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OPTIMISING INNOVATORTM SOURCING FOR BIO-SIMILAR DEVELOPMENT

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IN THIS PRESENTATION

-  Era Of Bio Therapuetics
-  Reverse Planning
-  Significance Of Source Markets
-  Effects On Registration, Costs And Time To Market
-  Key points in sourcing Bio-similar
-  Comparator Souring Organisation - Roles and Services.

ERA OF BIOTHERAPUTICS

-  Conventional Medication has been used and abused by Humanity for over a century now
-  Human body has started becoming immune to conventional medication
-  Antibiotic resistance is at it's all time high
-  The next frontier in medicines is Bio-Therapeutics Targeting of Cells at DNA and Gene level

REVERSE PLANNING

- What is Reverse planning ?
- Conventional RnD approach do not work for Bio-similars development
- Bio-similars are **expensive** to develop, clinical studies are more complex and Stability even more so.
- Top down approach of planning the full RnD process, Trials, Studies and then looking for Comparators has led to losses of Millions of Dollars in:
 - Excess stock
 - Expired Stock
 - Wrong Packs


REVERSE PLANNING

Reverse Planning:






 Start by identifying your Destination Markets

 For Example a Bio-similar to be registered in EU needs a EU sourced comparator from Innovator with EU number of the pack.

