Annex 5

Basic elements of good manufacturing practices in pharmaceutical production

Poor-quality medicines are not only a health hazard, but a waste of money for both governments and individual consumers, since they may contain toxic substances that have been unintentionally added. For example, in Haiti in 1996, more than 80 children died after receiving a syrup for cough and colds containing glycerol contaminated with diethylene glycol \( (I) \). If the manufacturer had followed good manufacturing practices (GMP), these deaths could have been prevented.

In addition, a medicine that contains little or none of the claimed active ingredient will not have the intended therapeutic effect. An antibiotic with some — but not enough — of the active ingredient will not cure infections. Even worse, bacteria exposed to low levels of the antibiotic may not be killed and may become resistant to the drug, even at the correct dosage, putting more lives at risk.

**Good manufacturing practices help boost pharmaceutical export opportunities**

Most countries will accept the import and sale of medicines only if they have been manufactured according to internationally recognized GMP. For this reason, governments seeking to promote their country’s export of pharmaceuticals can do so by making GMP mandatory for all pharmaceutical production and by training their inspectors in GMP requirements.

**What are good manufacturing practices?**

GMP are that part of quality assurance which ensures that products are consistently produced and controlled according to quality standards. They are designed to minimize the main risks involved in pharmaceutical production that cannot be eliminated through testing of the final product. These risks are:

— the unexpected contamination of products, causing damage to health or even death;
— incorrect labels on containers, which could mean that patients receive the wrong medicine;
— insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.
GMP cover all aspects of production, from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. Systems must be established to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process — every time a product is made.

WHO has established detailed guidelines for GMP (2), and many countries have formulated their own GMP requirements based on those of WHO. Others have harmonized their requirements, e.g. in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.

**Are good manufacturing practices necessary if there is a quality control laboratory?**

Good quality must be built in during the manufacturing process; testing products after they have been manufactured is not enough. GMP prevent errors that cannot be eliminated through quality control of the finished product. Without GMP it is impossible to be sure that every unit of medicine is of the same quality as those tested in the laboratory.

In the early 1970s, a manufacturer in the United Kingdom produced an infusion fluid which caused the death of five patients because it was heavily contaminated with bacteria (3). Before distributing the fluid, the manufacturer had tested several bottles and found them to be sterile. Eventually a technical fault was found in the sterilizer: the bottles at the bottom had not been properly sterilized. The bottles that the manufacturer had tested were from the upper part, giving the false impression that all the bottles were sterile.

**Can manufacturers afford to implement good manufacturing practices?**

Making poor-quality products does not save money. In the long run, it is more expensive finding mistakes after they have been made than preventing them in the first place. GMP are designed to ensure that mistakes do not occur.

Implementation of GMP is an investment in good-quality medicines, and will improve the health of both the individual patient and the community, as well as benefiting the pharmaceutical industry and health professionals.
Making and distributing poor-quality medicines leads to loss of credibility for everyone, including public and private health care services and pharmaceutical manufacturers.

References

