appellant, Walter Ayala, registered with the CTRx program.<sup>4</sup> He was advised at the time that he should “add at least one additional, authorized user to the CTRx system.”

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<sup>2</sup> Health & Saf. Code, § 127681(f).

<sup>3</sup> Exhibits 1 and 2.

<sup>4</sup> Exhibits 3, 4, and 5.

3. On or about February 10, 2021, Appellant submitted a New Drug Report.<sup>5</sup>
4. On or about July 9, 2021, HCAI sent a reminder email to Appellant's primary contact, Mr. Ayala, for the Saturday, July 31, 2021, due date.<sup>6</sup>
5. On or about July 30, 2021, Appellant contacted Mr. Garcia and requested that Walter Ayala be removed as the primary contact for Appellant and replaced by James Farley. Mr. Garcia updated Appellant's registration at approximately 12:13 p.m. PDT and confirmed that Mr. Farley had access for Appellant at approximately 1:50 p.m. PDT on Friday, July 30, 2021.<sup>7</sup>
6. At approximately 6:49 a.m. PDT on Monday, August 2, 2021, Mr. Farley logged in and updated his user profile.<sup>8</sup>
7. On or about August 18, 2021, Appellant submitted the quarterly WAC Increase Report at issue.<sup>9</sup>
8. Appellant was required under Health and Safety Code section 127679 to file its WAC Increase Quarterly Report for Donnatal Elixir by Saturday, July 31, 2021, at 11:59 p.m. Pacific Time.<sup>10</sup> Penalties accrued from August 1, 2021 until August 18, 2021 when the report was filed.
9. In accordance with Health and Safety Code section 127679, subsection (e), HCAI assessed penalties in the amount of \$1,000 per day for 18 days, resulting in a total penalty amount of \$18,000.<sup>11</sup> The Penalty Notice was transmitted to Appellant on October 4, 2021. Ms. Schneider of State License Servicing, Inc. contacted Mr. Garcia that same day to ask why the emailed report was not accepted. Mr. Garcia responded that he was unable to submit a report on behalf of a manufacturer.<sup>12</sup>
10. These facts were substantiated both by oral statements made under oath by Mr. Garcia at the hearing and written exhibits.

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<sup>5</sup> Exhibit 5.

<sup>6</sup> Exhibit 6.

<sup>7</sup> Exhibits 8 and 9.

<sup>8</sup> Exhibit 10.

<sup>9</sup> Exhibit 12.

<sup>10</sup> *See also* Cal. Code Regs., tit. 22, § 96071.

<sup>11</sup> Health & Saf. Code, § 127679. *See also* Cal. Code Regs., tit. 22, § 96080.

<sup>12</sup> Exhibit 13. *See also* Cal. Code Regs., tit. 22, § 96078.

11. Under Health and Safety Code section 127679, subsection (f), a penalty may “be reviewed on appeal, and the penalty may be reduced or waived for good cause.”
12. 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.
13. Appellant testified that it was aware of, registered with, and participating in the CTRx program prior to the report at issue. Appellant further testified that the CTRx team was not able to reassign login credentials prior to close of business on Friday, July 30, 2021. Appellant included an emailed spreadsheet with its communications with HCAI on Friday July 30, 2021, which it argued fulfilled the filing requirements as it was submitted in the Department’s format. Appellant further testified that Mr. Farley was unable to add its report preparer, Jennifer Schneider, for several weeks after he was granted access.
14. Appellant further testified that its previous representative, Mr. Ayala, left employment on or about May of 2021.
15. These facts were substantiated by oral statements made under oath by Ms. Kirkland at the hearing and written exhibits.
16. The initial statements of both parties were not rebutted.
17. Mr. Garcia further testified that he had no reason to believe the emailed spreadsheet was lacking data elements or materially different from the data that was submitted on August 18, 2021. The emailed spreadsheet was not attached to the exhibits submitted by either party.

## 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 its Donnatal Elixir quarterly WAC Increase Report by July 31, 2021, and whether the penalty should be reduced or waived.
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.”<sup>13</sup> 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.<sup>14</sup> However, good cause is not limited to the listed reasons, or to factors outside the control of the party. 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.<sup>15</sup>

3. A party’s diligence is a factor in determining good cause for an extension or a delay.<sup>16</sup> The substantiated facts show that Appellant was aware that its reports were coming due through its own processes. However, Appellant’s primary contact left employment and Appellant took no steps to update its contact information with the CTRx program until Friday, July 30, 2021, the day before the report at issue was due. HCAI staff acted on Appellant’s request to change its primary contact that same day and within normal business hours, albeit at approximately 4:50 p.m. EDT. Appellant further testified it made a good faith effort to comply with law by submitting the required information via email. In addition, Appellant testified has always acted in good faith; it registered with the CTRx program before its first reports were due and timely filed one previous report. This testimony was not rebutted and is credible.

4. However, Mr. Farley also accessed the filing system on behalf of Appellant on Monday, August 2, 2021, but Appellant failed to submit the report at issue for more than two weeks. Appellant merely offered that Mr. Farley had difficulty adding Ms. Schneider to the system as its only explanation for the additional delay between August 2, 2021 and August 18, 2021. Nor did

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<sup>13</sup> *Waters v. Super. Ct. of Los Angeles County* (1962), 58 Cal.2d 885, 893 (hereafter *Waters*).

<sup>14</sup> 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.

<sup>15</sup> *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

<sup>16</sup> *People v. Financial Casualty & Surety, Inc.* (2016) 2 Cal.5th 35, 45. See also *Wang v. Unemployment Ins. Appeals Bd.* (1990) 225 Cal.App.3d 412, 420.

Appellant offer any explanation for the delay in submitting its request to update its primary contact between May of 2021 and July 30, 2021. This failure occurred because, although Appellant had months to add additional users and update its primary contact information, it negligently waited until the last minute to do so. For these reasons, Appellant did not establish good cause for its delay.

5. HCAI regulations clearly state that CTRx reports “shall be submitted to the Office through the Office's website using the report submission portal at <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/>.”<sup>17</sup> Appellant did email the information in good faith, and there is no evidence which indicates that that email did not contain the elements required by statute. However, this did not comply with HCAI regulations. Furthermore, the fact that the report at issue was eventually submitted online using the CTRx system makes it clear that Appellant was aware that submitting the report via email was not an authorized submission method, and Appellant provided insufficient justification for the additional delay.

6. These facts taken together demonstrate that the circumstances which contributed to the late filing were largely within the Appellant’s control. Therefore, Appellant has not demonstrated good cause for a reduction or waiver of the \$18,000 penalty.

## CONCLUSION

For the reasons set forth above, the \$18,000 penalty assessed against Appellant for failure to timely file the quarterly WAC Increase Report for Donnatal Elixir by July 31, 2021 is upheld.

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<sup>17</sup> Cal. Code Regs., tit. 22, § 96078(a).

PROPOSED ORDER

The assessed penalty is upheld.

Dated: April 22, 2022

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MICHELLE L. CHURCH-REEVES  
Hearing Officer  
Department of Health Care Access and Information

DECISION

Pursuant to California Code of Regulations, Title 22, Section 96087, after due consideration of the record, the Proposed Decision is:

Accepted

Rejected

Dated: April 29, 2022

//original signed//

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ELIZABETH A. LANDSBERG  
Director  
Department of Health Care Access and Information