

CBER/FDA Pharmacological Classification-Rationale

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Introduction

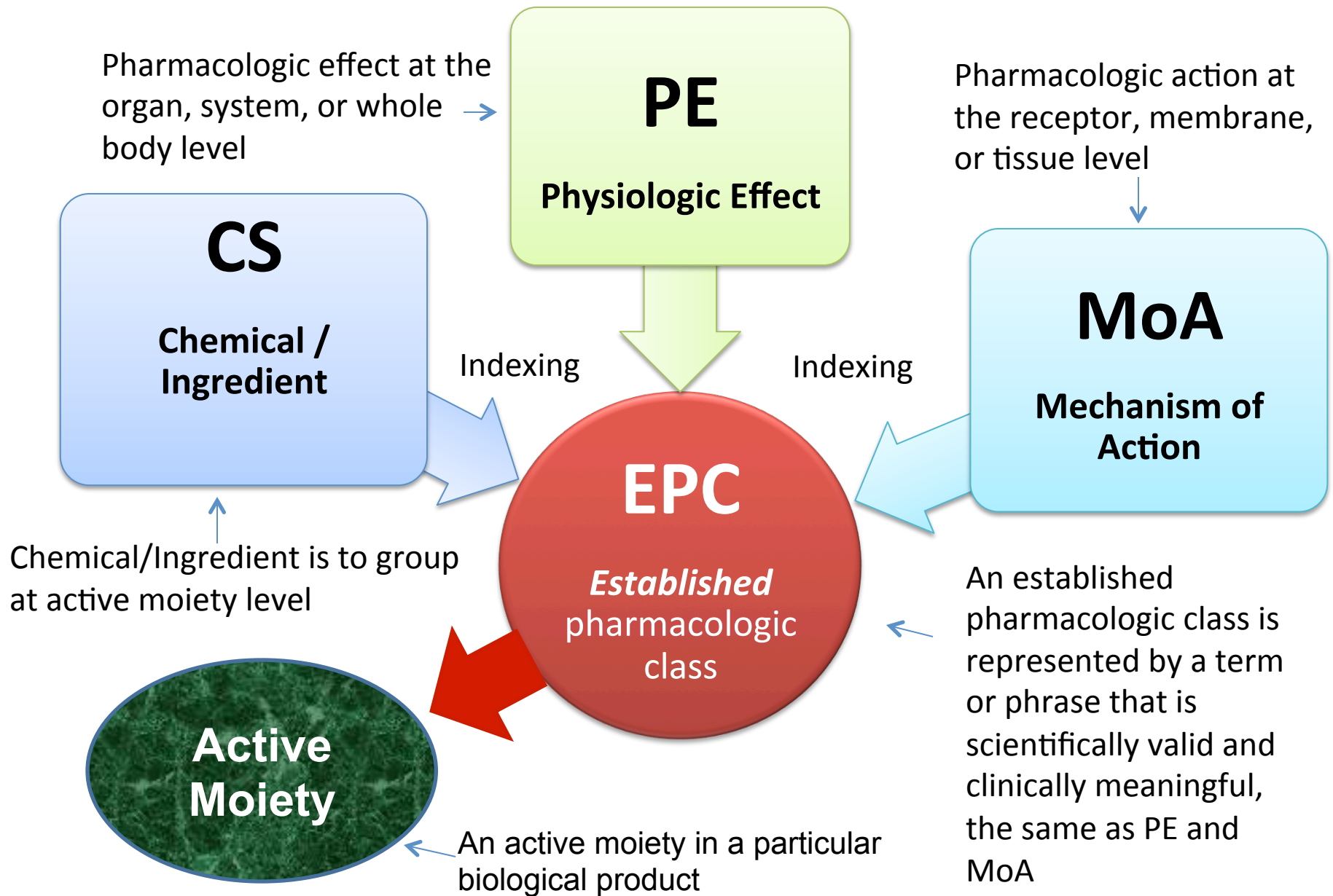
- Structured Product Labeling (SPL) is a document markup standard that defines the content of human drug product labeling in an XML (Extensible Markup Language) format. OD/CBER adopted SPL as a mechanism for exchanging medication information of approved biological products.
- The goal of this project is to index all CBER approved product labels with scientifically valid and clinically meaningful pharmacologic classification concepts, and make this information available on labels.fda.gov and the National Library of Medicine's DailyMed website to improve search functionality across health care systems.
- The Established Pharmacologic Classes can assist health care professionals with important information on what they will generally know about a drug and how the drug might relate to other therapeutic options. Such information can also help reduce the risk of duplicative therapy and drug interactions, as well as provide important treatment information in cases of drug product overdose.

Pharm Class Statistics

1996-2011

Product Category	Number of Products	Number of new active moieties	Number of EPCs	Number of PEs	Number of MoA	Number of C/S
Vaccine	74	104	33	3	0	33
Blood Derivatives	123	85	40	11	8	28
Cell Therapy and Gene Therapy	8	4	4	2	0	8
Non-Standardized Allergenic Extract	~1000	1267	18	3	0	21
Standardized Allergenic Extract	19	24	6	3	0	8
2011 approvals	8	6	5	2	0	12
2012 approvals	1	60	1	2	0	1
Total	1233	1550	107	26	8	111

Pharmacological classification concepts:



General Rationale (cont.)

