



by “The Max Elixirs”

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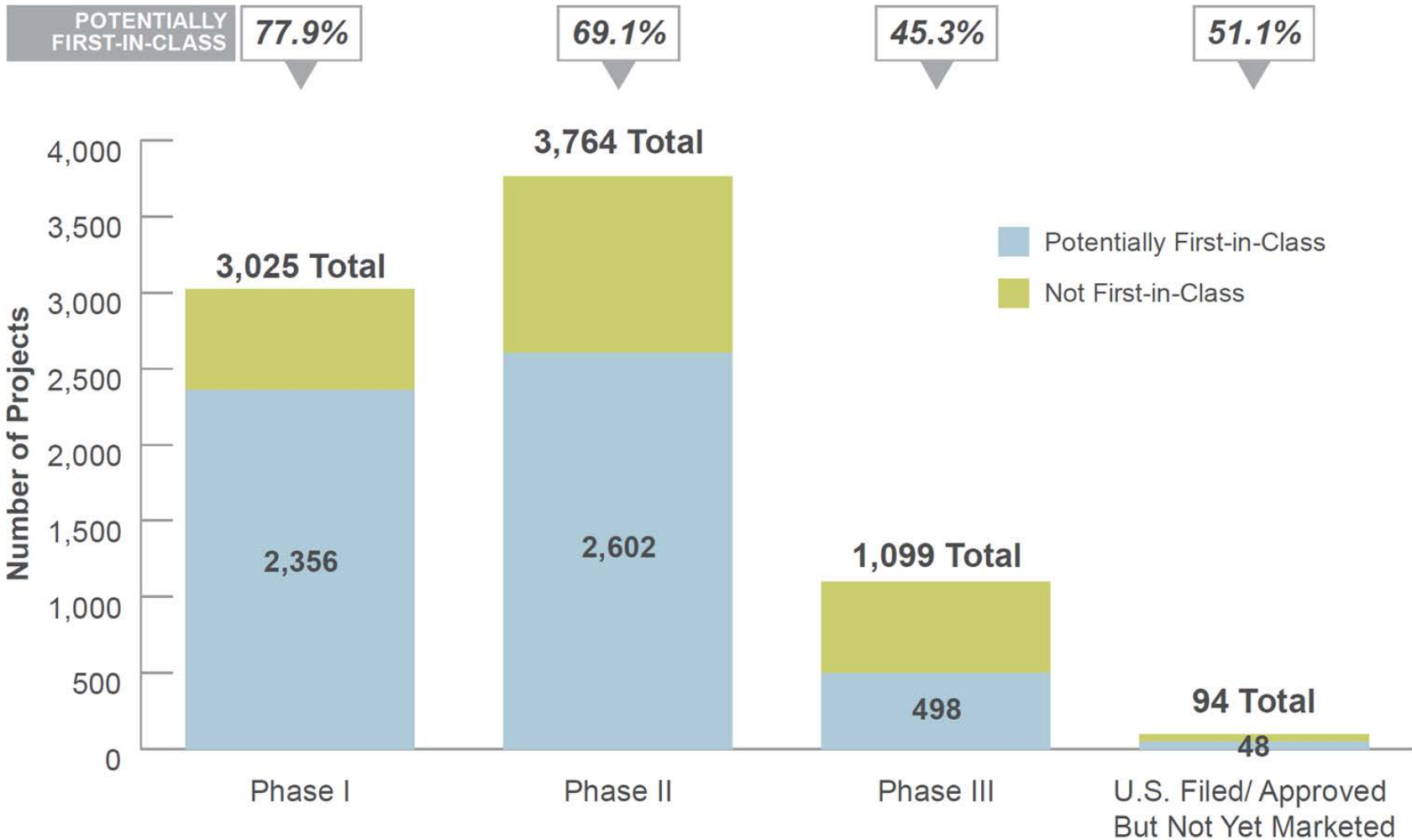


- A database to use as an everyday resource for healthcare professionals
- Integrated with current information and new tools
- Will include blood components, antibody and protein therapies.



