Issues and challenges faced in the implementation of Track and Trace system for pharmaceuticals in Chinese Taipei

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Outline

- Our Track and Trace system
- Issues and Challenges faced by TFDA
- Difficulties faced by stakeholders
- Progress and Prospect

Track and Trace system

Regulations of Track and Trace

- **Pharmaceutical Affairs Act** (Article 6-1)
- **Regulations Governing the Trace and Track System for Medicinal Products.** (Announced in 2016)

Applicable objects of the regulations

- The medicinal products **license holders** i.e. local manufacturers or importers.
- The **distributors** engaged in business of pharmaceutical **wholesaling**.

Declare Information

by license holders

1. Pharmaceutical manufacturing or importing information

(1) Name of the medicinal product, license number, indication, dosage form, ingredients, name of pharmaceutical company, name and address of manufacturer recorded on the medicinal product license.

(2) Bar code or other symbol for identification purpose.

(3) Batch number.

(4) Quantity.

(5) Manufacture date.

(6) Expiry date or shelf life.

(7) Import date.

Declare Information

by license holders

2. The information of active ingredient

(1) The source of active ingredient.

(2) Name, address and nation of manufacturer.

Declare Information

by license holders

3. Information regarding flow of medicinal product

(1) Name, address, contact person and telephone number of receptor.

(2) Name of medicinal product.

(3) Batch number.

(4) Quantity.

(5) Manufacture date.

(6) Expiry date or shelf life.

(7) Delivery date.

Declare Information

by Distributors

1. Information regarding supplier of medicinal product

(1) Name, address, contact person and telephone number of supplier.

(2) Name of the medicinal product and license number.

(3) Batch number.

(4) Quantity.

(5) Manufacture date.

(6) Expiry date or shelf life.

(7) Received date.

Declare Information

by Distributors

2. Information regarding flow of medicinal product

(1) Name, address, contact person and telephone number of receptor.

(2) Name of the medicinal product and license number.

(3) Batch number.

(4) Quantity.

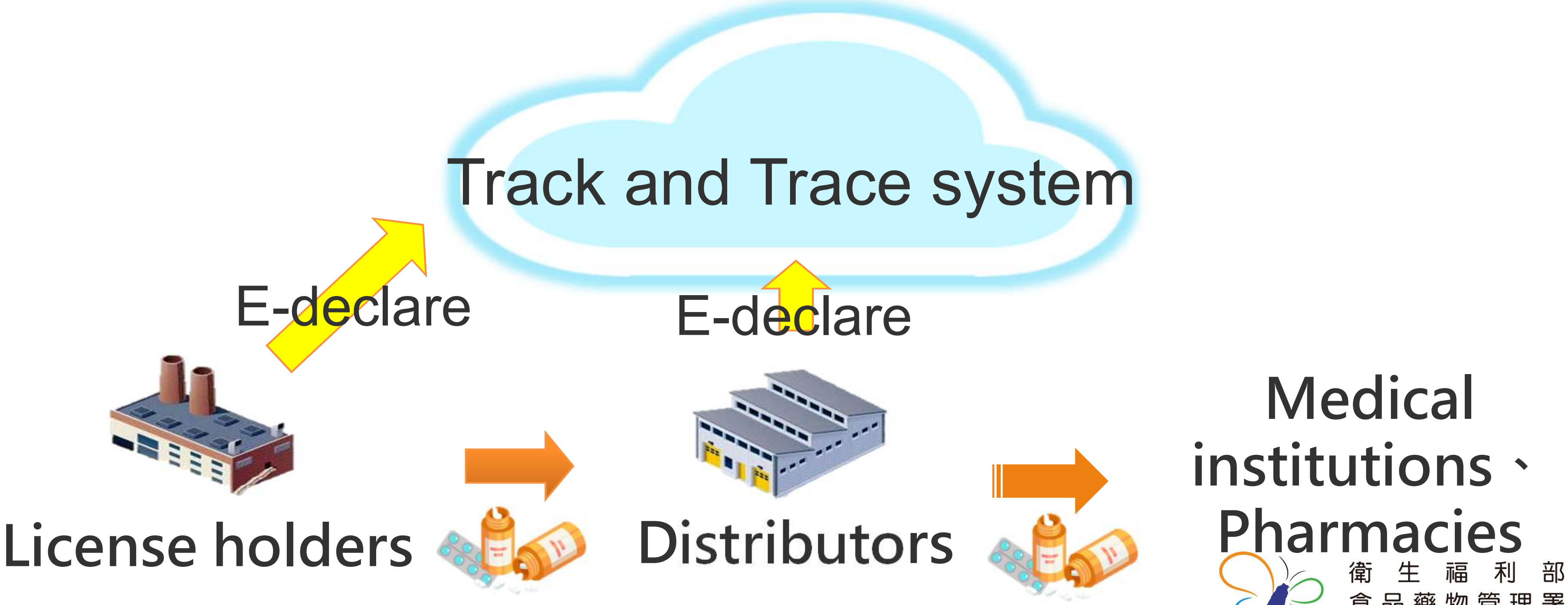
(5) Manufacture date.

