



kinetix
UNIVERSITY

Pharma 101



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- 5 Roles and Responsibilities within a Pharma Company
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OBJECTIVES

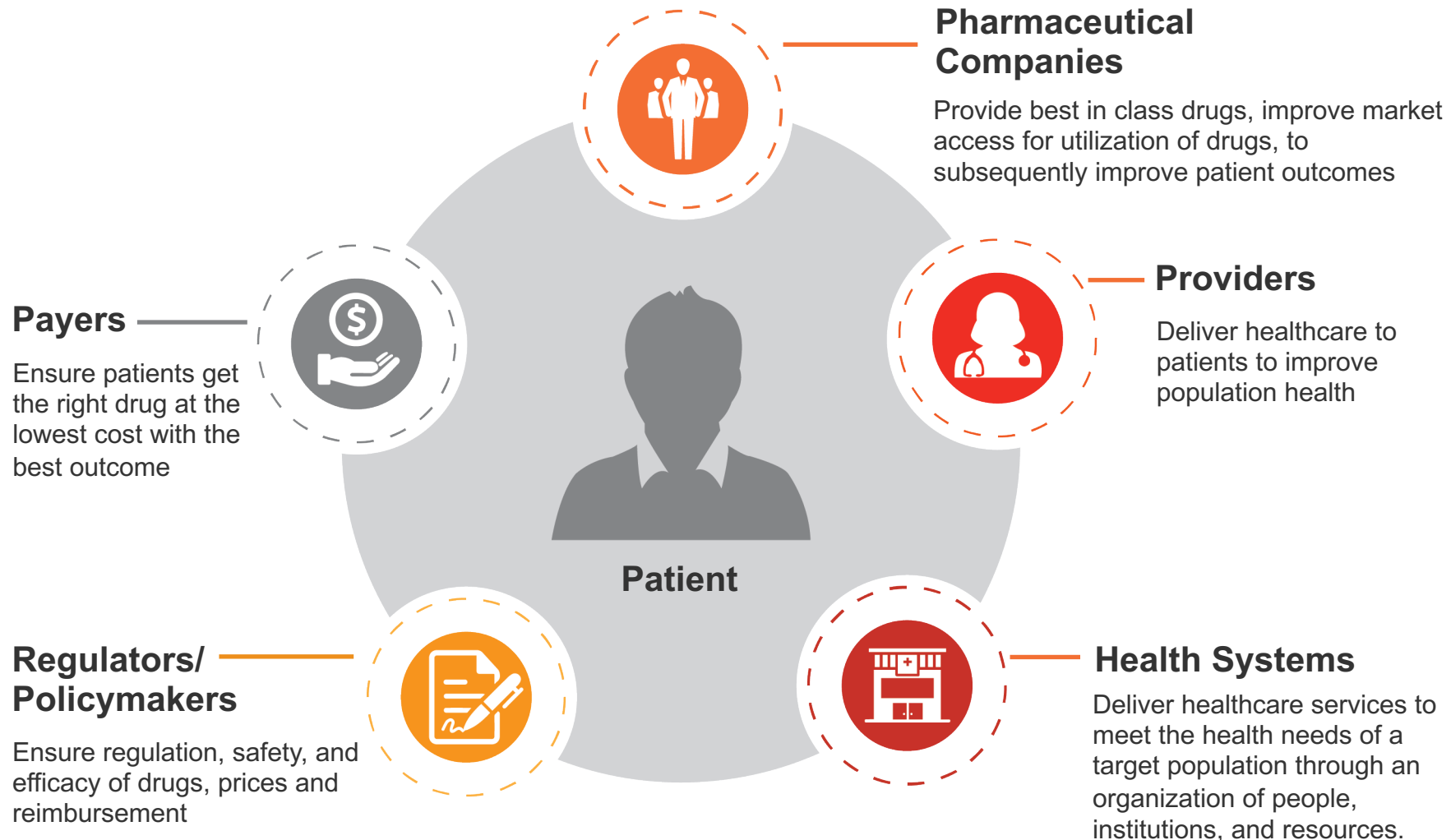
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Provide internal training on the pharmaceutical industry