- A *pharmacologic class* is a group of drugs that share scientifically documented properties.
- What is the rationale to index pharmacologic class in a particular package insert?

For example,

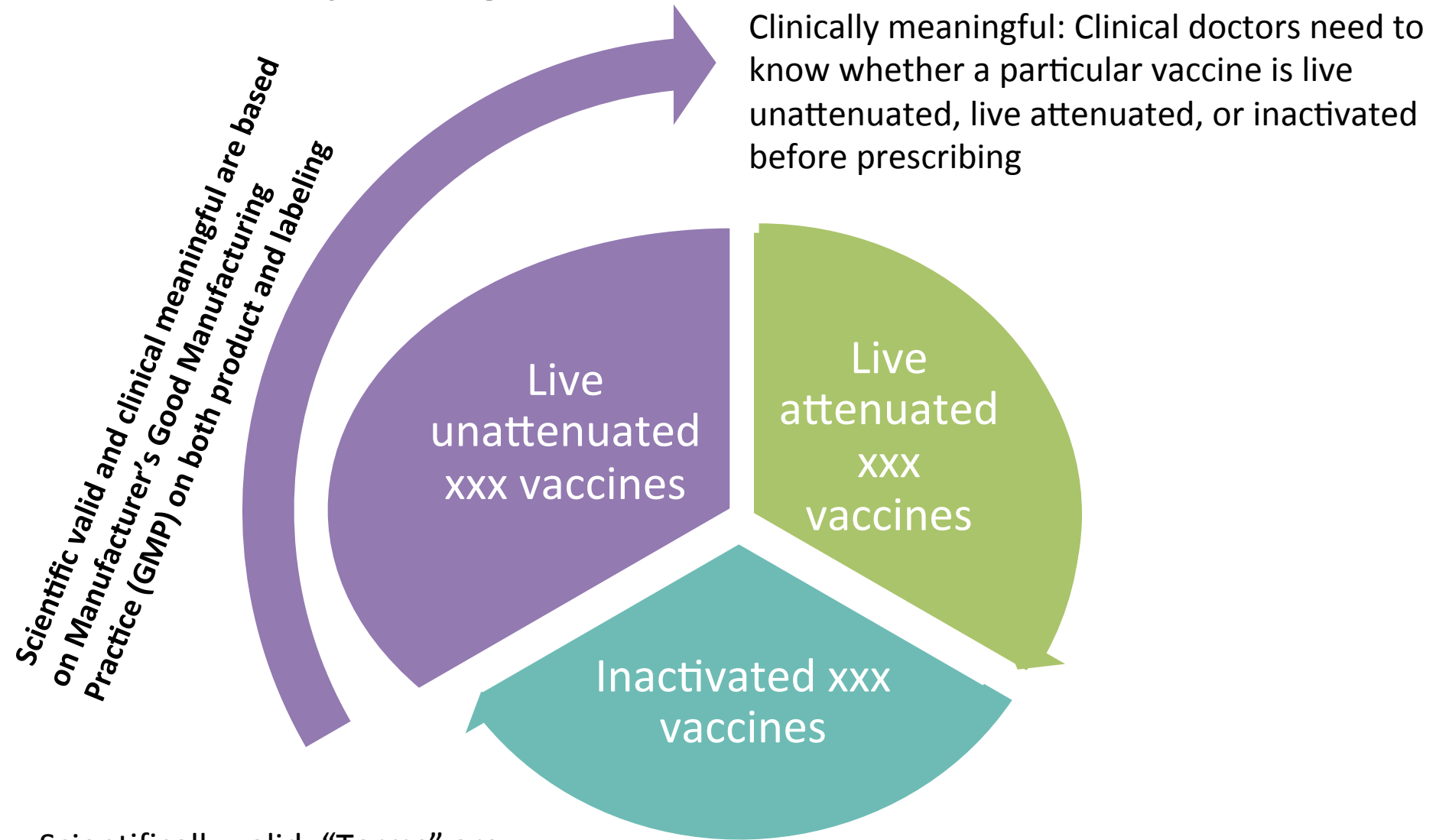
- How to choose an Established Pharmacologic Class (EPC) for a specific active moiety?
 - First need to understand the functionality, mechanism and molecule structure of the active moiety from a particular biological product
 - Search for scientifically valid and clinically meaningful “terms” in:
 - “(Drug) is a (name of pharm class) indicated for (indication(s)).”
 - If there is not enough information above, we need to search Package Insert for Section “Description” and “Section “Clinical Pharmacology”
 - Sometimes, we need to search out for other sources such as PubMed or directly contact the manufacturers .

