

## GLOSSARY

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	An Abbreviated New Drug Application (ANDA) contains data which, when submitted to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the branded drugs.  A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.
Axiron®		Brand name for Acrux's unique testosterone replacement therapy solution product licensed globally to Lilly and which is approved in various countries. The Axiron® trademark is owned by Lilly.
Decentralised Procedure	DCP	A regulatory application in Europe for marketing authorisation is submitted simultaneously to the competent authorities within the European Union. At the end of the DCP procedure, the draft Assessment Report, labelling and package leaflet, as proposed by the Reference Member State, may be approved.
Diclofenac		Diclofenac is a commonly used nonsteroidal anti-inflammatory drug (NSAID).
Elanco		Elanco provides products and knowledge services to improve animal health and food animal production in more than 70 countries around the world. The company has nearly 7,000 employees worldwide. Founded in 1954, Elanco is a division of Eli Lilly and Company. Worldwide headquarters and research facilities are located in Greenfield, Indiana.
Eli Lilly and Company	Lilly	Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. Lilly was founded more than a century ago and are committed to creating high-quality medicines that meet real needs. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism.
Ellavie®		Alternative brand name for Acrux's estradiol spray product. The Ellavie® trademark is owned by Acrux.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries. Estrogen is necessary for many processes in the body.
Estrogen		Generic term for any substance, natural or synthetic, that exerts biologic effects characteristic of estrogenic hormones.
European Medicines Agency	EMA	European Union agency responsible for the protection of public and animal health through the scientific evaluation and supervision of medicines.
Evamist®		Brand name for Acrux's unique estradiol spray product in the United States. The Evamist® trademark is owned by Lumara Health.
Food and Drug Administration	FDA	The FDA is responsible for protecting and promoting public health through the regulation and supervision of prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products in the United States.
Gedeon Richter		Gedeon Richter Plc., headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Richter's consolidated sales were approximately EUR 1.1 billion (US\$ 1.5 billion), while its market capitalization amounted to EUR 2.1 billion (US\$ 2.5 billion) in 2014. The product portfolio of Richter covers a broad range of therapeutic areas, including gynaecology, central nervous system, and cardiovascular areas. Richter is a significant player in the female healthcare field worldwide.
Generic		A generic medicine is a medicine that provides the same quality, safety and efficacy as the original brand name product which undergoes strict scrutiny before it is licensed and given market approval by national regulatory authorities.
Hypogonadism		Hypogonadism occurs when the body's sex glands produce little or no hormones. In men, these glands (gonads) are the testes.
Ibuprofen		Ibuprofen is a commonly used nonsteroidal anti-inflammatory drug (NSAID).
Lenzetto®		Brand name for Acrux's unique estradiol spray in the European Union. The Lenzetto® trademark is owned by Gedeon Richter.
Net profit after tax	NPAT	Total amount earned during the financial reporting period after deducting income tax expense. The financial statements are audited and comply with relevant accounting principles, taxation laws and accounting standards.
Non-steroidal anti-inflammatory drug	NSAID	All nonsteroidal anti-inflammatory drugs (NSAIDs) differ in structure but they all have similar antipyretic, anti-inflammatory and analgesic properties. NSAIDs work by blocking the variant forms of the cyclooxygenase (COX) enzyme, inhibiting production of prostaglandins and thromboxanes, which are produced as part of the body's inflammatory response.
NRx		New prescriptions over a period of time
Onychomycosis		Onychomycosis is a fungal infection of the toenails or fingernails that may involve any component of the nail unit, including the matrix, bed, or plate. Onychomycosis can cause pain, discomfort, and disfigurement and may produce serious physical and occupational limitations, as well as reducing quality of life.
Perrigo		Perrigo Company Plc., is a top five global over-the-counter ("OTC") consumer goods and leading specialty pharmaceutical company. It is one of the world's largest manufacturers of OTC healthcare products and suppliers of infant formulas for the store brand market.
Testosterone		Testosterone is a naturally occurring sex hormone that is produced in a man's testicles.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to, or affect a localised area of the surface of the body.
Transdermal		Transdermal is a route of administration wherein active pharmaceutical ingredients are delivered across the skin for systemic distribution. Examples include Axiron, Evamist and Lenzetto.
TRx		Total number of prescriptions over a period of time