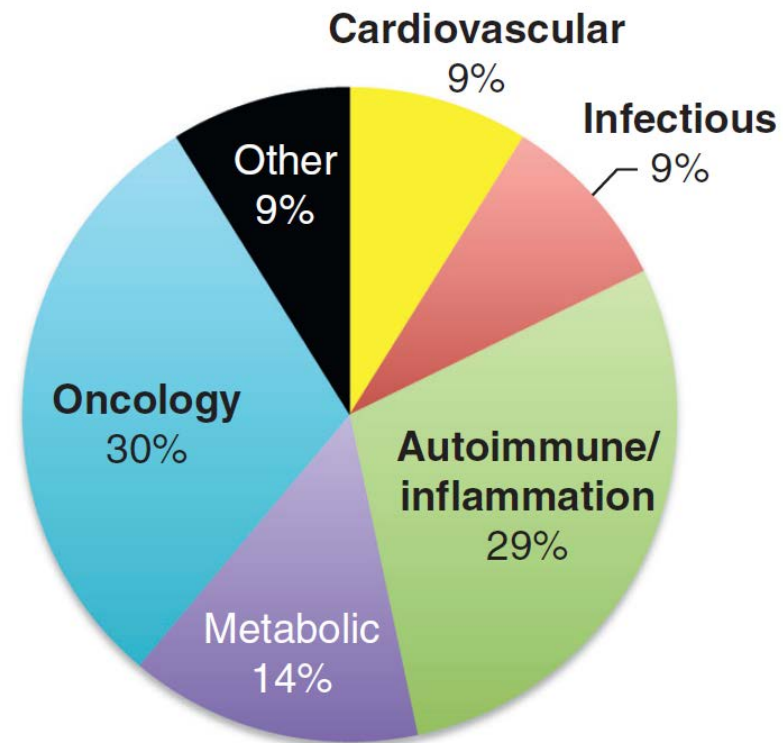
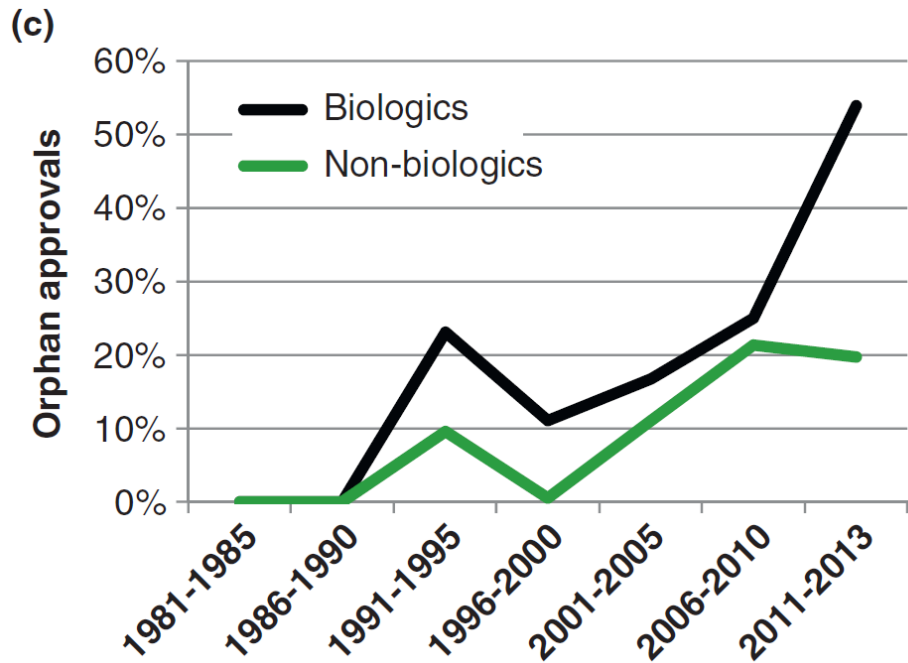
FDA Priority Areas

- Harness Diverse Data Through Information Sciences to Improve Health Outcomes
- Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security
 - Modernize tools to evaluate MCM product safety, efficacy, and quality
 - Enhance emergency communication
- Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products
 - Reach the audience
 - Ensure audience understanding





Biologics





- Home
- Food
- Drugs
- Medical Devices
- Radiation-Emitting Products
- Vaccines, Blood & Biologics
- Animal & Veterinary
- Cosmetics
- Tobacco Products

Vaccines, Blood & Biologics



Home > Vaccines, Blood & Biologics



FY 2014 Report from the Director

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Spotlight

- [What's New for Biologics](#)
- [Pregnancy and Lactation Labeling Final Rule](#)
- [Impact of Severe Weather Conditions on Biological Products](#)
- [Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies](#)

[Drugs](#)

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Search by drug name, NDC or Scan barcode



