APPENDIX

PHARMACEUTICAL R&D AND ITS COMPONENTS

Research and experimental development may be defined as creative work undertaken on a systematic basis to increase the stock of scientific and technical knowledge and to use this stock of knowledge to devise new applications. In the context of pharmaceuticals, R and D concerns primarily with the discovery of new prescription medicines.

For analytical purposes, pharmaceutical R and D can be divided into two broad categories: (a) Direct R and D for the drugs, and (b) supportive R and D or infrastructure.

(a) Direct Components

(i) **Basic Research**: Basic research is original investigation undertaken in order to gain new scientific knowledge and understanding. It is not primarily directed towards any specific practical aim or application.
Basic research yields new hypotheses, theories and general laws. It involves the analysis of the properties, structures and inter-relations of substances and phenomena of all types with a view to organizing the findings into general laws using explanatory outlines and interpretative theories. The investigation has no immediate specific practical application in view but may be oriented towards an area of interest to the performing organization.

(ii) **Applied Research**: Applied research is the practical application of knowledge derived from basic research and covers product and process researches including the problems concerning
production, maintenance and so on. This can be further divided into (a) product research on existing lines, which includes new combinations of active ingredients and products of purely imitative nature; (b) product research on new lines consisting of single chemical entities which have not been introduced previously in the Indian industries; and (c) process improvement, either in reduction in number of stages in production or replacement of costly or imported material by cheap and indigenous material or increase in yield / reduction in cost and efficient utilization of inputs.

(iii) Development: Concerns the definition of the optimum dosage form for the substance, transferring the compound into a medical preparation, such as tablets, to establish the most effective, stable, palatable and well-tolerated form of administration.

(iv) Therapeutic Research: This is primarily concerned with the clinical testing of new and existing compounds in humans. Generally, clinical testing is carried out in four phases. Phase one is concerned with determining how normal persons metabolize a drug and human safety aspects. In phase two, the drug is tested on a limited number of sick people to assess the drug's effectiveness against a disease and the dosage ranges of a product. Expanded studies are carried out in phase three to statistically confirm phase two findings and detect effects and check interactions with other drugs. Phase four studies are directed towards expanding the therapeutic claims of a product as well as monitoring long-term effects.

(b) Supportive R and D or Infrastructure

A Special feature of infrastructure or supportive R and D in the drug industry is that many components could have an independent
status of research areas by their own merit. However, they have been included here only to indicate their relationship with direct components. Secondly, no chemical – even if its therapeutic value has been established – could be expected to become an accepted drug unless it passes through the various stages of supportive research.

(i) **Animal House**: This is a vital aspect of the drugs and pharmaceutical industry. This facility is an absolute necessity for development of new drugs, and for testing existing ones for quality control during and after production. Many species of animals like mice, rats, hamsters, guinea pigs, rabbits, dogs and monkeys in various stages of growth are required. Physiological and genetic norms of these animals have to be consistent and known in order to have a good animal house.

(ii) **Fermentation Research**: This could be considered both as an infrastructure activity as well as primary activity. Fermentation research is mainly concerned with problems of production of antibiotics and some other types of drugs, which are products of fermentation. Raw materials, strain and medium improvement, better control of pit, variation of atmosphere in which the fermentation is conducted, etc are the fields in which investigations are carried out.

(iii) **Equipment, Machinery and Import Substitution**: The main plank of this is the development of equipment and machinery required for production of a drug. Drug making is often a multi-step process. So substitution at any stage will be beneficial not only for the economy, but also for establishing production competence within the country.

(iv) **Packaging**: This activity could hardly be considered as part of any research activity. Labeling, amount of material to be packed or bottled in containers, upkeep of the quality of the
formulations against temperature, humidity, transport etc are part of this activity. The problem of high illiteracy, low health and drug consciousness among the general public makes this type of research important.