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Regulation of Drug Delivery Systems from an Industry Perspective

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Drug Delivery Systems

What is a Drug Delivery System?

In a drug delivery system, the **drug** and **device** components are **combined** to provide a single therapeutic effect in which the **device** component functions solely as the **delivery vehicle** for the drug component.

Source: Issue Identification Paper Drug-Device Combination Products (DDCPs) Draft for Consultation - Date: 2021/05/10

Drug Delivery Systems

A drug delivery system may be:

pre-filled syringe

transdermal drug patch

Combined at time of manufacture:

This type of drug delivery system contains at least one drug and device component that are physically integrated at the time of manufacture.

metered dose inhaler

internal cream and applicator

Co-packaged and combined prior to administration of the drug:

In these drug delivery systems, the components are manufactured separately, co-packaged, and combined prior to administration.

Not always easy to classify!!

Source: Issue Identification Paper Drug-Device Combination Products (DDCPs) Draft for Consultation - Date: 2021/05/10

Drug Delivery Systems – Combined at time of manufacture

Combined at time of manufacture: this type of **drug delivery system** contains at least one drug and device component that are physically integrated at the time of manufacture.

Examples:

- Prefilled syringes
- Patches for transdermal drug delivery
- Implants whose primary purpose is to release a drug product
- Wound dressings whose primary purpose is to deliver a drug
- Dental products impregnated with a drug whose primary purpose is to deliver a drug
- Alcohol-based antiseptic wipes
- Benzalkonium chloride antiseptic wipes

Source: Issue Identification Paper Drug-Device Combination Products (DDCPs) Draft for Consultation - Date: 2021/05/10
Drug and Medical Device Combination Product Decisions – Date: 2024/09/13

Drug Delivery Systems – Combined at time of manufacture

- **Question:**

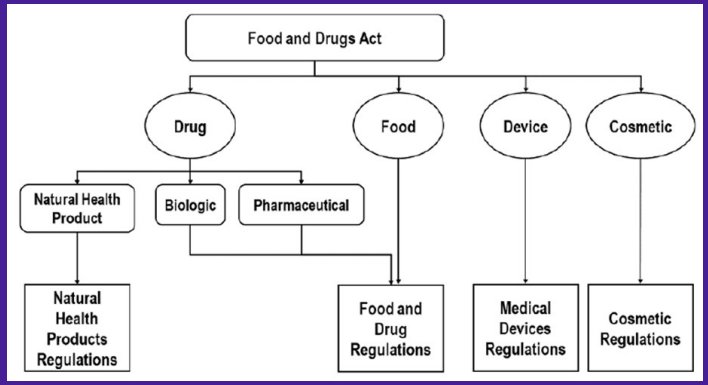
  How are these examples of "combined at time of manufacture" drug delivery systems regulated?

- **Answer:**

  Considered to be **Drug-Device Combination Products (DDCPs)** per the *Policy on Drug/Medical Device Combination Products (October 20,1998)*

A DDCP is a health product that combines one or more **drug components** (where "drug" could mean pharmaceutical, biologic or natural health product) with one or more **medical device components** (which by themselves would be classified as a drug or a device), such that the distinctive nature of the drug component and device component is **integrated in a singular product.**

Source: Policy on Drug/Medical Device Combination Products – Date: 1998/10/20
Drug and Medical Device Combination Product Decisions – Date: 2024/09/13



Reminder:

For any product that is determined to be a DDCP, the entire product is regulated under one single regulatory pathway, according to the **principal mechanism of action** by which the claimed effect or purpose is achieved:

- *Food and Drug Regulations* OR
- *Natural Health Products Regulations* OR
- *Medical Devices Regulations*

Drug Delivery Systems – Combined at time of manufacture

For all of these examples of drug delivery systems, the drug and medical devices are **combined at the time of manufacture** in a way that they cannot be used separately = physically integrated into a single product = **DDCP.**

The **principal mechanism of action** = drug or NHP

Therefore, these **drug delivery system DDCPs** will be subject to only the *Food and Drug Regulations* OR *Natural Health Products Regulations* (and they are not subject to the *Medical Devices Regulations*).