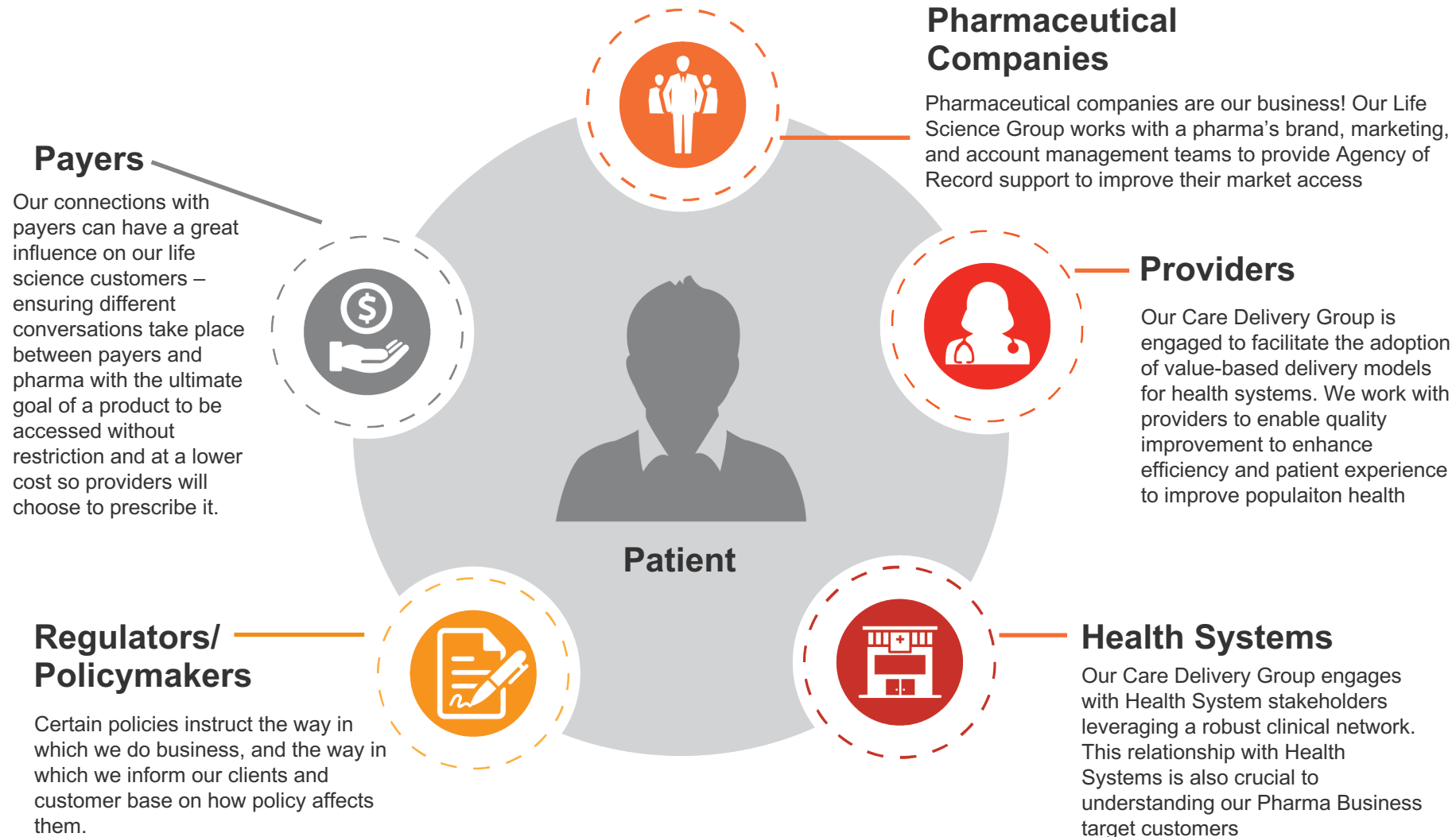
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Highlight our pharmaceutical clients, how they work, how they interact with other healthcare landscape stakeholders, and how TKG works with them