Drugs

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General Info

Indications

Interchangeability

Clinical data

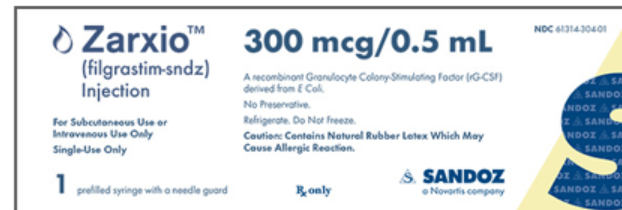
Medication Safety

Patient Counseling

Tools

Filgrastim - Neupogen/Zarxio

Colony Stimulating Factor



Biosimilar Substitution

BLA STN	PRODUCT (PROPER) NAME	PROPRIETARY NAME	DATE OF LICENSURE (mo/day/yr)	DATE OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE (I)/ BIOSIMILAR (B)	WITHDRAWN
125118	abatacept	Orencia	12/23/05				
103575	abxciximab	ReoPro	12/22/94	NA	NA		
125274	abobotulinumtoxinA	Dysport	04/29/09				
125057	adalimumab	Humira	12/31/02	NA	NA		
125427	ado-trastuzumab emtansine	Kadcyla	02/22/13				
125387	afibercept	Eylea	11/18/11				
103979	agalsidase beta	Fabrazyme	04/24/03	NA	NA		
125431	albiglutide	Tanzeum	04/15/14				
103293	aldesleukin	Proleukin	05/05/92	NA	NA		
103948	alemtuzumab	Campath, Lemtrada	05/07/01	NA	NA		
125141	alglucosidase alfa	Myozyme	04/28/06				
125291	alglucosidase alfa	Lumizyme	05/24/10				
125559	alirocumab	Praluent	07/24/15				
103172	alteplase, cathflo activase	Activase	11/13/87	NA	NA		
103950	anakinra	Kineret	11/14/01	NA	NA		
125513	asfotase alfa	Strensiq	10/23/15				
101063	asparaginase	Elspar	01/10/78	NA	NA		
125359	asparaginase erwinia chrysanthemi	Erwinaze	11/18/11				
103764	basiliximab	Simulect	05/12/98	NA	NA		
103691	becaplermin	Regranex	12/16/97	NA	NA		
125288	belatacept	Nulojix	06/15/11				
125370	belimumab	Benlysta	03/09/11				
125085	bevacizumab	Avastin	02/26/04				
125557	blinatumomab	Blinicyto	12/03/14				
125388	brentuximab vedotin	Adcetris	08/19/11				
125319	canakinumab	Ilaris	06/17/09				
103608	capromab pendetide	ProstaScint	10/28/96	NA	NA		
125160	certolizumab pegol	Cimzia	04/22/08				
125084	cetuximab	Erbitux	02/12/04				
101995	collagenase	Santyl	06/04/65	NA	NA		
125338	collagenase clostridium histolyticum	Xiaflex	02/02/10				
103749	daclizumab	Zenapax	12/10/97	NA	NA		Yes
761036	daratumumab	Darzalex	11/16/15				
103951	darbeoetin alfa	Aranesp	09/17/01	NA	NA		
103767	denileukin diftitox	Ontak	02/05/99	NA	NA		
125320	denosumab	Prolia, Xgeva	06/01/10				
125516	dinutuximab	Unituxin	03/10/15				
103532	dornase alfa	Pulmozyme	12/30/93	NA	NA		
125469	dulaglutide	Trulicity	09/18/14				
125277	ecallantide	Kalbitor	12/01/09				
125166	eculizumab	Soliris	03/16/07				
125460	elosulfase alfa	Vimizim	02/14/14				
761035	elotuzumab	Empliciti	11/30/15				
103234	epoetin alfa	Epogen/Procrit	06/01/89	NA	NA		
103795	etanercept	Enbrel	11/02/98	NA	NA		
125522	evolocumab	Repatha	08/27/15				
103353	filgrastim	Neupogen	02/20/91	NA	NA		
125553	filgrastim-sndz	Zarxio	03/06/15			B	
125117	galsulfase	Naglazyme	05/31/05				

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Filgrastim - Neupogen/Zarxio Biosimilar/Interchangeable

[Neupogen - filgrastim](#)[Injection](#)[Reference Drug](#)[Zarxio - filgrastim sndz](#)[Injection](#)[Biosimilar - Link Clinical Data](#)



