How you can act

In order to implement GMP effectively, countries must make GMP a legal requirement for all production of medicines, and establish a regulatory authority that is empowered to implement and enforce the requirement. Lawmakers, authorities and manufacturers are crucial, but other groups are equally necessary to ensure that medicines are of good quality:

• *Policymakers* by initiating and supporting efforts to strengthen legislation and the regulatory authority • *Drug regulatory authorities* by only approving products from GMP manufacturers, inspecting national production and taking action against those who do not comply with GMP • *Manufacturers* by following GMP requirements • *Distributors* by only distributing products approved by the authorities • *Prescribers* by only prescribing approved medicines • *Consumers* by only buying medicines through legal distributors • *We can all contribute* by notifying the authorities if we come across poor quality products and illegal manufacturers or distributors.

WHO works to strengthen GMP

WHO can assist countries that want to strengthen GMP. Guidelines and training materials are available, technical support may also be given. If you want to know more, please contact the WHO representative in your country, your WHO regional office or WHO headquarters in Geneva.

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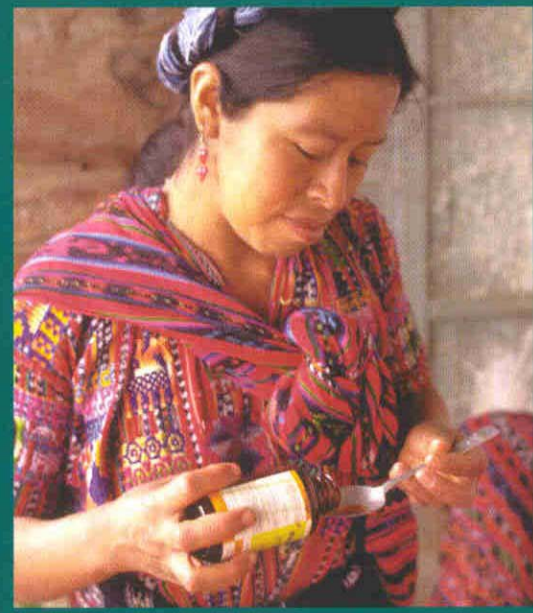
Making a Difference

Manufacturing Quality Medicines



Quality medicines can save lives. Poor quality products damage health. Good manufacturing practices concern us all. Learn how you can act to ensure that medicines help and do not harm.

Why are good manufacturing practices (GMP) important?

☛ Poor quality medicines are not only a health hazard, but a waste of money for both governments and individual consumers.

Poor quality medicines can damage health

☛ A poor quality medicine may contain toxic substances that have been unintentionally added. *In Haiti in 1996, more than 80 children died after receiving a cough and cold syrup containing glycerol contaminated with diethylene glycol. If the manufacturer had followed GMP, these deaths could have been prevented.*

☛ A medicine that contains little or none of the claimed 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.*

GMP helps boost pharmaceutical export opportunities

Most countries will only accept import and sale of medicines that have been manufactured to internationally recognized GMP.

☛ Governments seeking to promote their countries' export of pharmaceuticals can do so by making GMP mandatory for all pharmaceutical production and by training their inspectors in GMP requirements.

What is GMP?

☛ Good manufacturing practices (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards.

☛ It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: • unexpected contamination of products, causing damage to health or even death • wrong labels on containers, leading to the patient getting the wrong medicine • not enough or too much active ingredient, resulting in ineffective treatment or adverse effects.

☛ GMP covers 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. There must be systems 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 good manufacturing practices. Many countries have formulated their own requirements for GMP based on WHO GMP. Others have harmonized their requirements, for example in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.

Is GMP necessary if there is a quality control laboratory?

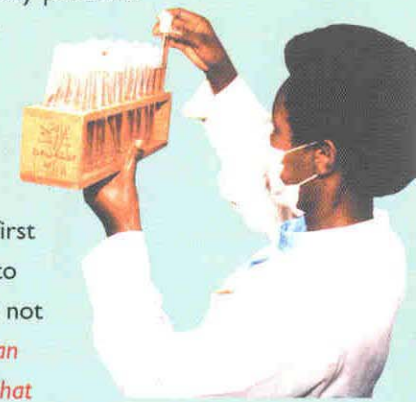
☛ Yes. Not even extensive testing of a product can detect all possible mistakes or accidents that may occur during production.

☛ Without GMP it is impossible to be sure that every unit of a medicine is of the same quality as the units of medicine tested in the laboratory.

In the early 1970s a UK manufacturer produced an infusion fluid which caused the death of five patients because it was heavily contaminated with bacteria. 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 GMP?

☛ Yes. 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 is designed to ensure that mistakes do not occur. *In 1998, a European manufacturer discovered that one of its products used for general anesthesia contained up to seven times the stated amount of active ingredient. By then, the product had already been exported to 24 countries all over the world. It is not known if anybody died, but the manufacturer had to recall the dangerous product – incurring major expense as well as adverse publicity.*



☛ Implementation of GMP is an investment in good quality medicines. This will improve the health of 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 involved: both public and private health care providers and manufacturers.