Cross-industry organizations

An update from the Inhalation Drug Delivery Association (IDDA) of the Chinese Society of Particuology

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On behalf of the IDDA of the Chinese Society of Particuology

Founding of the IDDA

The Inhalation Drug Delivery Association (IDDA) was formally established in Nanjing, China on November 18, 2013. In 2018, it was officially incorporated into the professional committee of inhaled particles of the Chinese Society of Particuology (CSP). The members of the alliance mainly include experts and scholars who have rich experience in research and development, production and clinical application of inhaled drugs. They work in drug research and development and production enterprises, universities, hospitals and other organizations.

The IDDA is a national non-profit organization, guided by the relevant drug laws, regulations and policies formulated by national government agencies. Its goals include promoting development of the inhalation drug administration industry in China, improving domestic R&D for inhaled drugs, working on product technical standards and clinical applications, and accelerating integration with the international inhalation industry. The alliance actively promotes the overall development of the inhaled drug delivery industry in China by mobilizing domestic resources for drug research, drug production, quality control and clinical applications.

Recent activities

Since 2013, the IDDA has organized four conferences covering topics related to inhalation technology. In addition, the IDDA is maintaining its cooperative communication with the China Food and Drug Administration Center for Drug Evaluation (CFDA CDE) and the Chinese Pharmacopeia Commission (ChP) to promote inhaled drug regulation and quality requirements for international standards.

The implementation of the Chinese national "4+7" policy (a purchasing policy) highlights the value of pharmaceutical preparations with high technical barriers. Inhaled drugs are one of the dosage forms on which domestic pharmaceutical companies focus. The *in vitro* and *in vivo* consistency evaluations for inhaled generic drugs, especially the *in vivo* bioequivalence study, have been the main bottleneck for inhaled drug development. Therefore, to exchange and share experiences about the equivalence of inhaled generic drugs *in vivo*, the National Federation of Inhaled Drug Delivery was scheduled to hold the academic seminar "Consistency Evaluation and Bioequivalence Study of Inhaled Generic Drugs" in Beijing, April 19-20, 2019. Well-known experts and scholars from China and abroad were invited to give special reports and presentations during the conference.

Future plans

The IDDA intends to organize teams of experts to improve inhalation drugs, quality control, equipment selection, characteristics of drugs and drug compliance in patients. It also plans to share information with clinical physicians about various available formulations, advantages and disadvantages of different inhaled technologies, and the correct use of inhalers by patients. Through these communications, the IDDA hopes to reach consensus on clinical research, improve regulations and promote the continuing development of the inhalation product industry in China.

Additional major plans for 2019 include:

- Working with the National Institutes for Food and Drug Control (NIFDC) and the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) to jointly organize a presentation on pharmaceutical bioequivalence studies and IVIVC for an OINDP seminar to be held in October 2019 in Beijing.
- Preparation of a scientific journal on inhalation, scheduled to be published quarterly.
- Actively participating in the scientific research evaluation activities of the Chinese Society of Particuology and cultivating research talents in the field of inhalation.

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Statistics on Asthma and COPD in China

In mainland China, which has a population of 1.4 billion, a variety of factors are considered major causes of human respiratory diseases. These include the increasing population in Chinese cities, large numbers of people smoking cigarettes (more than 350 million smokers and 150 million people who suffer from second-hand smoke), use of motor vehicles, rapid industrial expansion and worsening environmental pollution.

Asthma

- There were more than 32 million asthma patients in 2017 and the incidence of asthma in the total population has been increasing at 4% per year.[1,2]
- Among young persons below 14 years of age, 3.7% suffer from asthma.[1, 2]
- For the last 10 years, asthma cases have increased in those aged 14 years and older.[2]

COPD

- The number of COPD cases in China is very high, with 100 million patients in 2017.[3]
- Among smokers, the incidence of COPD was 13.7% and more than double the prevalence in non-smokers.[2, 3]
- The incidence of COPD was greater than 40% for smokers over 60 years of age and 25% for smokers over 40 years of age.[3]

Inhaled products and the market[2, 4]

Due to the continuous increase in asthma and COPD, there has been an average growth in drug treatment of more than 20% for the past five years. The total inhaled drug market in China was approximately $2.2 billion USD in 2017. Products from GSK, AstraZeneca, Boehringer Ingelheim and other international pharmaceutical companies account for 80% of the total market. The main branded inhaled drugs were:

- Pulmicort Respules® (budesonide) AstraZeneca
- Symbicort® (budesonide/formoterol fumarate dihydrate) AstraZeneca
- Seretide® Accuhaler® (fluticasone propionate/salmeterol) GlaxoSmithKline
- Spiriva® HandiHaler® (tiotropium bromide) Boehringer Ingelheim
- Atrovent® HFA (ipratropium bromide HFA) Boehringer Ingelheim
- Combivent® Respimat® (ipratropium bromide/albuterol) Boehringer Ingelheim
- Ventolin® HFA (albuterol sulfate) GlaxoSmithKline

In addition, approximately 100 local pharmaceutical companies are becoming involved in this market.[2]

In the regulatory area, the China Food and Drug Administration (CFDA) issued a new regulation in 2016 requiring a linked filing registration for drug packaging, excipients and drug products. It is expected this will pose a major challenge for local Chinese companies.

References

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4. Menet Report on Respiratory Products, 2018.