Medication Safety

- Adverse Effects
- Contraindications
- Black Box Warnings
- REMS
- Monitoring

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Black Box Warnings

REMS

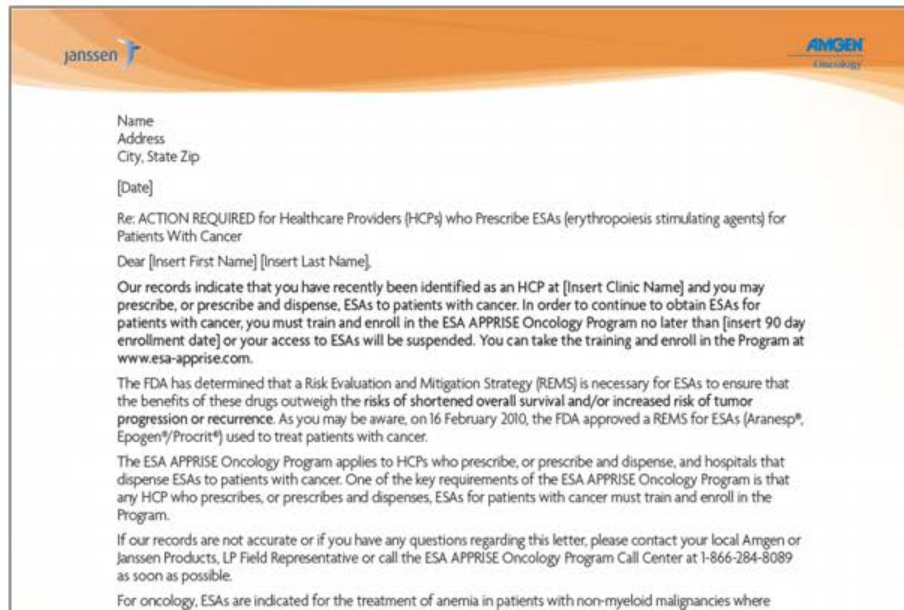
Monitoring



Patient Counseling

Tools

Aranesp - Darbepoetin alfa

Dear Health Care Provider



Name
Address
City, State Zip
[Date]

Re: ACTION REQUIRED for Healthcare Providers (HCPs) who Prescribe ESAs (erythropoiesis stimulating agents) for Patients With Cancer

Dear [Insert First Name] [Insert Last Name],

Our records indicate that you have recently been identified as an HCP at [Insert Clinic Name] and you may prescribe, or prescribe and dispense, ESAs to patients with cancer. In order to continue to obtain ESAs for patients with cancer, you must train and enroll in the ESA APPRISE Oncology Program no later than [insert 90 day enrollment date] or your access to ESAs will be suspended. You can take the training and enroll in the Program at www.esa-apprise.com.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ESAs to ensure that the benefits of these drugs outweigh the risks of shortened overall survival and/or increased risk of tumor progression or recurrence. As you may be aware, on 16 February 2010, the FDA approved a REMS for ESAs (Aranesp®, Eprex®/Procrit®) used to treat patients with cancer.

The ESA APPRISE Oncology Program applies to HCPs who prescribe, or prescribe and dispense, and hospitals that dispense ESAs to patients with cancer. One of the key requirements of the ESA APPRISE Oncology Program is that any HCP who prescribes, or prescribes and dispenses, ESAs for patients with cancer must train and enroll in the Program.

If our records are not accurate or if you have any questions regarding this letter, please contact your local Amgen or Janssen Products, LP Field Representative or call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 as soon as possible.

For oncology, ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where



What materials are included in the REMS?

The REMS includes a [REMS Document](#). In addition, the REMS includes the following materials intended for patients and healthcare providers:

 [Download This List](#)

Material Name	Category	Target Audience
Dear Healthcare Provider (DHCP) Letter to Directors of Pharmacy/ Administrators of Newly Identified Hospitals That Dispense ESAs to Patients With Cancer (PDF)	Communication	Dispenser
Dear Healthcare Provider (DHCP) Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer (PDF)	Communication	Prescriber
ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers (PDF)	Enrollment	Prescriber
ESA APPRISE Oncology Program Enrollment Form for Hospitals (PDF)	Enrollment	Dispenser
ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (PDF)	Enrollment, Practice Support	Patient, Prescriber
ESA APPRISE Oncology Program Training Module for Healthcare Providers (PDF)	Training	Prescriber
ESA APPRISE Oncology Program Training Module for Hospital Designees (PDF)	Training	Dispenser
ESA APPRISE Oncology Program Website Screenshot (PDF)	Communication	N/A
Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics (PDF)	Other	Dispenser
REMS document (PDF)		



Drug Shortages and Next Availability

- Tab will show current biologic shortages from the FDA and ASHP websites
- “Reason for the Shortage” and “Estimated Resupply Date” will be displayed

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Advate - Antihemophilic Factor (Recombinant) Dosage Calculator

Step 1:

Enter Required IU

Next →

Step 2:

Enter Available IU or Lot Number

LOT | IU

LOT | IU

+ Add Additional

Next →

Step 3:

Required Dosage:

