THE VALUE OF PHARMACEUTICAL EXCIPIENTS

a European perspective

WHAT IS AN EXCIPIENT?

"Any constituent of a medicinal product other than the active substance and the packaging material."
(Article 1(1)(a)3b DIRECTIVE 2011/62/EU on falsified medicinal products)

WHAT ABOUT EXCIPIENTS?

1200

There are more than **1,200 excipients** used in medicines

Those used depend on many factors including the **drug type, route of administration** and **dosage form**

Excipients are diverse materials from many origins, **animal, vegetable** or **mineral**

Many are not exclusive to medicines, but are used widely in **food** and **cosmetic industries**

Whatever their origin, however they are developed, made and handled, excipients **must not compromise quality** or **harm patients**

WHAT CAN EXCIPIENTS DO?

Act as **filler/diluent** for highly potent medicines

Enhance solubility for poorly soluble medicines

Control the rate of drug release and bioavailability

INNOVATION & DEVELOPMENT

Excipients can boost research and innovation into medicines and:

Increase access to new drugs (for poorly soluble, unstable drugs)

Provide alternative routes of delivery and dosage forms (easier to use, taste better)

Improve patient compliance (reduce frequency of dosing, extend duration of action)

It can take **10-15 years for such a new drug formulation** to move from the laboratory to the market

HOW ARE THEY MANUFACTURED?

Excipients are mostly produced on a large scale using traditional chemical or biosynthetic processes

REGULATIONS

Excipient manufacturers in general **are not covered by EU law directly. The manufacturer** of the medicinal product **must ensure excipients and their suppliers are controlled appropriately**

The key EU excipients regulatory references are: **2011/62/EU Falsified Medicines Directive, European Commission Guidelines on Risk Assessment EC2015/C95/02** and **Eudralex Vol 4, Part 1, Chapter 5 Starting Materials**

GMP & QUALITY STANDARDS

Medicines must be safe, effective and of high quality. So all ingredients including **excipients should be made according to Good Manufacturing Practices (GMP)**

Excipients manufacturers may apply standards from a **wide range of markets including food and cosmetics. For medicines,** the voluntary guidance in the **IPEC/PQG GMP Guide is an important reference**

EXCIPIENTS MATTER!

They can represent the biggest part of the medicines (up to 95%)

The patient can consume more excipient than active ingredient

They have an important influence on drug safety

IT IS ESSENTIAL THAT EXCIPIENT MANUFACTURERS, DISTRIBUTORS AND EXCIPIENT USERS COMPLY WITH ALL EXCIPIENTS STANDARDS AND REGULATIONS TO PROTECT PATIENTS

THAT'S THE VALUE EXCIPIENTS BRING TO MEDICINES AND PATIENTS!

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