

OPPI

Anti-Counterfeiting Guidelines

INTRODUCTION

With over 5 Bn. US.\$ in domestic sales and another 2 Bn.US\$ in exports, India is emerging as a global powerhouse in pharmaceuticals. It is increasingly being recognised as a reliable source of quality medicines at affordable prices. Unfortunately, a small number of unscrupulous elements are engaged in producing counterfeit medicines which is not only a major public health hazard but also tarnishes the good image of the Indian Pharmaceutical Industry as well as the country. OPPI has been in forefront in fighting this menace, and has conducted several seminars, published reports and actively partnered with Ministry of Health, Government of India, to develop policies to curb this evil. In continuation of this cause, the Technical Committee of OPPI has developed an Anti-counterfeit Policy which gives guidelines and an operating procedure to prevent counterfeiting. Members of OPPI as well as other pharmaceutical manufacturers are strongly recommended to adopt these guidelines in their organisations.

PURPOSE

Counterfeit medicines represent an unacceptable risk to patient safety whilst at the same time jeopardizing the original manufacturer's image, reputation and, in extreme cases, their economic viability. It is therefore imperative that every manufacturer of prescription and OTC medicines has in place an effective operating procedure, to make counterfeiting difficult and, to facilitate detection and investigation.

SCOPE

These guidelines help in establishing requirements that facilitate authentication and discourage counterfeiting and re-cycling of original manufacturer's packs. These Guidelines can be adopted by companies that are engaged in manufacturing, distributing or marketing of medicinal products.

Every Company needs to protect its products and customers from the risks of counterfeiting and to protect the Company name by :

- Making it difficult for its products to be counterfeited.
- Enabling the authentication of products and its source.

This does not purport to be an exhaustive list of anti-counterfeiting measures and should be used more as a guide to the understanding of the requirements. Other proven anti-counterfeiting measures not mentioned in this Guide may also be adopted.

ANTI-COUNTERFEITING PHILOSOPHY

The drugs & medicines counterfeiter, or the “spurious drug manufacturer” as it is known in India, typically counterfeit:

- Large volume, well distributed brands.
- High value, high visibility brands.
- Dosage forms and packs that are easy to duplicate.

A ‘risk-based’ approach to anti-counterfeiting may, at first sight, seem attractive. Products / Brands not falling in the above categories, for example a high value product but having a complicated device like an ‘actuator’ or a high value parenteral with a pre-filled syringe and hence difficult to copy, may therefore seem at less risk. However such products / packs may be at risk of being re-cycled. Other products falling in the above categories are certainly at high risk of being counterfeited. A multi-pronged approach that makes use of overt and covert features as well as tamper evident features coupled with a policy on control of used packs is what is recommended in this Guide.

While selecting the stockists and C & F agents for distribution and storage of products, it is important to select them based on their previous experience, integrity and knowledge of handling medical products. A formal contract which includes appropriate measures / clauses to prevent stocking of counterfeit products should be integral part of the contract.

Anti-Counterfeiting Measures

This Guide addresses the following anti-counterfeiting measures :

- Overt (visible) features

- Covert (hidden) features
- Design of packaging components.
- Other design considerations.
- Control of components.
- Incident management

OVERT (VISIBLE) FEATURES

Whilst companies should have the widest possible flexibility in designing the commercial image of the dose form, all solid dose forms must be identifiable without reference to the primary or secondary packaging. This feature will enable companies to visually identify the solid dosage form even when it has been separated from its original packaging. All companies therefore must have a policy to move, over time, to a standardised marking on all solid dose forms.

Each Company must adapt a uniform code that can be applied to the solid dose form. Ideally the Brand name must be printed or embossed on the surface. Current technology permits printing of capsules with not just brand names but even logos. The better hard capsule shell suppliers offer innovative printing which are difficult to duplicate. New product development must also consider such features whilst developing solid dose forms.

Currently, companies outsource production under several models. Whenever possible a Company should own the tooling used to produce Company specific components so that when it is no longer required it can be defaced or destroyed under Company control.

This applies to all medicinal solid dosage forms (e.g. tablets, soft and hard gelatin capsules, pastilles and lozenges but not to transdermal patches or clinical trial material).

TYPE SETTING

Should be as simple as possible to ensure clarity of code. As a routine, advice should be sought from tablet tooling or capsule shell manufacturers.

STYLE

All letters should preferably be in higher case (Capitals). All characters should be of equal height. Characters should be selected with embossing / printing in mind in that 'open' letters (e.g. L, H, F, S) should be used in preference to close letters (e.g. Q, B).

SIZE

The size of character should be determined by the size of the solid dosage form to be marked, but the character should be easily readable. There may be dose forms (like tablets less than 6 mm or smaller capsules) on which the Brand name or Company name may not physically fit. An abbreviated name or a code should be considered in such cases.

