

# Investigation Report on China's Prothrombin Complex Concentrate (PCC) Market, 2019-2023

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## Abstracts

### DESCRIPTION

Hemophilia is an X-linked recessive hemorrhagic disease. It is classified into hemophilia A, a deficiency in clotting factor VIII and hemophilia B, a deficiency in clotting factor IX. Both hemophilia A and hemophilia B are caused by gene mutations.

There is no racial or regional difference in the incidence of hemophilia. In the male population, the incidence of hemophilia A is about 1/5,000, and the incidence of hemophilia B is about 1/25,000. Of all hemophiliacs, patients with hemophilia A account for 80% to 85% and patients with hemophilia B account for 15% to 20%. Hemophilia is rarely seen in women. Because of economic factors and other factors, the incidences of hemophilia vary greatly from one country to another and even vary greatly from one period to another in the same country. It is estimated that there were more than 100,000 hemophiliacs in China at the end of 2018. And most of them failed to receive timely treatment because they had no ability to pay.

Prothrombin complex concentrate (PCC) is made from healthy human plasma. Made up of clotting factors II, VII, IX and X, PCC has been on the global market for more than 50 years. In earlier years, PCC was used to treat hemophilia B. In recent years, with the development of medical technologies and the accumulation of clinical experience, the indications and demand for PCC are expanding.

In China, PCC has been approved to:

(1) prevent and treat bleeding caused by the deficiency in clotting factors II, VII, IX or X, for example, the bleeding caused by hemophilia B, severe liver diseases (acute severe

hepatitis, cirrhosis, etc.), disseminated intravascular coagulation (DIC) and surgeries;

- (2) reverse the bleeding induced by anticoagulants such as coumarins and indandione;
- (3) prevent and treat the bleeding in patients who have hemophilia A and have produced inhibitory antibodies against clotting factor VIII;
- (4) treat newborn babies who have secondary vitamin K deficiency and those who take broad-spectrum antibiotics in severe bleeding or preoperative preparation; and
- (5) treat diphacinone sodium salt poisoning.

According to CRI's market survey, the market size of PCC kept rising after the drug was launched in China. In 2017, it reached about CNY 70 million, representing a CAGR of about 25.90% from 2013 to 2017. PCC is only sold in the dosage form of injection in China. As PCC production requires high technologies, China prohibits the import of PCC and there are few manufacturers of PCC in China, China's PCC market is highly concentrated with CR5 of more than 90%. In 2017, Hualan Biological Engineering Inc. took up the largest share of China's PCC market. Its market share was about 55% by sales value and about 63% by sales volume. The other major market players were Shandong Taibang Biological Products Co., Ltd., China Meheco Xinxing Pharma Co., Ltd., etc.

CRI expects that as the numbers of hemophiliacs and patients with severe liver diseases continue to increase and medical expenses become more affordable to Chinese people with China's economic growth, China's PCC market will have huge growth potential from 2019 to 2023. The high profit rate of PCC is attracting more competitors to the market. For example, in Aug. 2019, Boya Bio-pharmaceutical Group Co., Ltd. announced that its PCC was under the priority review of the Center for Drug Evaluation of China's National Medical Products Administration (NMPA CDE) and was expected to be launched in China in one to two years.

## **TOPICS COVERED:**

Incidences of hemophilia and severe liver diseases in China

Supply of and demand for PCC in China

Competition on China's PCC market

Prices of PCC in China

Major factors influencing the development of China's PCC market

Prospect of China's PCC market from 2019 to 2023

## Contents

### **1 RELEVANT CONCEPTS OF PCC**

- 1.1 Indications for PCC
- 1.2 Development of PCC in China
- 1.3 Patents and Government Approval on PCC in China

### **2 SALES OF PCC IN CHINA, 2013-2017**

- 2.1 Sales Value of PCC
  - 2.1.1 Overall Sales Value
  - 2.1.2 Sales Value in by Region
- 2.2 Sales Volume of PCC
  - 2.2.1 Overall Sales Volume
  - 2.2.2 Sales Volume by Region
- 2.3 Sales of PCC by Dosage Form in China, 2013-2017
  - 2.3.1 Injections
  - 2.3.2 Development Trend of Dosage Forms

### **3 ANALYSIS ON MAJOR PCC MANUFACTURERS IN CHINA, 2013-2017**

- 3.1 Analysis on Market Share of Major PCC Manufacturers
  - 3.1.1 Market Share by Sales Value
  - 3.1.2 Market Share by Sales Volume
- 3.2 China Meheco Xinxing Pharma Co., Ltd.
  - 3.2.1 Enterprise Profile
  - 3.2.2 Sales of PCC by China Meheco Xinxing Pharma Co., Ltd. in China
- 3.3 Shanghai RAAS Blood Products Co., Ltd.
- 3.4 Hualan Biological Engineering Inc.
- 3.5 Shandong Taibang Biological Products Co., Ltd.
- 3.6 Guizhou Taibang Biological Products Co., Ltd.
- 3.7 Potential Competitors

### **4 PRICES OF PCC IN CHINA, 2017-2018**

- 4.1 China Meheco Xinxing Pharma Co., Ltd.
- 4.2 Shanghai RAAS Blood Products Co., Ltd. (Prothorass)
- 4.3 Hualan Biological Engineering Inc. (KangShuNing)

4.4 Shandong Taibang Biological Products Co., Ltd.

4.5 Guizhou Taibang Biological Products Co., Ltd.

## **5 PROSPECT OF CHINA'S PCC MARKET, 2019-2023**

5.1 Factors Influencing Development of China's PCC Market

5.1.1 Driving Forces and Market Opportunities

5.1.2 Threats and Challenges

5.2 Forecast on Market Size

5.3 Forecast on Market Trend

## Selected Charts

### SELECTED CHARTS

Chart Patents on PCC in China  
Chart Government Approval on PCC in China  
Chart Sales of PCC in China, 2013-2017  
Chart Sales Value of PCC in Parts of China, 2013-2017  
Chart Sales Volume of PCC in China, 2013-2017  
Chart Sales Volume of PCC in Parts of China, 2013-2017  
Chart Sales Value of PCC Injections in China, 2013-2017  
Chart Market Share of Top 5 PCC Manufacturers by Sales Value, 2013-2017  
Chart Market Share of Top 5 PCC Manufacturers by Sales Volume, 2013-2017  
Chart Sales Value of PCC by China Meheco Xinxing Pharma Co., Ltd., 2013-2017  
Chart Sales Volume of PCC by China Meheco Xinxing Pharma Co., Ltd., 2013-2017  
Chart Sales Value of PCC by Shanghai RAAS Blood Products Co., Ltd., 2013-2017  
Chart Sales Volume of PCC by Shanghai RAAS Blood Products Co., Ltd., 2013-2017  
Chart Prices of PCC by China Meheco Xinxing Pharma Co., Ltd. in Parts of China, 2017  
Chart Prices of PCC by Shanghai RAAS Blood Products Co., Ltd. in Parts of China, 2017  
Chart Prices of PCC by Hualan Biological Engineering Inc. in Parts of China, 2017  
Chart Prices of PCC by Shandong Taibang Biological Products Co., Ltd. in Parts of China, 2017  
Chart Prices of PCC by Guizhou Taibang Biological Products Co., Ltd. in Parts of China, 2017  
Chart Forecast on Sales Value of PCC in China, 2019-2023

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