Examples:

- Prefilled syringes = *Food and Drug Regulations*
- Patches for transdermal drug delivery = *Food and Drug Regulations*
- Implants whose primary purpose is to release a drug product = *Food and Drug Regulations*
- Wound dressings whose primary purpose is to deliver a drug = *Food and Drug Regulations*
- Dental products impregnated with a drug whose primary purpose is to deliver a drug = *Food and Drug Regulations*
- Alcohol-based antiseptic wipes = *Natural Health Products Regulations*
- Benzalkonium chloride antiseptic wipe = *Food and Drug Regulations*

Source: Policy on Drug/Medical Device Combination Products – Date: 1998/10/20
Drug and Medical Device Combination Product Decisions – Date: 2024/09/13

Drug Delivery Systems – Co-packaged

Co-packaged and combined prior to administration of the drug: in these **drug delivery systems**, the components are manufactured separately, co-packaged, and combined prior to administration.

- **Question:**
  How are "co-packaged" drug delivery systems regulated?
- **Answer:**
  NOT AN EASY ANSWER!

Health Canada published the *Draft guidance on co-packaged drug products* for public consultation on March 18, 2025.

Health Canada published the resulting *What we heard: Draft guidance on co-packaged drug products* on October 27, 2025:

"Stakeholders requested that final guidance outline clearer criteria for distinguishing between drug kits, convenience kits, and DDCPs…..For example, it was noted that **drugs co-packaged with a medical device delivery system (such as a syringe) are sometimes classified as DDCPs and, in other cases, as drug kits with a convenience component…"**

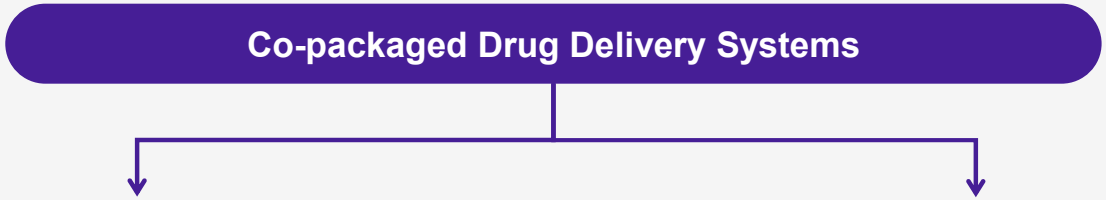
Source: Draft guidance on co-packaged drug products for public consultation – Date: 2025/03/18
What we heard: Draft guidance on co-packaged drug products – Date: 2025/10/27

Drug Delivery Systems - Co-packaged

Question:

How are “co-packaged” drug delivery systems regulated?

Answer:



Considered to be a drug-device combination product (**DDCP**):

- Entire product is only subject to ONE *Regulation* (e.g., *Food and Drug Regulations*)
- Only ONE registration (e.g., DIN or NPN) required that includes all components

Considered to be a **Convenience Pack:**

- Entire product is subject to MORE THAN ONE *Regulation* (each component is subject to their applicable *Regulation*)
- MULTIPLE registrations required as each component within the product is independently registered (e.g., DIN and Medical Device Licence(s))

Drug Delivery Systems - Co-packaged

- **Question:**

  When is a “co-packaged” drug delivery system considered to be a DDCP?

- **Answer:**

  For a “co-packaged” drug delivery system to be classified as a DDCP, **all** of the following three (3) criteria **must be met**:

  - The drug and device must be used **concurrently**;
  - The drug and device should form **a unique combination** that is required to achieve the intended use, indication or effect of the product; and
  - The **device** component **cannot be reused** after the original co-packaged **drug is exhausted.**

Drug Delivery Systems - Co-packaged

- **Question:**

  When is a “co-packaged” drug delivery system considered NOT to be a DDCP (and therefore considered to be a convenience pack)?

- **Answer:**

  For a “co-packaged” drug delivery system to NOT be classified as a DDCP, at least one of the following three (3) criteria must **NOT** be met:

  - The drug and device must be used **concurrently**;
  - The drug and device should form **a unique combination** that is required to achieve the intended use, indication or effect of the product; and
  - The **device** component **cannot be reused** after the original co-packaged **drug is exhausted.**

BUT ALSO…

Drug Delivery Systems - Co-packaged

Convenience Packs – Other Requirements to be Met:

- The convenience pack must contain market-authorized therapeutic products in their **original packaging and labelling**.

  NOTE: The original packaging and labelling of the delivery medical devices must not be altered!

- They are sold as a **single unit** for the convenience of the user.

- All components included in the convenience pack **are not specific to each other** and **can be substituted**.

Source: Draft guidance on co-packaged drug products for public consultation – Date: 2025/03/18

Drug Delivery Systems - Co-packaged

Convenience Packs – NOTE:

- Each component is regulated **individually** and therefore **individually** registered (e.g., DIN for the drug or drug kit, and a medical device licence for each Class II – IV medical device).
- Each component maintains its original **packaging and labelling** (e.g., needle is provided in its original packaging and labelling).
- The outer convenience pack label must include information about the medical devices within the pack (e.g., device name, device identifier/catalogue #, quantity, manufacturer's name and address).

