



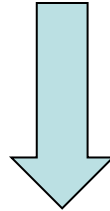
# The Compendium of Pharmaceutical Product: The Past the Present and the Future

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Department of Health

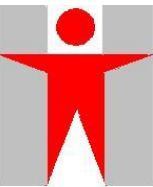
22 November 2010



# The Pharmaceutical Service of Department of Health



## A Drug Record Keeper for 32 Years



# The Past, the Present and the Future

- Register of Pharmaceutical Products
- Compendium of Pharmaceutical Products
- Electronic Health Record



# Register of Pharmaceutical Products

- History
- Purposes
- Development
- Current status and outlook



# History



# Register of Pharmaceutical Products

## History:

From 1978, all records of registered pharmaceutical products are kept in paper-based

Books of “Register of Pharm. Products” were kept over the years

- Book 1 – HK000001-00900
- Book 2
- Book 3
- .....



REGISTER OF PHARM. PRODUCTS

REG. NO. HK00001-00900





## REGISTER OF PHARMACEUTICAL

Date of Registration	Registration No.	File No.	Name and Address of Applicant
1 JUL 1978	00001	PR 1/78	Advance Pharmaceutical Corporation Ltd. J. Sieling & Co. 3 heung Fai Terrace, 1/F., Causeway 21A, Wah Wing Ind. Bldg., Kwai Chung, H.K.
1 JUL 1978	00002	PR 4/78	Siber Hegner & Co (HK) Ltd Rm 606, Prince's Bldg, H.K.
1 JUL 1978	00003	PR 5/78	"
1 JUL 1978	00004	PR 7/78	Bristol Myers H.K. Squibb (Far East) Ltd. 1, Hyson Avenue, H.K.
1 JUL 1978	00005	PR 8/78	"
1 JUL 1978	00006	PR 9/78	"
1 JUL 1978	00007	PR 2/78	Au Kah Chuen Medicine Factory 867, King's Rd., 1/F., N.P. H.K.
4 JUL 1978	00008	PR 3/78	"
4 JUL 1978	00009	PR 6/78	"

## PRODUCTS

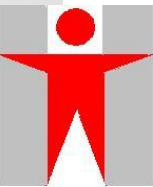
Name of Product	Certificate expired on	Notification sent on	Fee (Cert.) paid	Certificate and Product classification issued on	Remark	Certificate renewed on
Dr. Morse's Indian Root Pills	1 JUL 1983	15-7-78	19-7-78	Part II Poison	Renewed 28.6.1988	Renewed 12.8.1983
Collyre Blue Eye Drops	1 JUL 1983	15-7-78	with drawn	Part I Poison	"	"
Specton Tab	1 JUL 1983	"	"	Not a poison	"	"
Anatensol Inj., 25mg in 1ml	1 JUL 1983	"	19-7-78	P1S1S3 Poison	Renewed 8.6.1988	Renewed 31.5.1983
Anatensol Tab. 1mg.	1 JUL 1983	"	"	P1S1S3 Poison	Renewed 15.6.1988	Renewed 17.6.1983
Anatensol Tablets 2.5mg	1 JUL 1983	"	"	P1S1S3 poison	Renewed 15.6.1988	Renewed 17.6.1983
Au Kah Chuen Fuyical Cream	1 JUL 1983	"	27-7-78	Not a poison	Renewed 6.6.1988	Renewed 18.6.1983
Au Kah Chuen Skin Oint.	1 JUL 1983	"	"	"	Renewed 6.6.1988	Renewed 18.6.1983
Au Kah Chuen Skin Lotion	1 JUL 1983	"	"	Part II Poison	Renewed 6.6.1988	Renewed 18.6.1983





# First Drug Registration

- HK00001
- Registration Date – 14 July 1978
- Applicant - Advance Pharmaceutical Corporation Limited
- Name of Product – Dr. Morse's Indian Root Pills (for blood cleansing)