Vaccine Pharmacological Classification

- Vaccine pharmacological classification groups CBER approved vaccine products (active moiety) by their EPC, PE, MoA and Chemical/Ingredient- an example, BioThrax (Anthrax vaccine)

Active Moiety	FDA UNII	FDA Text Phrase	NDF-RT Concept	NDF-RT NUI	NDF-RT Concept Type
BACILLUS ANTHRACIS STRAIN V770-NP1-R ANTIGEN	873OI62848	live attenuated Bacillus anthracis vaccine	Live Attenuated Bacillus Anthracis Vaccine [EPC]	N0000183903	EPC
BACILLUS ANTHRACIS STRAIN V770-NP1-R ANTIGEN	873OI62848		Actively Acquired Immunity [PE]	N0000183364	PE
BACILLUS ANTHRACIS STRAIN V770-NP1-R ANTIGEN	873OI62848		[MoA] Omitted	N/A	MoA
BACILLUS ANTHRACIS STRAIN V770-NP1-R ANTIGEN	873OI62848		Vaccines, Attenuated [Chemical/Ingredient]	N0000170873	Chemical/Ingredient
BACILLUS ANTHRACIS STRAIN V770-NP1-R ANTIGEN	873OI62848		Anthrax Vaccines [Chemical/Ingredient]	N0000170890	Chemical/Ingredient

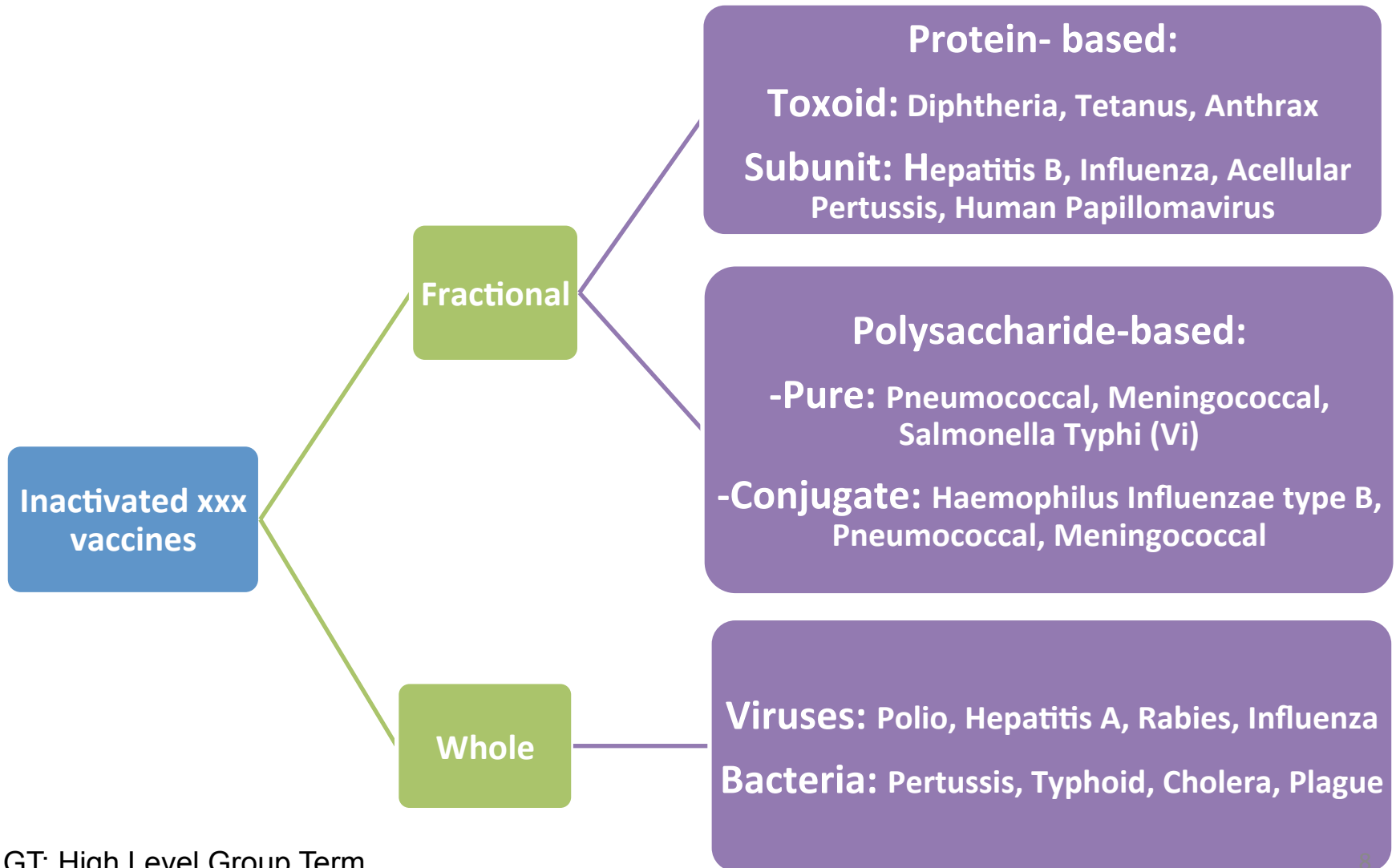
Vaccines have 3 EPC terms both scientifically valid and clinically meaningful