(6) Expiry date or shelf life.

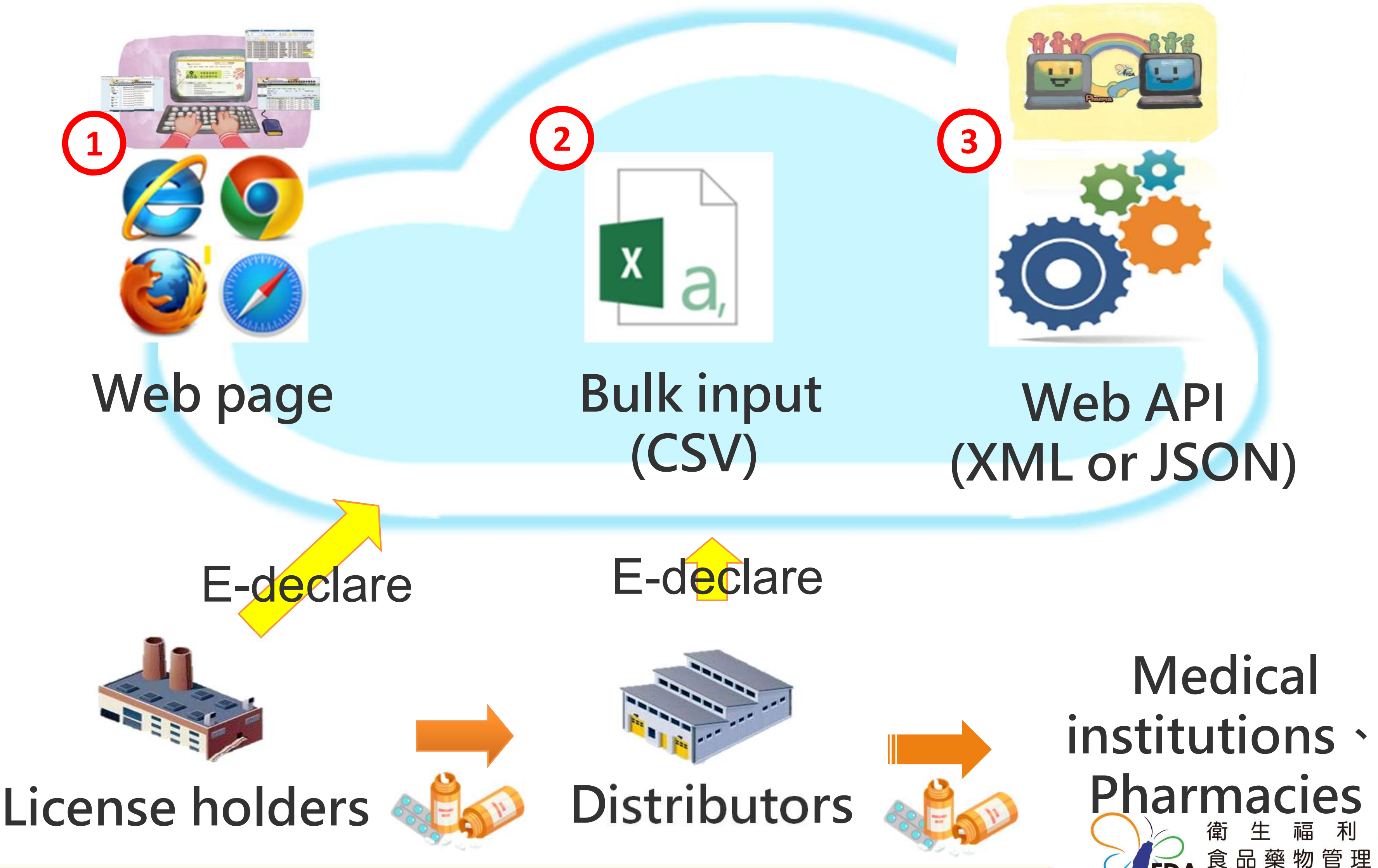
(7) Delivery date.