# Information Kept in the Register

- date of registration
- HK registration number
- file number
- **name and address of applicant\***
- **name of product\***
- expiry date of certificate
- date of sending the notification
- date of fee (certificate) paid
- date of issue of certificate and product classification
- date of certificate renewal

(\*registrable particulars)



# PURPOSES



# PURPOSES

- a registry for all registered pharmaceutical products in Hong Kong
- for checking the registration status of the products, i.e. whether they are registered, renewed or cancelled
- a record on the progress of an application for registration of a product



# Development



# Pharmaceuticals Registration Database

From 1990's to 2002

- Simple Database on PC
- FoxPro
- Single terminal





# From 1990s to 2002

## Available information:

- Registration Date
  - Product Registration No
  - File Reference No
  - **Product Name\***
  - **Registration Holder Name and Address\***
  - **Manufacturer Name and Address\***
  - Pharmacological Classification
  - Forensic Classification
  - Payment Date of Certification
  - **Active Ingredients\***
  - **Others\* (preservatives and colourants)**
- (\* registrable particulars)



# **Current Status and Outlook**



# Pharmaceutical Registration System (PRS) 1.0



First Networked Drug Database of Pharmaceutical Service



# Pharmaceuticals Registration System 1.0

- drug registration data is kept in electronic database
- linked to the Pharmaceuticals Registration System
- internal networked system
- support simple and multiple-criteria search



# Pharmaceuticals Registration System 1.0

Data captured are enriched, including:

- Registration Date
  - Product Registration No
  - File Reference No
  - **Name of Product\***
  - **Dosage Form\***
  - **Certificate Holder Name and Address\***
  - **Manufacturer Name and Address\***
  - Pharmacological Classification
  - Legal Classification
  - Payment Date of Certification
  - **Active Ingredients\***
  - **Inactive ingredients\* (preservatives & colourants)**
- (\* registrable particulars)



# **PRS 2.0**

## **Possible Areas for Improvement**







- Enhancement based on:
  - Review on drug registration requirements and evaluation processes
- To meet territory-wide eHR drug data-sharing requirements
- To enable enriched medicines information search over internet





- Enhancement at data level, to add:
  - Brand (trade) name
  - Active ingredient (salt and/or base) + strength
  - Route of administration
  - Indication + common dosages
  - Pack Size Information
  - Images of Actual Sales Pack & Package Insert for therapeutic drugs



# **COMPENDIUM of Pharmaceutical Products**



# History

- first published in 1995
- published yearly
- CD-Rom available in 2004
- uploaded to internet website in 2005



# Information included in the Compendium:

HK registration no.

Product Name\*

Active Ingredient(s)\*

(\* registrable particulars)



# Purposes of the Compendium

For use by:

- public
  - healthcare professionals
  - traders
- 
- availability of a registered product in HK
  - active ingredient(s) of the product