Scientifically valid: “Terms” are documented in scientific publications, MeSH, and empiric evidence

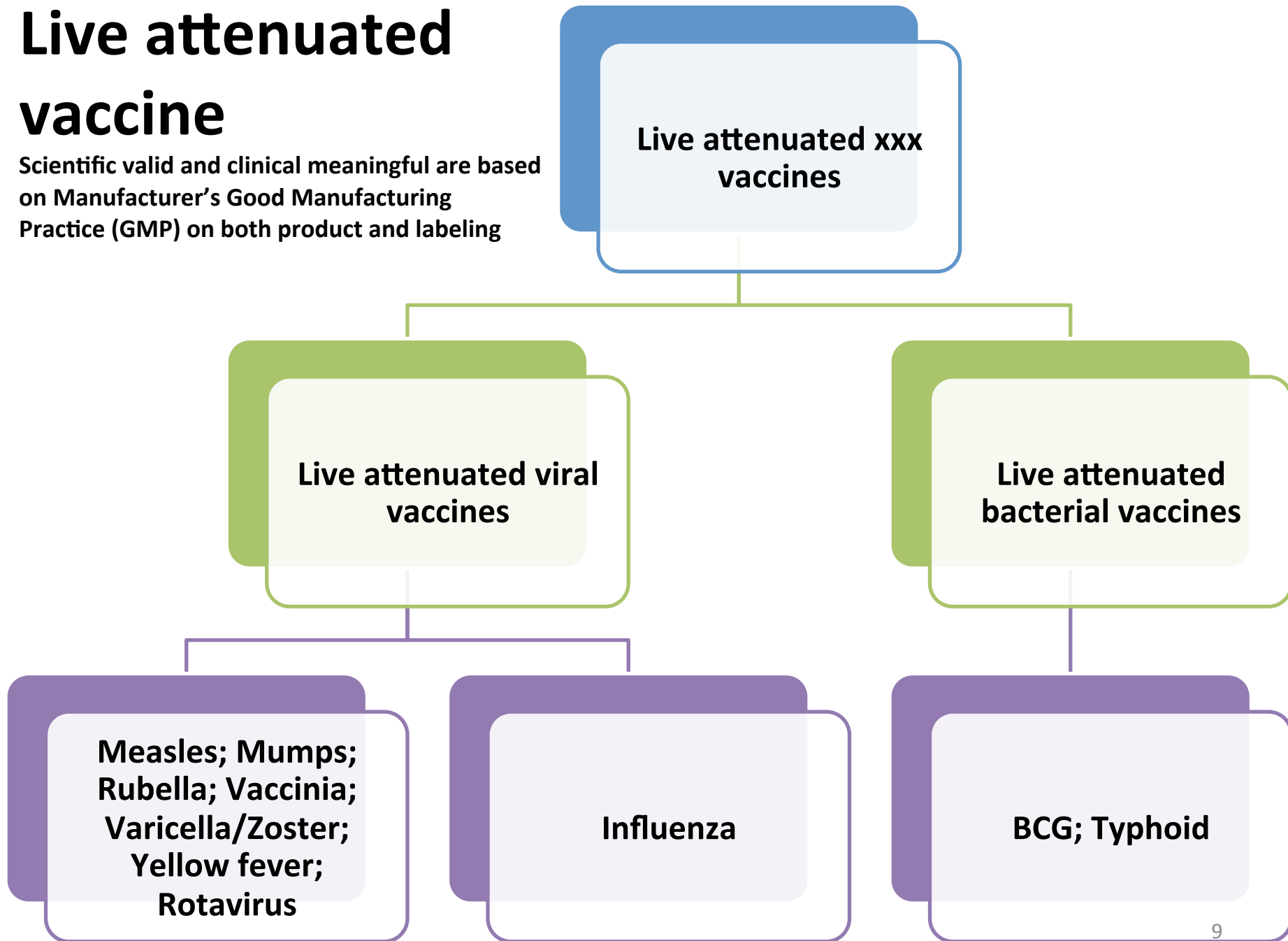
Inactivated xxx vaccine

Scientific valid and clinical meaningful are based on Manufacturer's Good Manufacturing Practice (GMP) on both product and labeling