ROLES AND RESPONSIBILITIES OF EACH HEALTHCARE LANDSCAPE STAKEHOLDER



WHAT EACH STAKEHOLDER MEANS TO TKG



THE NEEDS OF EACH STAKEHOLDER GROUP

“

I want to accelerate innovation and license products and diagnostics that demonstrate real outcomes

Regulator

I should be informed of decisions relating to my health and be able to manage my condition

Patient

I must contain healthcare costs without compromising patient outcomes

Payer

My policies need to encourage uptake of innovation and meet my stakeholders' needs

Policymaker

I need to adhere to evidence-based medicine to optimize my performance and delivery excellent patient outcomes

Provider

”

OVERVIEW OF THE PHARMACEUTICAL INDUSTRY

1

BRAND NAME

A drug that has a trade name and is protected by a patent. When patents run out, generic versions are marketed at a lower cost by other companies

2

GENERIC

A medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics

3

BIOTECHNOLOGY/BIOLOGICAL DRUGS

The exploitation of biological processes (especially the genetic manipulation of microorganisms) for the production of antibiotics, hormones, etc. (referred to as biologics)

4

BIOSIMILARS

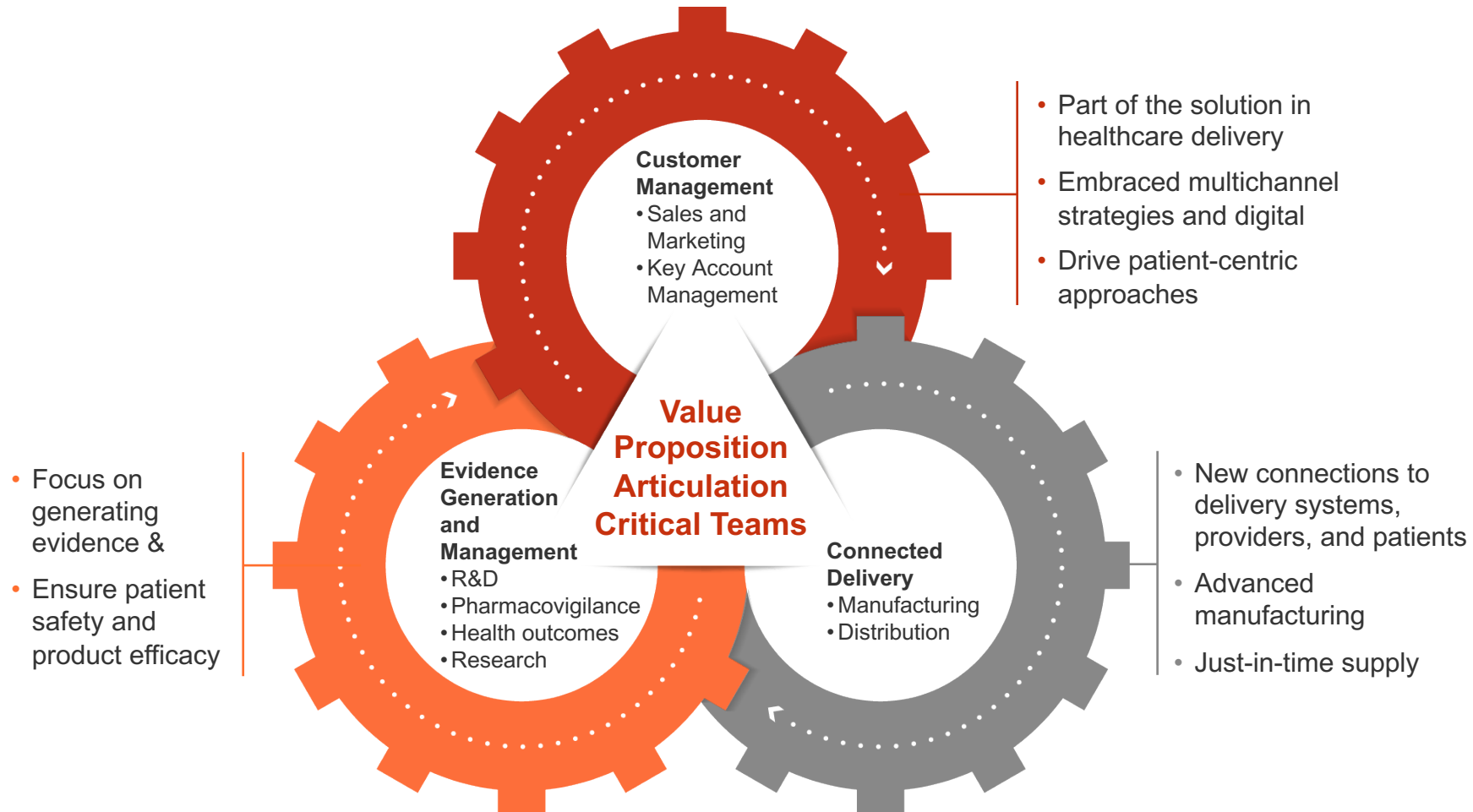
A biologic medicine that is approved based on showing that it is highly similar to an existing approved innovative biological product, known as a reference product. Biosimilars differ from generic products because that are not identical to the reference biologics