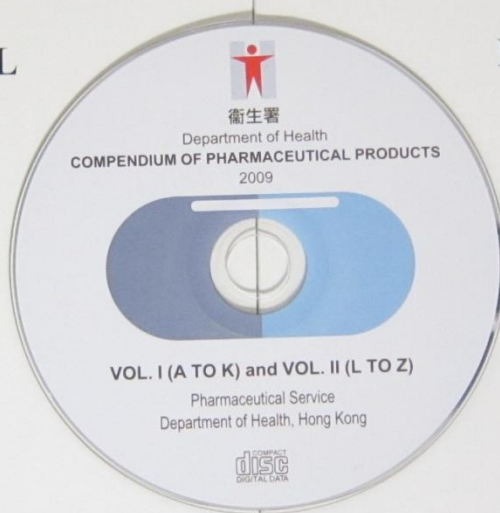


**COMPENDIUM  
OF  
PHARMACEUTICAL  
PRODUCTS  
2009**

**VOL. I**

**A TO K**

Pharmaceutical Service  
Department of Health  
Hong Kong

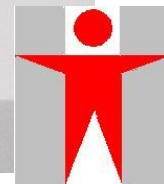


**COMPENDIUM  
OF  
PHARMACEUTICAL  
PRODUCTS  
2009**

**VOL. II**

**L TO Z**

Pharmaceutical Service  
Department of Health  
Hong Kong



Product Name	Active Ingredients	Permit No.
ACADEM EMULSION 25% EXTERNAL	BENZYL BENZOATE	HK-24464
ACADIN TAB 250MG	CLARITHROMYCIN	HK-53106
ACARBAY TAB 100MG	ACARBOSE	HK-56228
ACARBAY TAB 50MG	ACARBOSE	HK-56229
ACARBAY-100 TAB 100MG	ACARBOSE	HK-53928
ACAROSE TAB 50MG	ACARBOSE	HK-57616
ACB POLIBAR POWDER 93%	BARIUM, DIMETHICONE	HK-19226
ACCOLATE 20MG TAB	ZAFIRLUKAST	HK-43720
ACCULOL EYE DROPS 0.5%	BETAXOLOL	HK-51670
ACCUPRIL TAB 10MG	QUINAPRIL	HK-32539
ACCUPRIL TAB 5MG	QUINAPRIL	HK-32540
ACCURE CREAM	DIPHENHYDRAMINE, TRIAMCINOLONE, NEOMYCIN, MICONAZOLE	HK-52824
ACEDOL SYRUP 250MG/5ML	PARACETAMOL	HK-39281
ACEMET CAP 60MG	ACEMETACIN	HK-52308
ACEMET RETARD CAP 90MG	ACEMETACIN	HK-55919
ACEMYCIN INJ 250MG/ML	AMIKACIN	HK-34615
ACEOMEL TAB 12.5MG	CAPTOPRIL	HK-43674
ACEOMEL TAB 25MG	CAPTOPRIL	HK-43675
ACEOMEL TAB 50MG	CAPTOPRIL	HK-43676
ACEPHEN TAB 300MG	PARACETAMOL	HK-38754
ACEPRIN TAB 100MG	ASPIRIN	HK-57543
ACERECUR POWDER	SALICYLIC ACID, BORIC ACID, RESORCINOL, TANNIC ACID	HK-43936
ACEREDERM POWDER	SALICYLIC ACID, BORIC ACID, RESORCINOL, TANNIC ACID	HK-42823
ACERTIL AR TAB 10MG	PERINDOPRIL	HK-57451
ACERTIL AR TAB 5MG	PERINDOPRIL	HK-57450



# **Electronic Health Record**



# Electronic Health Record

- bring the Compendium to a higher level
- integrate with the electronic health record
- provide additional drug information for healthcare providers to support continuous healthcare delivery