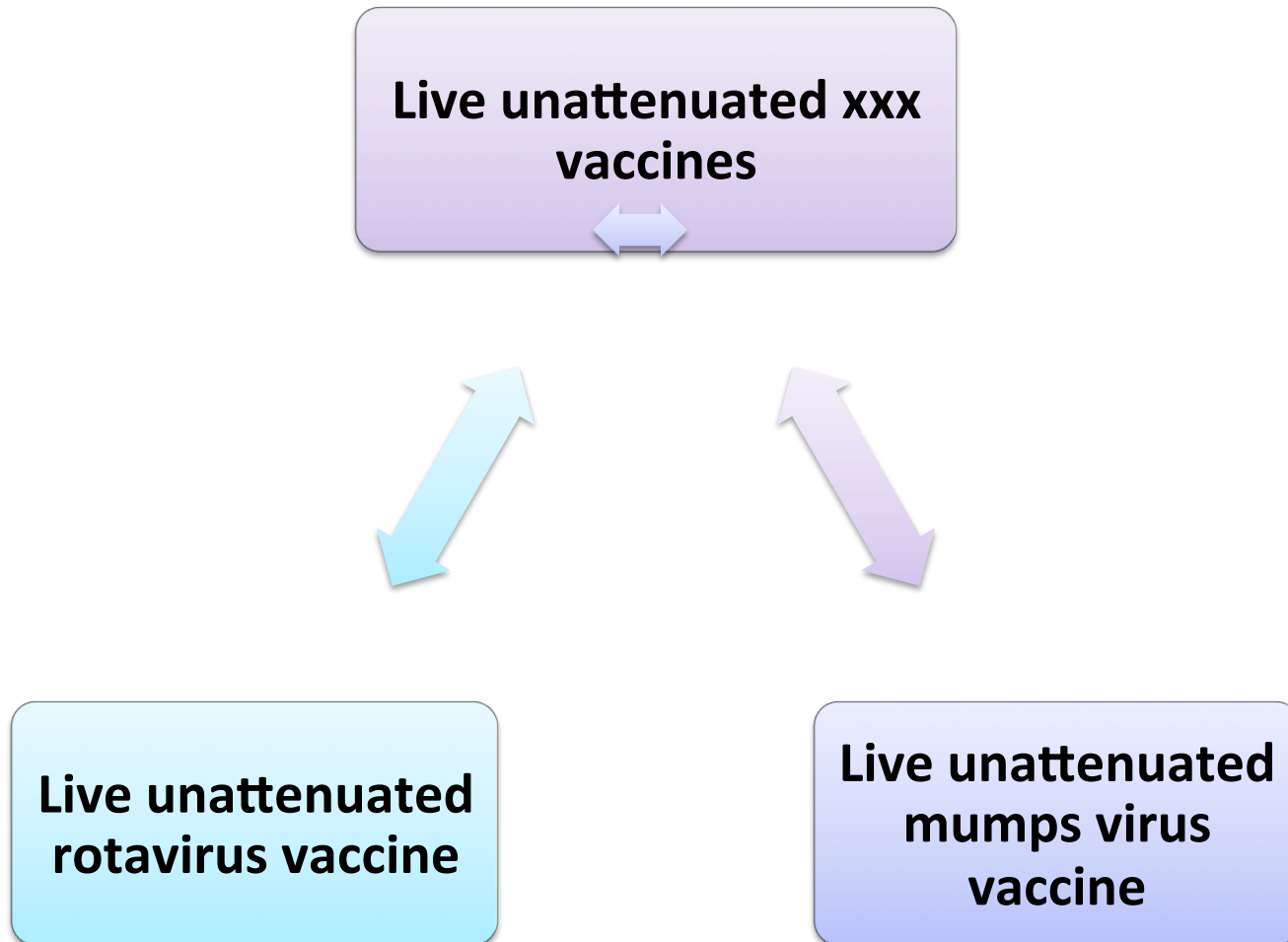
Live attenuated vaccine

Scientific valid and clinical meaningful are based on Manufacturer's Good Manufacturing Practice (GMP) on both product and labeling