1x TAN15024BA

2x TAN15038AA

Deviation from ordered: ~4%

Done ✓

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Filgrastim Continuing Education Opportunities



Academy of
Managed Care
Pharmacy®

Continuing Education - Journal of Managed Care Pharmacy
Pharmacoeconomics and Considerations for
Injectable Products: Focus on Colony-Stimulating Factors



Counterfeit drugs

- Strategic plan to decrease risk of counterfeit drugs entering US market and to protect consumers
- Use of current and emergent technologies to protect drug supply
 - Anti-counterfeit packaging
 - Serial numbers
 - RFID tags
- FDA-Logic will be a source of information for healthcare professionals and consumers to verify authenticity of medications

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Anti-counterfeiting
Features

Serial Tracking

MedWatch

BPD Report

Botox - OnabotulinumtoxinA

Counterfeit resistant packaging



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Features](#)[Serial Tracking](#)[MedWatch](#)[BPD Report](#)

Botox - OnabotulinumtoxinA

Serial Track and Trace

Scanned Serial Number: 123456789

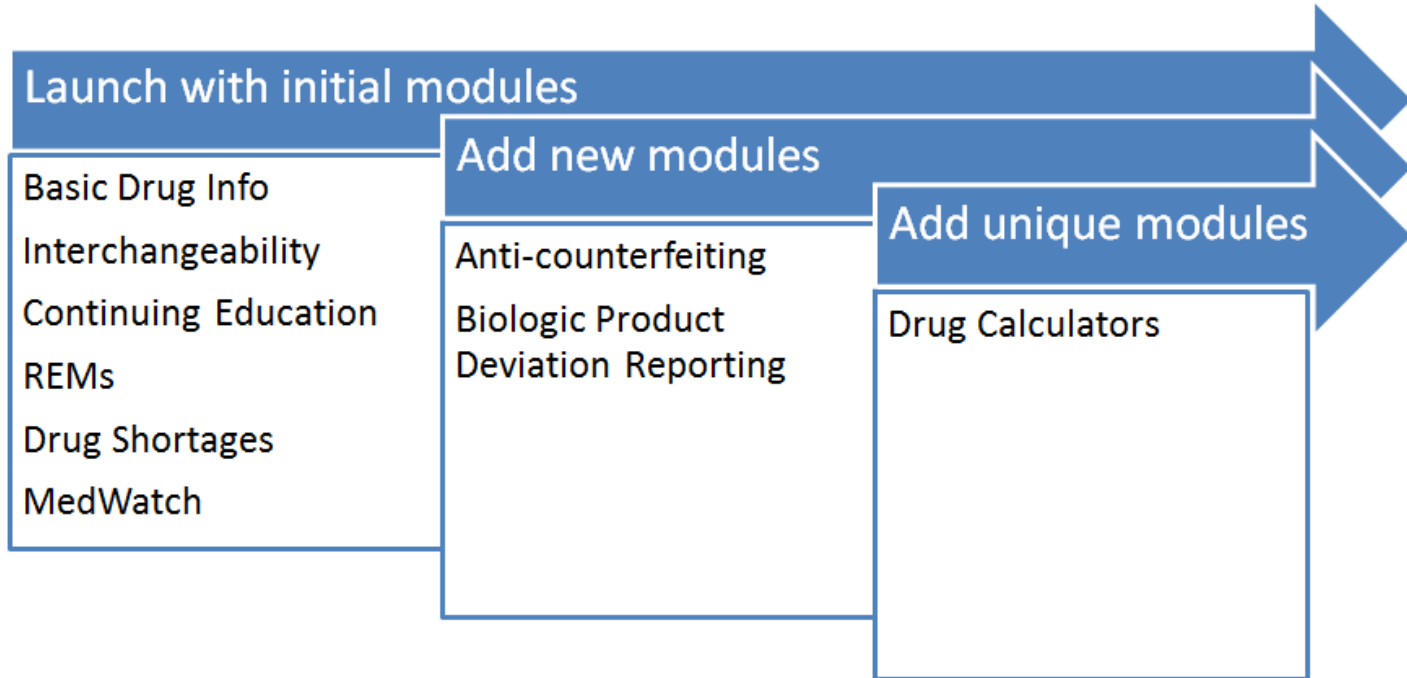
Manufactured: Allergan - Westport, Ireland

Bulk Distributor: McKesson - Baltimore, MD, USA

Delivered: **Not Yet Delivered**



Implementation Strategy and Feasibility





Feasibility

- Incorporate as many existing databases and resources to reduce costs
 - Provide existing information in a central location and in a more accessible format
- There will be some cost in developing new resources



Questions?