Source: Draft guidance on co-packaged drug products for public consultation – Date: 2025/03/18

Drug Delivery Systems - Co-packaged

Example #1

Syringe pre-filled with drug + specific needle

DDCP or Convenience Pack?

Fulfill all 3 DDCP criteria? YES

1. The drug and device are be used concurrently? **YES**
2. The drug and device form a unique combination that is required to achieve the intended use, indication or effect of the product? **YES**
3. The device component cannot be reused after the original co-packaged drug is exhausted? **YES**

Fulfill the Convenience Pack criteria? NO

1. The pack only contains market-authorized therapeutic products in their original packaging and labelling?
2. Components are sold as a single unit for the convenience of the user?
3. All components included in the convenience pack are not specific to each other and can be substituted?

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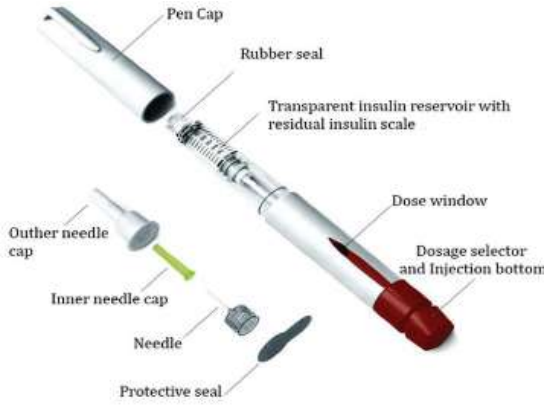
Drug Delivery Systems - Co-packaged

Example #2

Administration pen pre-filled with drug + pen needles



DDCP or Convenience Pack?

Fulfill all 3 DDCP criteria? NO

1. The drug and device are be used concurrently? **YES**
2. The drug and device form a unique combination that is required to achieve the intended use, indication or effect of the product? **NO**
3. The device component cannot be reused after the original co-packaged drug is exhausted? **YES**

Fulfill the Convenience Pack criteria? YES

1. The pack only contains market-authorized therapeutic products in their original packaging and labelling? **YES**
2. Components are sold as a single unit for the convenience of the user? **YES**
3. All components included in the convenience pack are not specific to each other and can be substituted? **YES**

Drug Delivery Systems - Co-packaged

Example #3

Drug kit + device for reconstitution + administration devices

DDCP or Convenience Pack?

Fulfill all 3 DDCP criteria? NO

1. The drug and device are be used concurrently? **YES**
2. The drug and device form a unique combination that is required to achieve the intended use, indication or effect of the product? **NO**
3. The device component cannot be reused after the original co-packaged drug is exhausted? **YES**

Fulfill the Convenience Pack criteria? YES

1. The pack only contains market-authorized therapeutic products in their original packaging and labelling? **YES**
2. Components are sold as a single unit for the convenience of the user? **YES**
3. All components included in the convenience pack are not specific to each other and can be substituted? **YES**

Drug Delivery Systems - Co-packaged

Example #4

Drug vial + specific infusion pump

DDCP or Convenience Pack?

Fulfill all 3 DDCP criteria? NO

1. The drug and device are be used concurrently? **YES**
2. The drug and device form a unique combination that is required to achieve the intended use, indication or effect of the product? **YES**
3. The device component cannot be reused after the original co-packaged drug is exhausted? **NO**

Fulfill the Convenience Pack criteria? YES

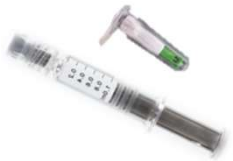
1. The pack only contains market-authorized therapeutic products in their original packaging and labelling? **YES**
2. Components are sold as a single unit for the convenience of the user? **YES**
3. All components included in the convenience pack are not specific to each other and can be substituted? **NO**

Drug Delivery Systems – Co-packaged

Example Summary

	The drug and device must be used concurrently?	The drug and device should form a unique combination that is required to achieve the intended use, indication or effect of the product?	The device component cannot be reused after the original co-packaged drug is exhausted?	Classification
1	✓	✓	✓	DDCP
2	✓	✗	✓	Convenience Pack
3	✓	✗	✓	Convenience Pack
4	✓	✓	✗	Convenience Pack

1
Syringe pre-filled with drug + specific needle



2
Administration pen pre-filled with drug + pen needles

3
Drug kit + device for reconstitution + administration devices

4
Drug + specific infusion pump

Thank you

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