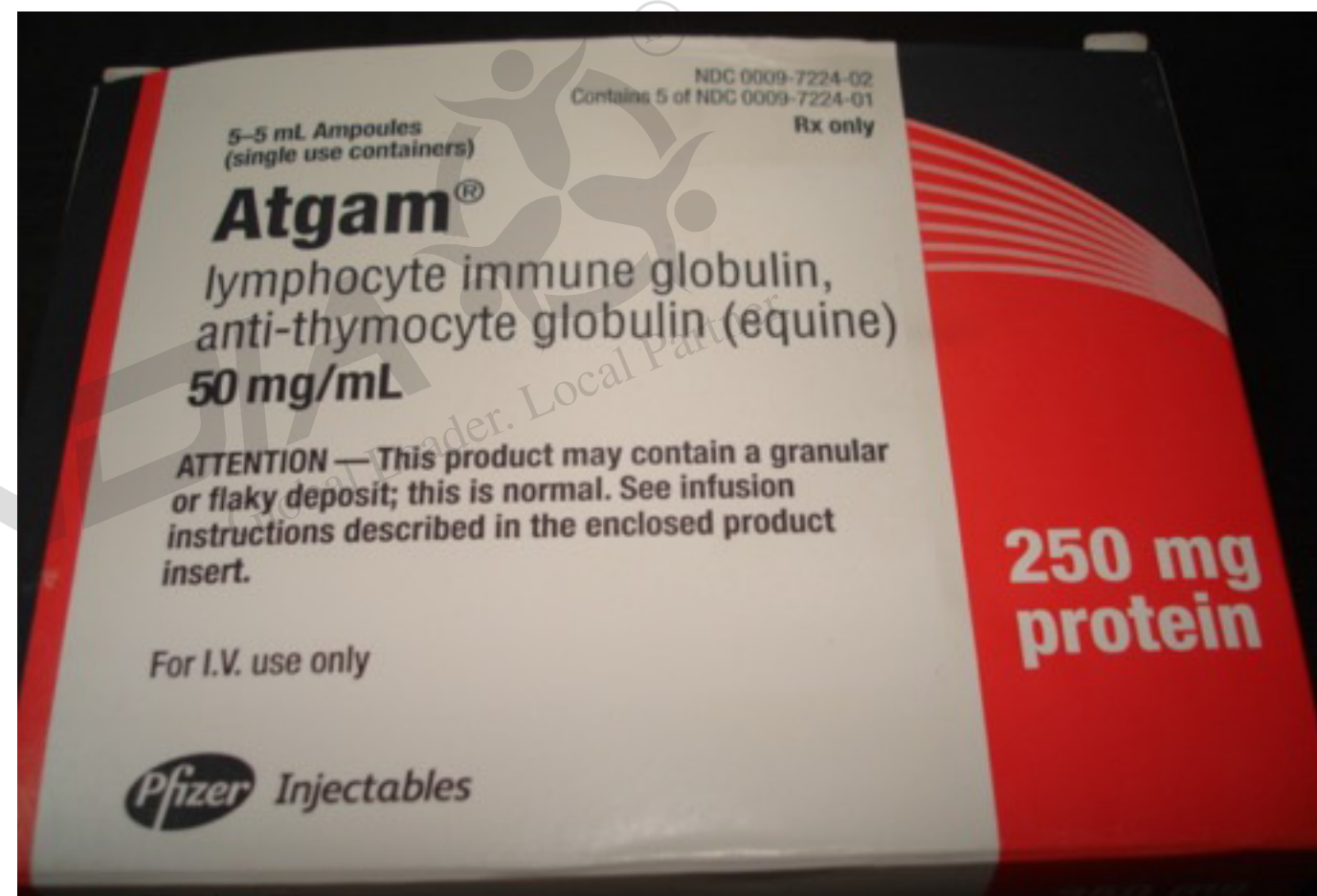
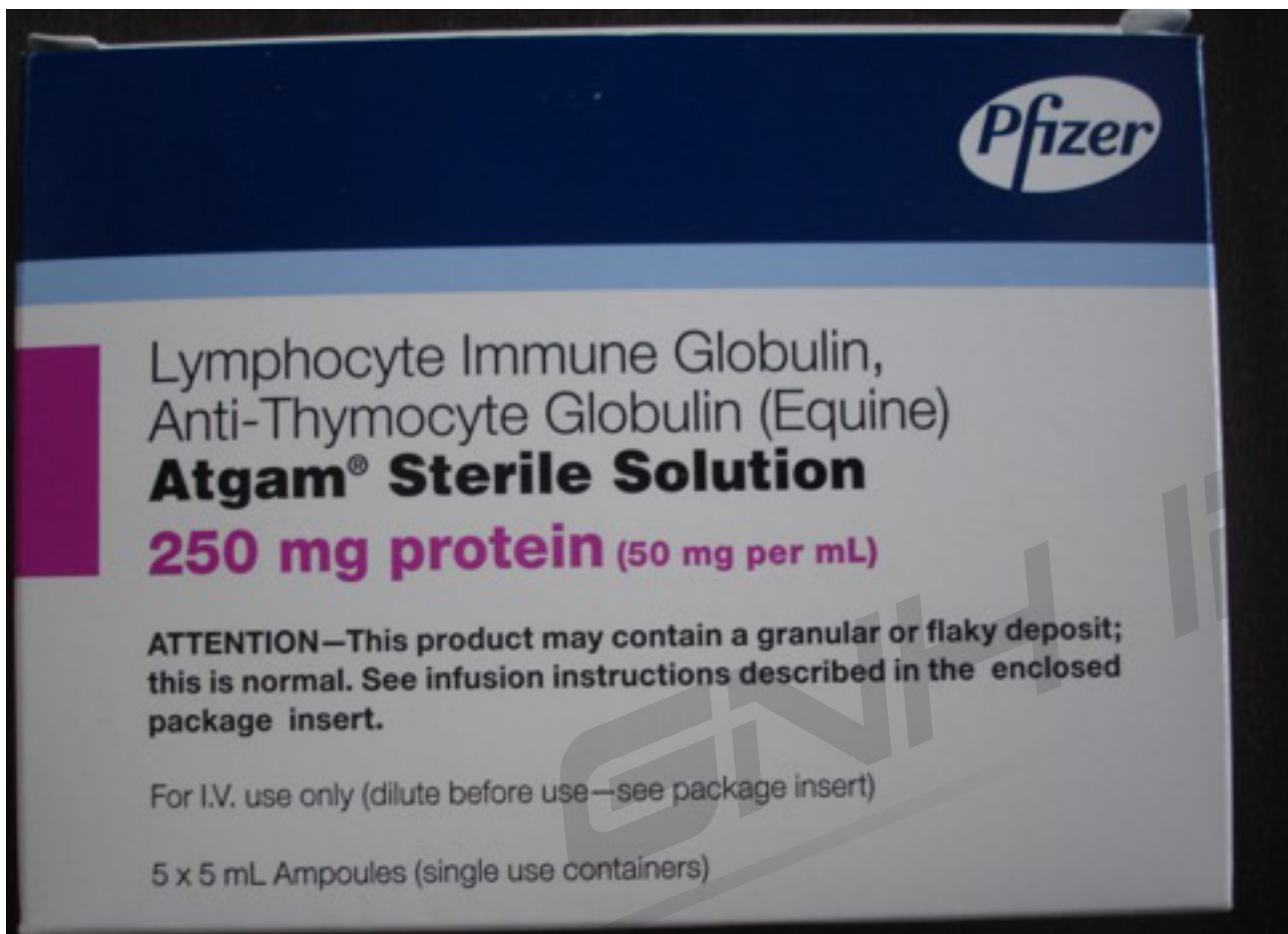
 While a Bio-similar for registration in RoW markets will accept comparator from any markets as long as it's from the innovator.