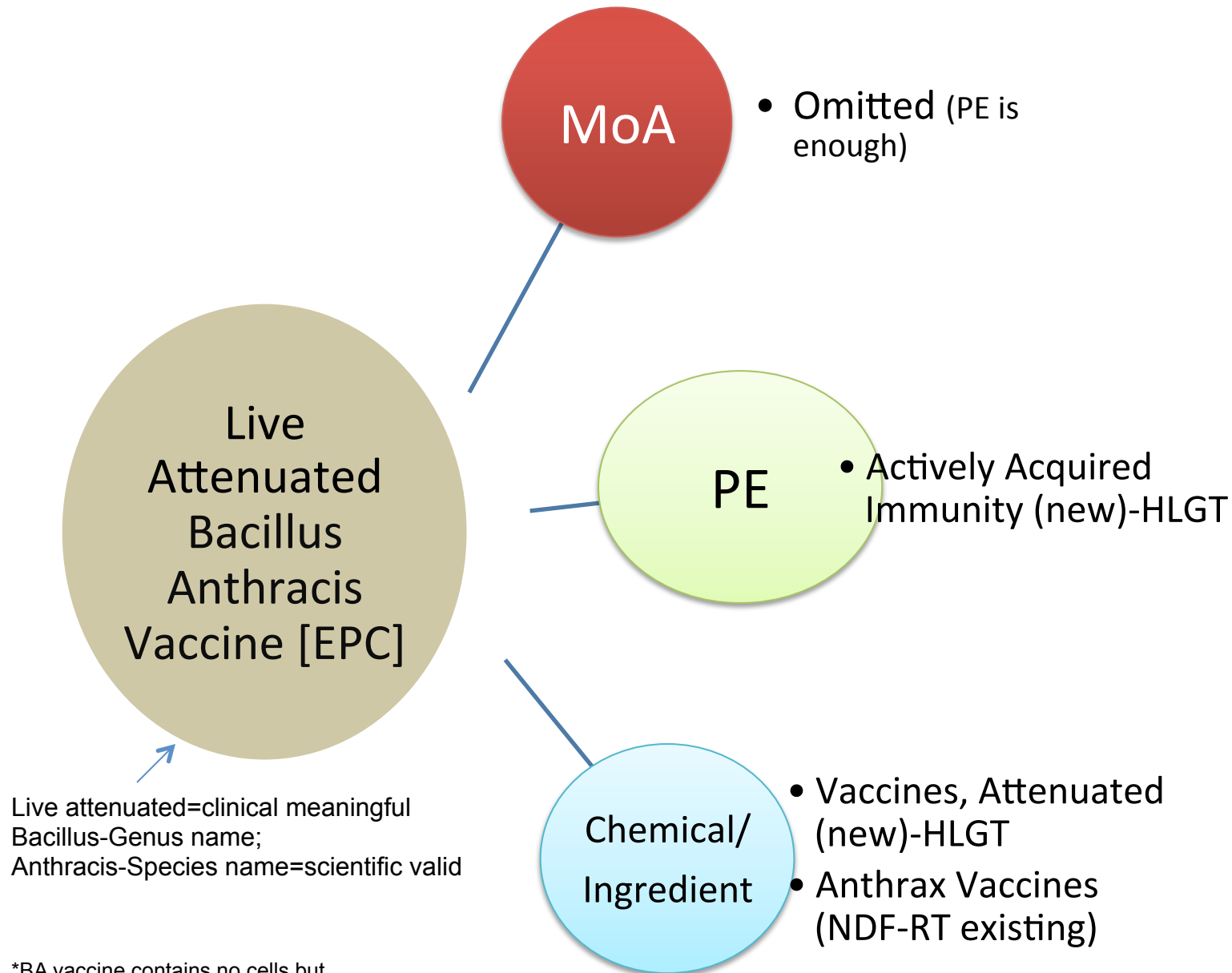


Live Unattenuated vaccines

Scientific valid and clinical meaningful are based on Manufacturer's Good Manufacturing Practice (GMP) on both product and labeling

