

April 6, 2021

To whom it may concern,

Company Name: Nichi-Iko Pharmaceutical Co., Ltd.

(Securities Code: 4541, Tokyo Stock Exchange)

Representative: Dr. Yuichi Tamura, President & CEO

Contact: Mr. Hiroshi Mogami, Head of Corporate Communication Department

**Notification of Resumed Operations  
for Manufacturing and Distribution of Pharmaceutical Products by Nichi-Iko  
and Manufacturing of Pharmaceutical Products by the Toyama Plant 1**

Nichi-Iko Pharmaceutical Co., Ltd. (“Nichi-Iko”) and our Toyama Plant 1 (“the Plant”) have served our full term of business suspension based on the administrative disposition order. Nichi-Iko has resumed its operation for manufacturing and distribution of the pharmaceutical products from March 29, 2021 and the Plant resumes its manufacturing operation of the pharmaceutical products from April 6, 2021.

Nonetheless, we will continuously and carefully evaluate quality of our products manufactured at the Plant, utilizing one of risk evaluation methodologies called FMEA\* etc. And upon consultations with Pharmaceuticals and Medical Devices Agency (PMDA) and Toyama prefectural government, we will resume manufacturing and distribution accordingly.

We deeply apologize once again to all stakeholders, including patients, their families, and medical personnel for causing great concerns and inconvenience on this matter.

We will thoroughly comply with laws, ordinances and the related pharmaceutical regulations, and as a company that provides medical drugs contributing to the health of patients and their families, all board members and every employee of Nichi-Iko Group are determined to seriously and sincerely engage in recurrence prevention measures and quality improvement activities and to make every effort to regain trust from all people.

\*FMEA (Failure Mode and Effect Analysis) is a technique to eliminate or mitigate risks as much as possible in advance by evaluating risks inherent in a product and/or process from its product and/or process design phases. Even ICHQ9 recommends FMEA as a risk evaluation method and it is widely used for risk assessment by pharmaceutical companies.

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