 This reverse planning can **SAVE** millions of Dollars in sourcing by selecting the right source markets.

Significance of Source Markets

-  Source Markets should be chosen based on your Destination markets
-  For Example if you plan to Target RoW Markets, there's no point in sourcing products from US market
-  US products with NDC numbers are at least 3 time more expensive as compared to same brand in International packs
-  US stocks are difficult to get, highly controlled, traced and the sheer cost makes the development process un-viable.
-  In contrast to this : An International pack from Europe / Eastern Europe is available at 1/3rd the cost, in Large quantities and with Pedigree Documents.

Market Intelligence




Effects on Registration

 Ultimate goal of any development is to **SELL** the product

 **Sell - Fast and First to Market**

 **Sell - At Most competitive price**

 Example : India is a Right Hand Drive Country - Is there any point launching a Left Hand Drive Car here ?







 Similarly if your destination is RoW - there's no point in Sourcing of US / EU stock for RnD

 Lack of reverse planning : Only increase development cost hence the END product COST

 Lack of product availability from US / EU markets - delays development

 And off course you are not FAST or First to market

Key points in Sourcing Bio-Similars

-  Identify your Destination Markets First
-  Check availability, Pack descriptions, SPC etc... of your comparator in planning stage
-  Call for Pack photos, Pack Scans in planning stage
-  Estimate the Quantity, Frequency etc.... in advance
-  Understand availability issues for Comparators right in the beginning.
-  Tie up your source even before you start development process

CSO - Comparator Sourcing Organisation

 While Development and RnD is the a focus of Manufacturers or CROs

 Sourcing of Innovators / Comparators can be big challenge

 An ideal CSO should be :

 WHO GDP Certified Site

 With validated Storage and Shipping systems

 With Global Reach

 Ability to source and transport products world wide






 Knowledgable about Global Market place

 In depth Experience in Sourcing, Imports and Exports

GNH India - 1st CSO in India

-  A WHO GDP certified by SGS India
-  DFGT recognised Export house
-  Over 12 years of Industry Experience
-  Qualified QP on site in Warehouse
-  Fully licensed by State FDA and DGFT to carry imports and Exports of Drugs and related products
-  Over 135,000 products

GNH India - 1st CSO in India

-  Shipping and importing Globally to over 180 countries
-  Validated Storage and Shipping systems
-  Full Traceability and Pedigree for every supply
-  In Depth Market knowledge and Market intelligence
-  Complete Regulatory and compliance support up-till Market launch

Market Intelligence - 1 product - 2 packs ??