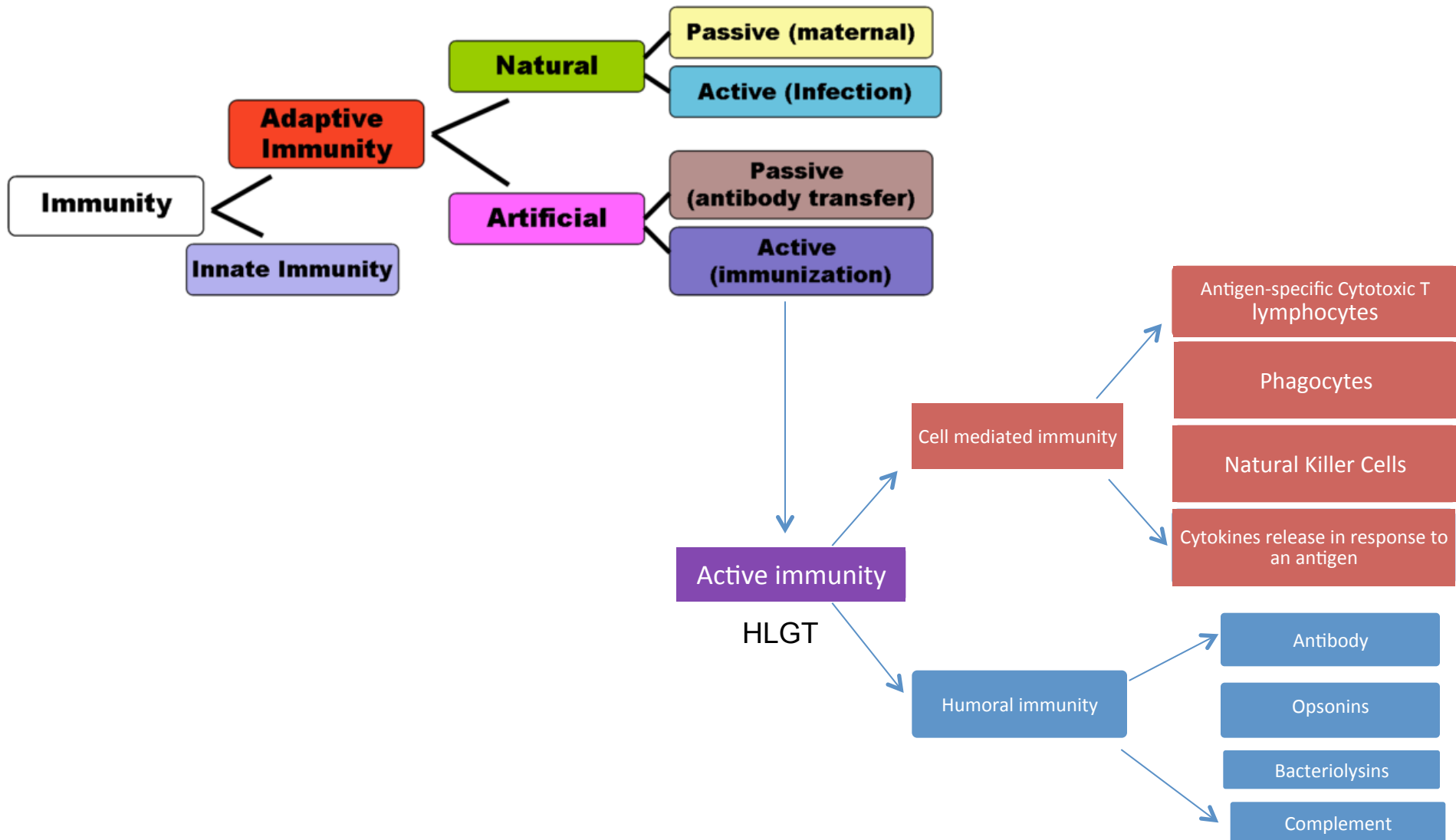


Rationale



*BA vaccine contains no cells but culture supernatant

Reference for Active Immunity of PE



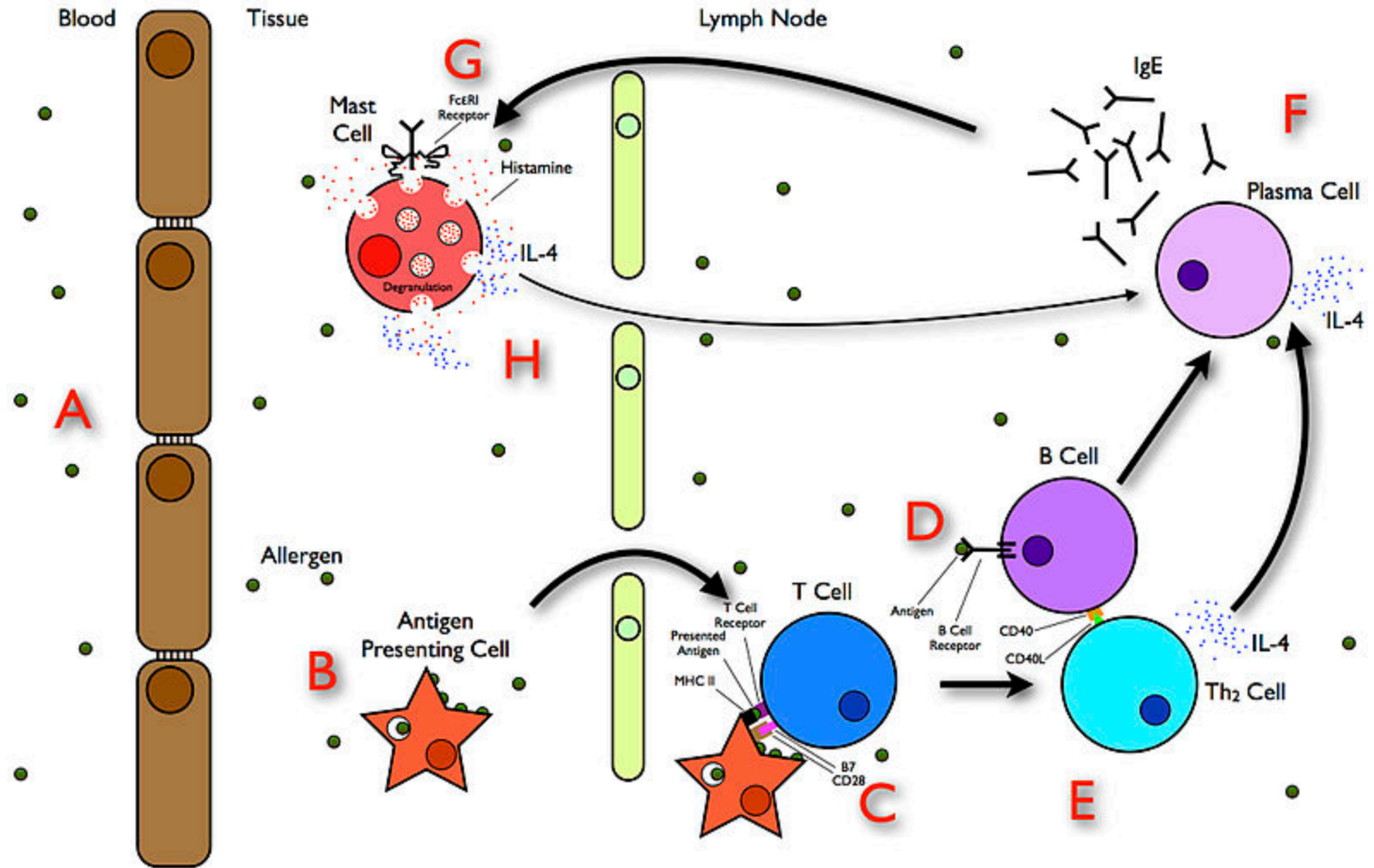
Non-Standardized Allergenic Product

Pharm Class

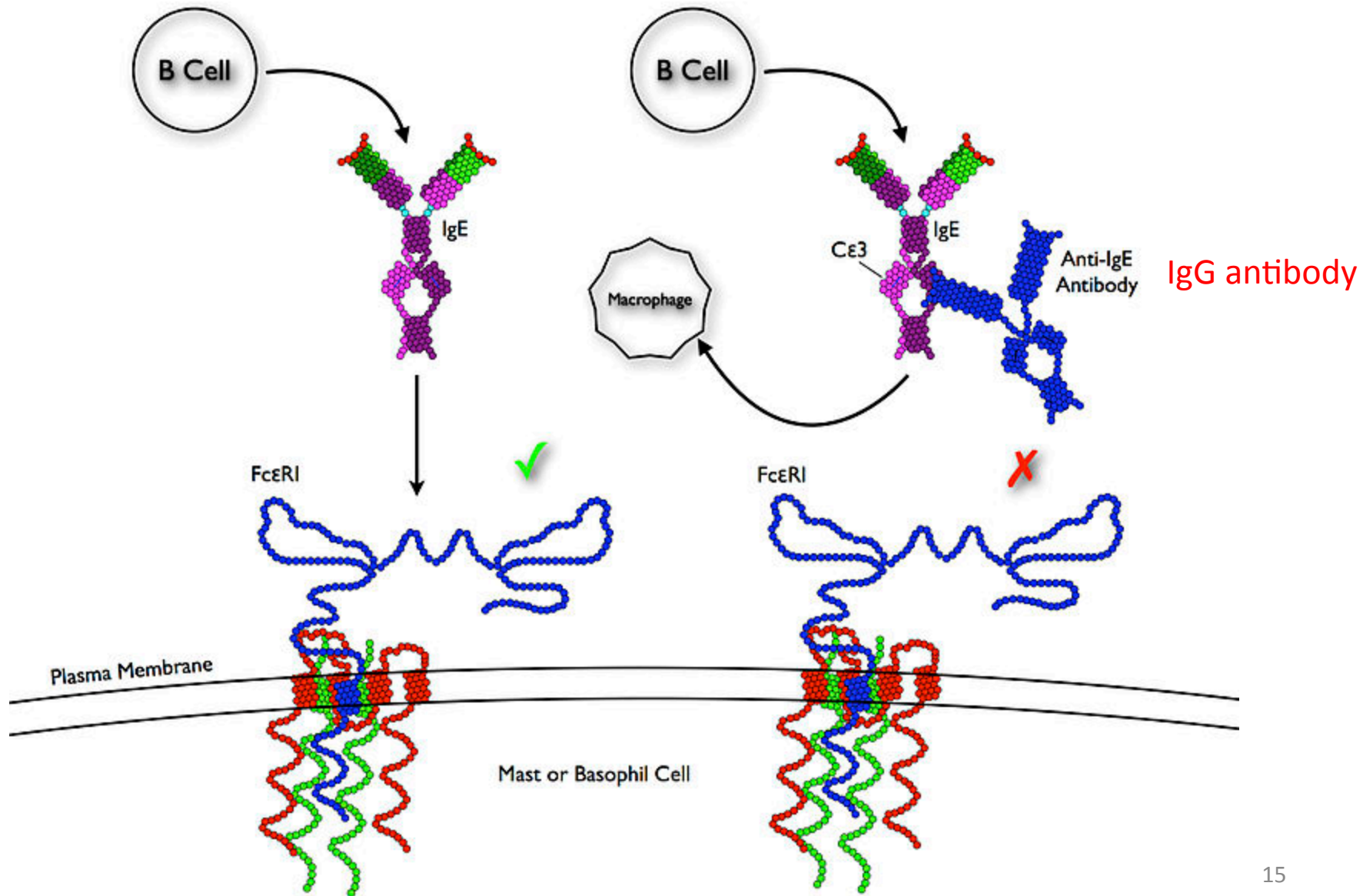
- The pharmacological classification groups active moieties in CBER-approved non-standardized allergenic products by their PE, MoA and/or CS

CHERRY	BUC5I9595W	non-standardized food allergenic extract	Non-Standardized Food Allergenic Extract [EPC]	code needed	EPC	Vada/OD/CBER
CHERRY	BUC5I9595W		Increased Histamine Release [PE]	N0000175629	PE	Vada/OD/CBER
CHERRY	BUC5I9595W		Cell-mediated Immunity [PE]	N0000184306	PE	Vada/OD/CBER
CHERRY	BUC5I9595W		Omitted [MoA]	N/A	MoA	Vada/OD/CBER
CHERRY	BUC5I9595W		Allergens [Chemical/Ingredient]	N0000171131	Chemical/Ingredient	Vada/OD/CBER
CHERRY	BUC5I9595W		Dietary Proteins [Chemical/Ingredient]	N0000007512	Chemical/Ingredient	Vada/OD/CBER
CHERRY	BUC5I9595W		Fruit Proteins [Chemical/Ingredient]	code needed	Chemical/Ingredient	Vada/OD/CBER

Mechanism Illustration of Anaphylaxis



Mechanism Illustration of Immunotherapy



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