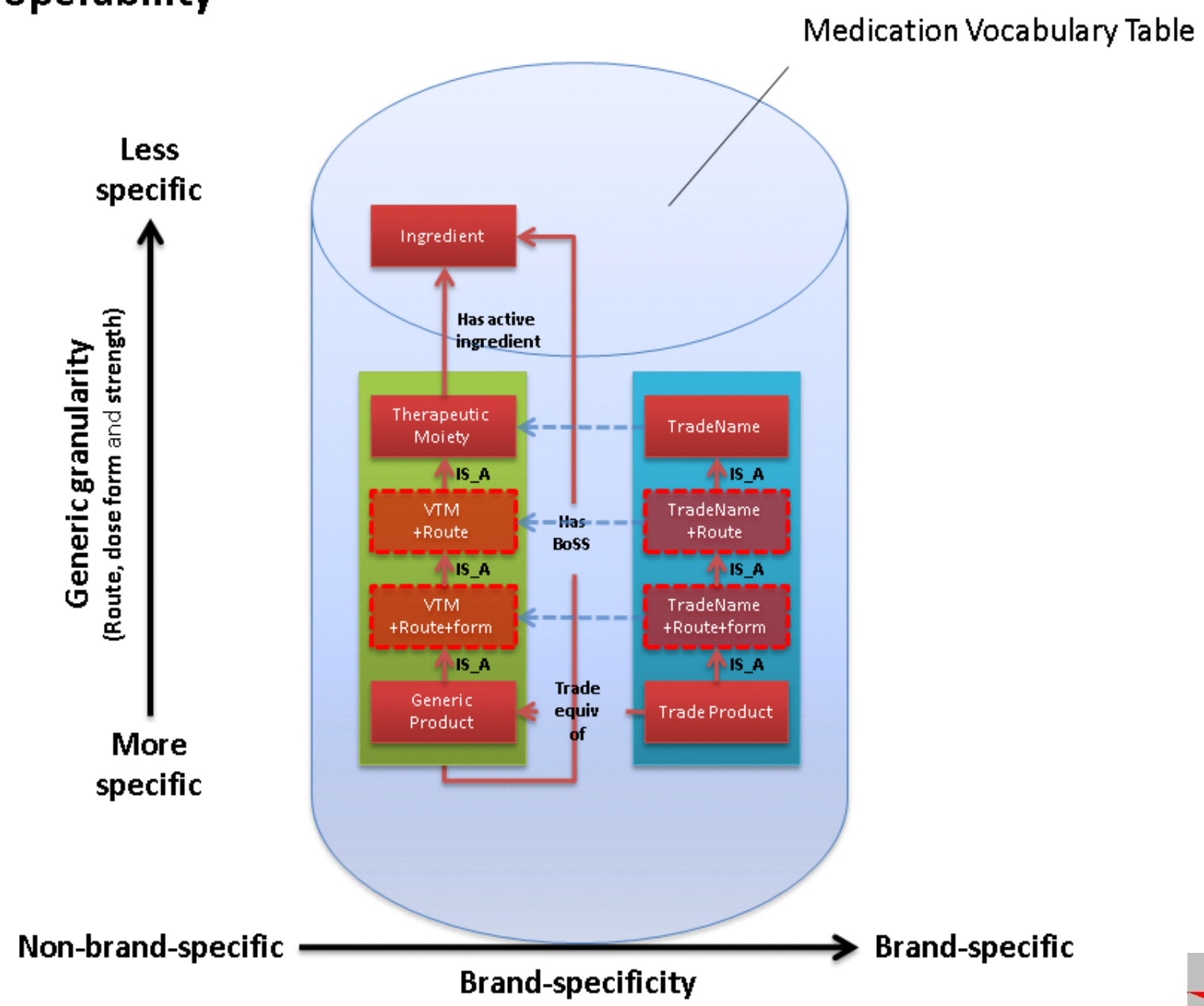


# **Concept of MVT**

## **“Medication Vocabulary Table”**



# Local Interoperability



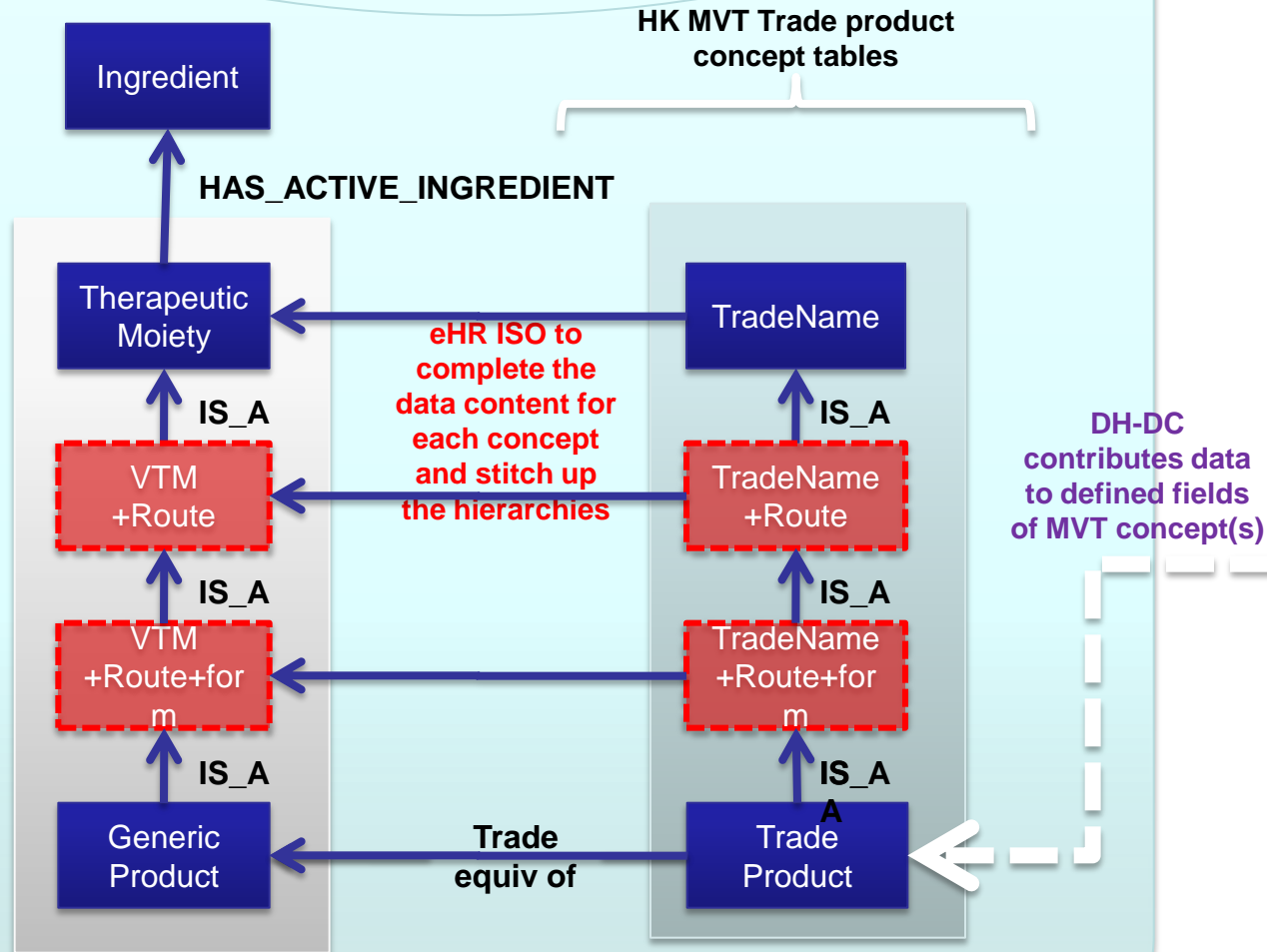
Contributor of drug record may decide to contribute data according to the level of mapping to the MVT table.  
Data granularity allows sharing of more specific drug data



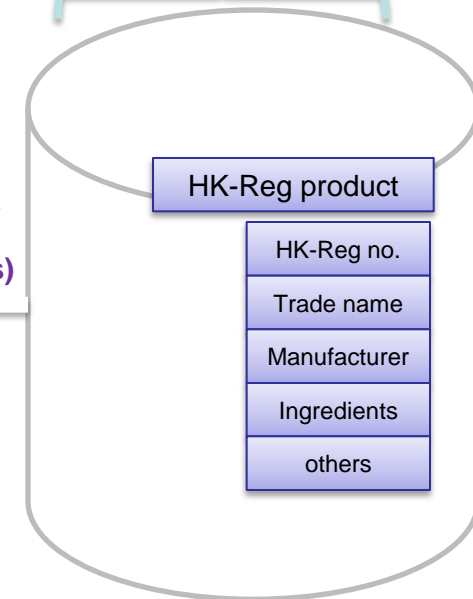


## HK MVT Generic product concept tables

## DH-eHR's Co-Production Model



## DH Drug Compendium



Extracted from "Update on HK Drug standards – 6<sup>th</sup> DH-HA Liaison Meeting 21 July 2010"