Track and Trace system

- Established in 2016.
- The medicinal products license holders and distributors engaged in business of pharmaceutical wholesaling are required to declare the tracking and tracing information electronically every month(before the 10th of each month).


Track and Trace system
E-declare
E-declare
License holders
Distributors
Medical institutions、Pharmacies

Diverse ways to declare



① Web page

② Bulk input (CSV)

③ Web API (XML or JSON)

E-declare

E-declare

License holders

Distributors

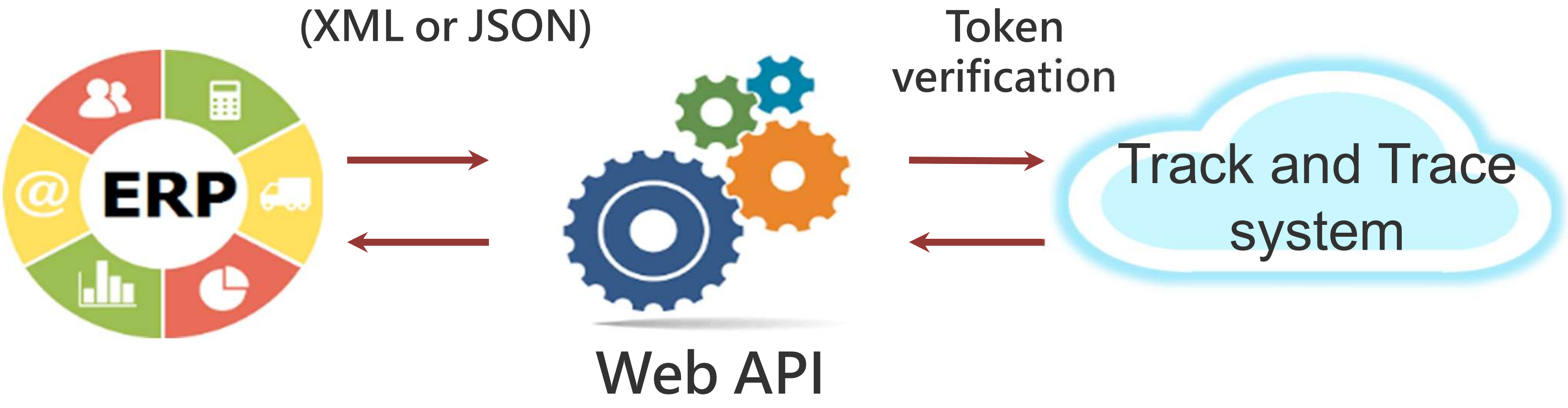
Medical institutions、Pharmacies

Automatic declaration mechanism

declare through Web API

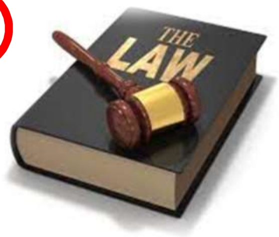
① apply for API Key & Security Key

② Use API Key & Security Key to obtain Token


(XML or JSON)
Token verification
ERP
Web API
Track and Trace system

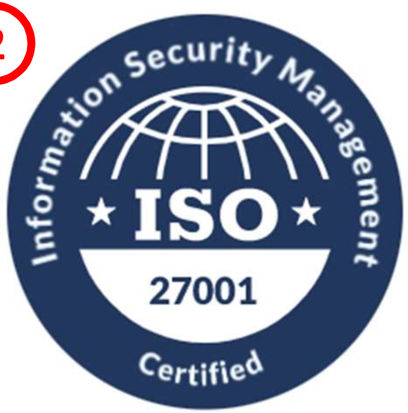
Information security management

①



Cyber Security Management Act

②

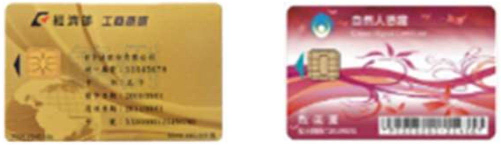

Information Security Management
ISO
27001
Certified

certified since 2020

Track and Trace system

E-declare

③



login verification

Business certificate

Issues and Challenges faced by TFDA

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- Prioritizing Applicable Categories

Prioritizing Applicable Categories

- Considering the wide variety of drugs, it may be necessary to implement track and trace system step by step.
- Prioritization is a big Challenge.