5

MEDICAL DEVICES

Any apparatus intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application

NEW PHARMA COMPANY OPERATING MODEL



Legal and Regulatory Team

- The legal and regulatory process ensures that all pharmaceutical product promotions are medically accurate and comply with FDA regulations (i.e. FDAMA 114) and protect the pharmaceutical company from litigation
- The legal and regulatory team is involved with all critical teams

1

Evidence Generation and Management

Research and Development (R&D)

- Conduct research to uncover the **scientific basis** underlying a drug's mechanism of action
- Coordinate stages of **clinical trials** to determine the efficacy, safety and quality of a drug

Pharmacovigilance

- The science relating to the detection, assessment, and prevention of **adverse effects** or any other drug related problem
- Occurs after product launch/license

Health Economics and Outcomes Research (HEOR)

- A discipline used to complement traditional clinical development information (i.e., efficacy, safety, quality) to guide decision-makers regarding patient access
- Captures data to help payers determine efficacy, cost, and reimbursement
- Occurs after product launch

2

Connected Delivery

Manufacturing

- Drug manufacturing is the process of industrial-scale synthesis of pharmaceutical drugs by pharmaceutical companies.
- Biotech manufacturing is more costly than traditional manufacturing due to the use of living organism for manufacture

Distribution

- Drug distribution is the process by means of which people get access to drugs. There are many stakeholders involved in this drug distribution model, including;
 - Pharma company (manufacturer)
 - Wholesaler
 - Pharmacy Benefit Manager (PBM)
 - Pharmacy
 - Payer
 - Provider/Physician
 - Patient

3

Customer Management

Sales

- Sales are conducted through a select number of account managers who act as pharmaceutical companies' representatives to
 - Influence healthcare stakeholders to improve formulary access for their chosen drugs
 - Improve the utilization and sales of drugs.

Marketing

- Marketing is the business of promoting the sale of pharmaceutical drugs.

Account Management

- Focuses on the needs of a particular customer segment to address needs beyond those touched by traditional sales team within compliance guardrails

PHARMA MARKETING TARGET AUDIENCE



Patients

- End user of product/service in health care
- Highly engaged patients may consult message boards and disease advocacy groups
- Pharma typically interact with this audience via traditional consumer marketing e.g. TV and radio advertising



Health Systems

- An organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations
- Pharma typically interact with executive level decision makers to influence at a health system level



HCPs

- Includes physicians, pharmacists, nurse and other care team members involved in the utilization, prescribing and coordination of products and services in health care
- Pharma typically interact with this audience via a trained field force