The concept tables should support the co-production mechanism from DH's Drug Compendium (the fields or tables which data interface should occur will need further discussion and agreement with DH)





## DoH Drug Compendium

1. New product is registered by DoH

2. New Drug Compendium product record created

### What critical data are required?

3. Selected co-production data interfaced to MVT

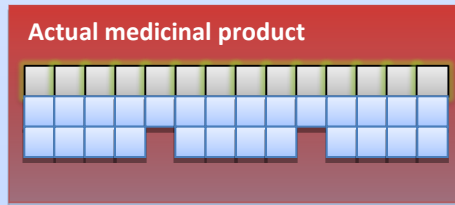
MVT Core Information	MOE-related	Drug-checking

4. eHR ISO to review product information and extract core data, and other data to support MOE-related and drug-checking functions

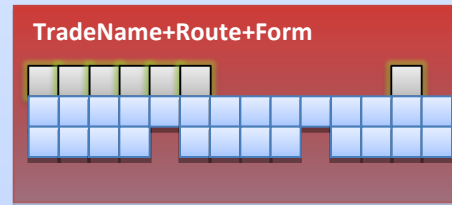
5. MVT utilizes core data elements to create **AMP** concept

6. MVT copies the core data

7. ...to create upstream concepts and define relationships



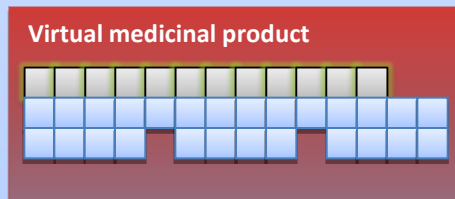
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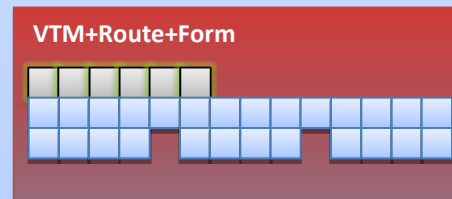
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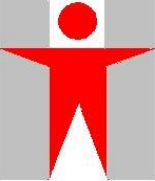
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These structural data elements, as seen in previous meetings, are divided into THREE groups – Core MVT data, MOE-related, and Drug. Within which, we have identified the “critical data” that we should “co-produce” with DH.



# **Critical Data Elements for : Building the MVT**



Critical Data Elements of MVT  
and  
Registration Particulars of Pharmaceutical Product



# Critical Data Elements

1. HK Registration Number
2. Name of Product\*
3. Trade Name
4. Route of Administration\*
  - a. single route of administration
  - b. multiple routes  
e.g. infusion/injection, eye/ear
5. Dose Form\*  
(\* registrable particulars)



# Critical Data Elements

6. Active Ingredient(s)\*
  - a. Single Ingredient
  - b. Multiple Ingredients
7. Strength(s) of Active Ingredient(s)\*
8. Legal Classification
9. Manufacturer Name and Address\*
10. Package Insert Information\*  
(\* registrable particulars)



**MVT**  
**Critical Data**      =      **Registration Particulars**  
**Elements**                      **for Pharmaceutical**  
   **Products**



# Usage of MVT





**Essential for :**

- Prescribing & Dispensing**
- Allergy Checking**
- Drug-drug interaction checking**



# **Working on:**

- **build up critical data elements**
- **verify data**
- **fine-tune user requirements**
- **enable and enhance the value of eHR**



Thank You !