➢ Implemented according to regulatory objectives.

TFDA‘s Regulatory objectives of track and trace system

① Monitor the source and flow of drugs

② Prevent counterfeit drugs from entering the legal supply chain

Track and Trace

③ Avoid illegal use of legal drugs

④ Strengthen supply management of important reserve medicines

①Monitor the source and flow of drugs

- First three priority categories based on risk

Plasma derivative

Vaccine

Botulinum toxin

- implemented since July 1st, 2017

② Prevent counterfeit drugs from entering the legal supply chain

high concern drug

- ▲ **Due to the counterfeit Crestor event in 2017.**
- ▲ **Use the national health insurance data to select 50 drugs which are more likely to be counterfeited as pilot category.**

principle of selection

1. High usage

2. High price $

20 high concern drug items
Implemented on January 1, 2018

30 high concern drug items
Implemented on July 1, 2018

Amend of high concern drug items
Implemented on October 31, 2019

③ Avoid illegal use of legal drugs

Category of drug	Implementation date	Purpose
preparations containing pseudo-ephedrine or ephedrine	since October 31st, 2019	To avoid it from being used as an ingredient in illegal drugs
Medicinal nitrous oxide	since October 1st, 2020	To prevent it from being used for recreational purposes

④ Strengthen supply management of important reserve medicines

- **In response to the needs of wars and disasters, there are 25 reserve medicines under The Mobilisation of Reserve Medicines and Medical Devices Regulations.**

- **Select the reserve medicines which have been reported about drug shortage in the past two years, or which are also essential medicines.**

1. Bupivacaine 0.5% injection
2. Benzylpenicillin (penicillin G) injection
3. Amoxicillin oral dosage form
4. Epinephrine 1mg/1ml (1:1000) 或 1mg/10ml (1:10000) injection

- **implemented since July 1, 2021**

Difficulties faced by stakeholders

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- Massive declaration information