Payers

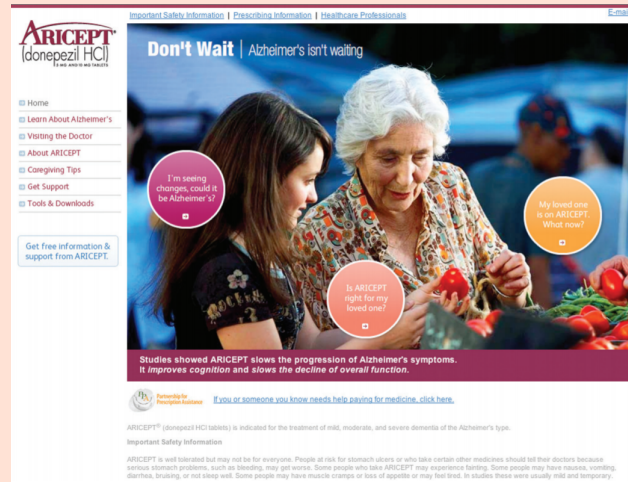
- Includes entities other than the patient that finance or reimburse the cost of health services, in most cases this is an insurance carrier
- Pharma typically interact with this audience via a trained field force

BRANDED, UNBRANDED, AND ABOVE BRAND

Traditionally, non-personal promotion tactics have been conceptualized as **branded** or **unbranded**

Branded

- Branded content includes the product's name, indications, and attributes



Unbranded

- Unbranded content does not include the product's name, indications, and attributes
- Traditionally, unbranded content has been used in advance of product approval to help support product awareness and market preparation



Above Brand

- Educational materials that are disease and brand agnostic and utilized primarily to build stronger relationships with customers

HEALTH SYSTEM TACTICAL EXAMPLES

Value Proposition Resources (Presentations/Leave Behind)



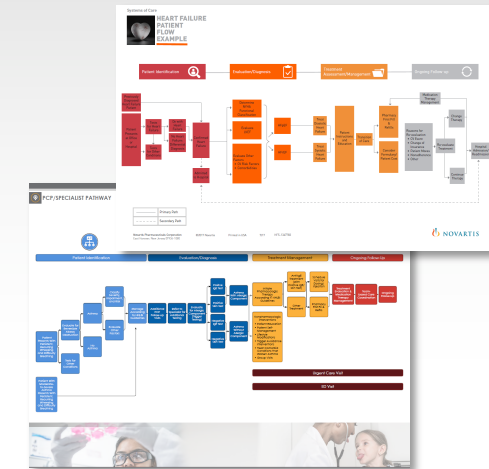
A tool used to communicate the value proposition of a service, product or the account management team itself

Program Sell-in Presentations



Used to provide an overview of a program to executive level decision makers that may be implemented with healthcare providers

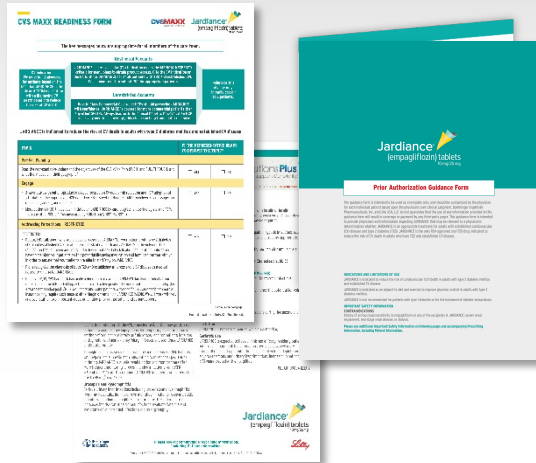
Patient Journey



A conversation piece that enable the account manager to better understand their customer and the issues they face to identify areas of shared priority (i.e. where pharma can help with the ultimate goal of improving patient outcomes)

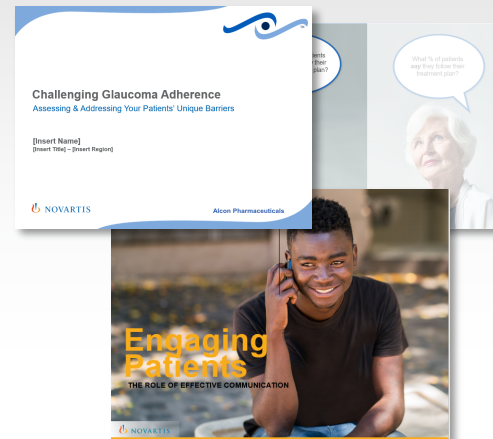
HEALTHCARE PROVIDER FACING TACTICAL EXAMPLES

