

TABLE 14.1 Key Biopharmaceutical Products

Product	End use
A. Hormones and peptide factors	
Human insulin	Diabetes
Factor VIII-C	Hemophilia
Human growth hormone	Growth deficiency
Erythropoietin	Anemia, chronic renal failure
Interferon-alpha 2a	Hairy cell leukemia, AIDS-related cancer
Interferon-alpha 2b	Hairy cell leukemia, Herpes
Interferon-beta	Cancer
Interferon-gamma	Cancer, venereal warts, infectious disease
Interleukin-2	Cancer immunotherapy, AIDS
Muromonab-CD3	Acute kidney transplant rejection
Granulocyte colony stimulating factor (G-CSF)	Chemotherapy effects, AIDS
Granulocyte macrophage-colony stimulating factor (GM-CSF)	Autologous bone marrow transplant
B. Enzymes	
Tissue plasminogen activator	Acute myocardial infarction, stroke
Prourokinase/urokinase	Heart attack
DNase	Pulmonary treatment
Glucocerebrosidase	Gaucher
C. Vaccines	
Hepatitis B	Hepatitis B vaccine
Herpes	Herpes
D. Monoclonal antibodies	
	Wide range of different antibodies for diagnostics
	Prevention of blood clots
	Breast cancer
	Lung cancer

milk production requires that the increased value of the milk produced be substantially greater than the cost of the hormone and any increase in feed costs due to increased milk production.

For food use, product safety is important, but purity requirements are less stringent than for an injectable. The volume of the required product is often substantial (several metric tons per year), and price is critical because alternative products from natural sources may be available. Proteins used as specialty chemicals (e.g., adhesives and enzymes for industrial processes) usually can tolerate the presence of contaminating proteins and compounds. The manufacturing costs for such proteins will greatly influence the market penetration.

For nonprotein products based on metabolically engineered cells, processing costs compared to costs of other routes of manufacture (usually nonbiological) will determine the success of such a process.

As the reader has certainly noted, the constraints on production can vary widely from one product class to another. These constraints determine which host cells, vectors, genetic constructions, processing equipment, and processing strategies are chosen.