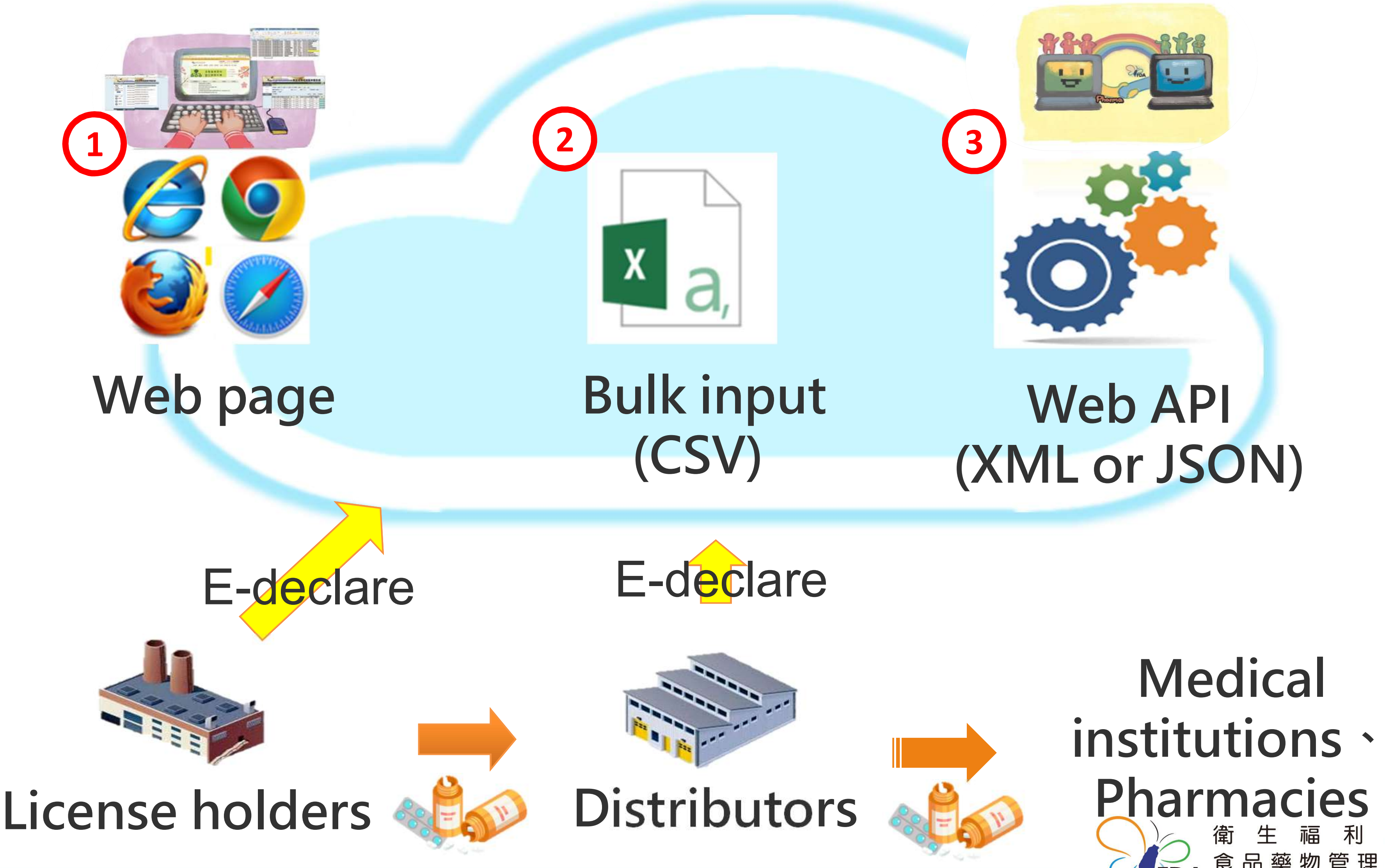
Public meeting

communicate face-to-face with pharmaceutical companies

Increase the willingness to declare

reduce the difficulty of declaration

Diverse ways to declare



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E-declare

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License holders

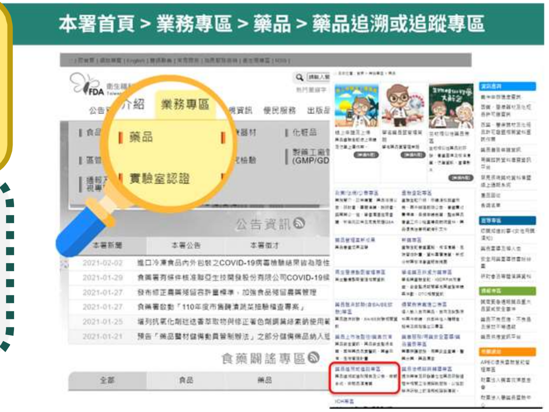
Distributors

Medical institutions、Pharmacies

Training course & Consulting service

Establish special zone of track and trace on TFDA's website

Provide relevant information on declaration operation procedures and FAQs



本署首頁 > 業務專區 > 藥品 > 藥品追溯或追蹤專區

Provide training course

Provide training courses for stakeholders (2-3 times/year)

Provide hotline for consulting service

Proactively remind pharmaceutical companies that have delayed declarations

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Progress and Prospect

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Taiwan Food and Drug Administration

Improve functions of statistical analysis

- **Analyze transaction data, stock quantity, declaration status, etc.**
- **Analyze the flow of the medicinal products and trace the source rapidly (for drug recall efficiently)**
- **Compare declaration differences between upstream and downstream**

Establish functions of early warning

Warning of Risk

- Abnormal transaction volume
- Flow disconnection
- Distributed to illegal institutions (suspension/termination of business)