Push Through Materials



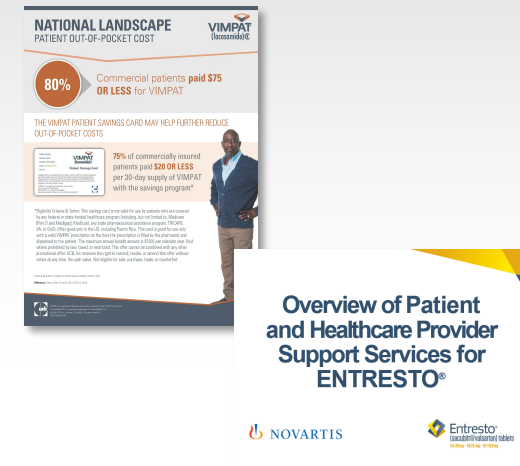
Increase utilization by educating HCPs and office staff on overcoming restrictions and available access resources

Educational Materials



Educational materials on disease state or care delivery (i.e. effective communication, motivational interviewing, Electronic Health Records)

Pull Through Materials



Communicating access and affordability of the product to HCPs to encourage them to prescribe the product to increase uptake/"pull" in more patients

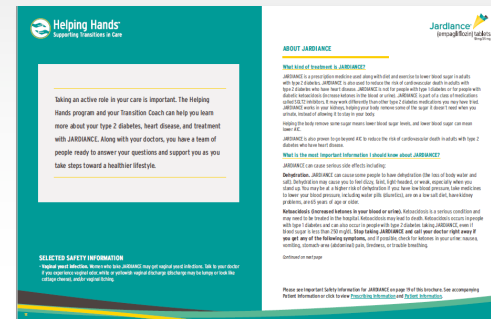
PATIENT-FACING TACTICAL EXAMPLES

Disease State Education



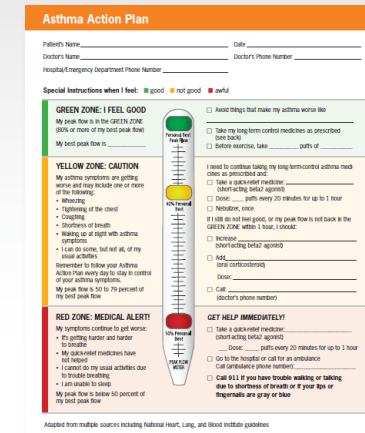
General information about disease states to enable patients to **better understand their condition**

Product Leave Behinds



Informative pieces to communicate important information about the **product, access, safety and administration**

Disease Management Tools (i.e. Worksheet, Disease Diary)



Tool to help patients better **manage their disease**

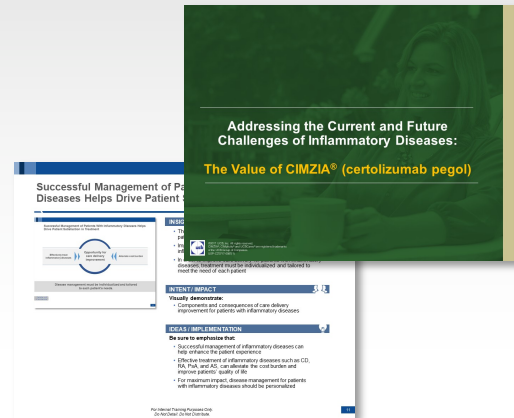
MARKET ACCESS TACTICAL EXAMPLES

Access Training Materials



Provides information on a **product's access** to a patient

Value Proposition Presentations and Implementation Guides



Sets up strong, compelling, **customer-centric** product value proposition

Formulary Kit and Monograph



Provides a detailed clinical product overview for **formulary decision makers** including disease state and product information

APPENDIX

Food and Drug Administration Modernization Act of 1997 Section 114

Overview

- Allows biopharmaceutical companies to disseminate health care economic information (HCEI) to those who need it for formulary decision making
 - HCEI definition: An analysis that identifies, measures, or compares the economic consequences of the use of a drug
- Renewed interest due to growing prevalence of comparative effectiveness research, “big data,” new data sources available for deriving HCEI, and recent court decisions
- Greater clarity in legal lexicon is important given demands by payers and other stakeholders for evidence of value