Effective Management and inspection

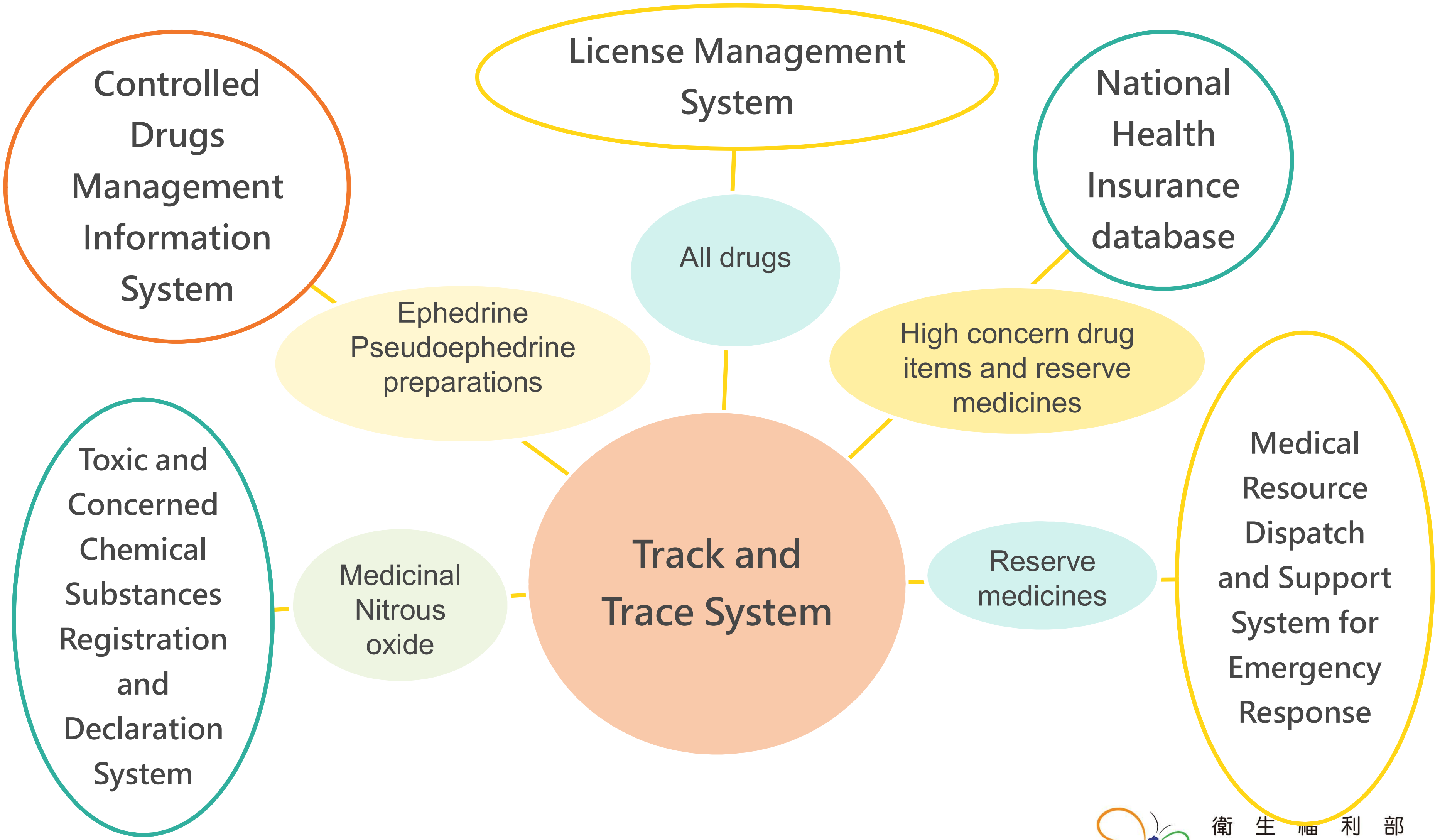
Cooperate with local authority

Find out the abnormal supply by Track and Trace system

Establish screening mechanism for Priority of inspection

Precisely inspect for abnormal situations

Promote collaboration with other systems



License Management System

All drugs

Controlled Drugs Management Information System

Ephedrine Pseudoephedrine preparations

National Health Insurance database

High concern drug items and reserve medicines

Toxic and Concerned Chemical Substances Registration and Declaration System

Medicinal Nitrous oxide

Track and Trace System

Reserve medicines

Medical Resource Dispatch and Support System for Emergency Response

Thank you for your attention

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