COVERT (HIDDEN) FEATURES

The purpose of covert features is to enable the detection of counterfeited products. This will prove to the Regulatory and other Authorities that the Original Company is not the source of such a product and that it is not a "spurious drug manufacturer". The covert feature must not be easy to detect or copy without specialist knowledge or equipment. Covert features are typically placed on printed packaging materials. Also, FDA approved markers which are chemicals to be used in trace quantities are available which can be incorporated in the product itself.

Examples of such covert features are :

Invisible Printing

Using special inks invisible markings can be added which only appear under certain conditions, such as :

- UV fluorescing pigment.
- "Rub and reveal" inks – revealed by rubbing surface with a coin.
- Photochromic inks - which change colour when exposed to a specific wavelength of light.

Watermarks

Package inserts or leaflets could carry Company watermarks which would be difficult to reproduce without much expense.

Hidden Marks

Special marks may be printed in areas which are not normally visible, such as carton glue flaps, and in a way which does not attract attention and is not easy to copy. Other examples include adding an extra 'full stop' at the end of a paragraph on the label or carton.

DESIGN OF PACKAGING COMPONENTS

Packaging components should be designed, wherever possible, to maximize the opportunity for preventing or detecting counterfeits through non-compliance. Tamper evident features can also provide effective counterfeit protection, especially where they deface the primary or secondary container when the seal integrity is compromised. Holograms are especially effective when incorporated as a tamper evident seal on the primary or secondary pack.

Primary packaging should be designed such that it makes it difficult or expensive for the counterfeiter to copy the pack. Examples are :

- Double foil (Alu-Alu) strips for solid dose forms, rather than conventional strips.
- Hologram printed plain foils for conventional strip packs.
- Bottles with Company Logo incorporated in the mould design.
- Printing on glass vials and ampoules in addition to the mandatory label.

Secondary Packaging should be designed incorporating overt features like :

- Hologram flap seals that tear when opened.
- Laminated or glossy, varnished cartons.
- Cartons with several colour printing
- Using 'raised' printing or Braille on printed components.

Such pack designs enable the end users to verify the authenticity of the pack. These features will certainly mean additional cost but will deter the counterfeiter from being

able to copy the packs cheaply. However some customer education may also be needed to ensure that they do not get re-cycled packs.

A combination of overt and covert measures are most suitable.

OTHER DESIGN CONSIDERATIONS

Tablets and capsules can be designed with unique shapes that need expensive tooling to reproduce or copy. Printed coated tablets and capsules with banding locks are also very difficult to copy.

Several design considerations such as these with respect to the product, the primary pack and other packaging components are feasible which make it difficult for the counterfeiter to copy cheaply.

All these features are effective only if the packaging components and materials are controlled and when there is some awareness amongst the end user to tell apart a fake from a genuine product. Therefore reconciliation of such packaging materials after manufacturing activity completed is of paramount importance.

CONTROL OF COMPONENTS

Control of Supply

Suppliers should be carefully selected to ensure that they do not get tempted to sell to a counterfeiter. Ideally all supplies must be shipped to the original service provider and there should be in place a system by which orders only from the original service provider will be executed by the supplier.

In the current scenario of 'contract manufacturing' or outsourcing such a rigid model may not be feasible. However controls must be in place to ensure that the service provider is bound by contract not to allow materials to fall into the wrong hands and that purchase orders are executed only if authorised by the original contract provider.

A signed agreement with the supplier of the packaging materials, which includes confidentiality and commitment, may be in order.

Control of Use

Security features are best controlled if they are used and applied In-house. Wherever possible the precise details of the technology used should be disclosed to as few people as necessary on a 'need to know' basis.

Printed material should be stored and handled securely, and off-line overprinted items should be kept in sealed containers. Security items such as hologram seals should be kept in locked and secure areas, with restricted access and should be handled with maximum security both at the suppliers and at own premises.

Machine trials should be carried out using blank or defaced components wherever possible. Samples used for display should be superscribed with the words 'SAMPLE' or similar word of caution to prevent misuse.

Control of Disposal

Disposal at the user's end is a major threat to anti-counterfeiting. A large source of recycled vials could be hospital waste. Ideally special arrangements should be arrived at with major customers such as hospitals to ensure that used components and packaging materials are destroyed after use. If several Companies approach the large hospitals (through Trade Bodies) with support from the Regulatory Authorities, it may be possible to help the hospitals with a disposal plan.

The other potential source for counterfeiting is rejected packing materials, components, redundant printing stereotypes / plates, machine parts or tooling that could be used by counterfeiters. These could arise at the suppliers or In-house end. Again strict procedures must be in place to ensure that such items do not find their way to scrap in a state that facilitates unauthorised use. Another source is disposal of date-expired items.

Extreme vigilance should be maintained if contractual services are being used and it is imperative that no assumptions are made with respect to destruction & disposal.

INCIDENT MANAGEMENT

All Companies are under threat of having their products counterfeited. The first action therefore is to have a well understood procedure in place (akin to the 'complaints' procedure) to handle an incident of counterfeiting.

If the Company has a well established anti-counterfeiting policy this should ensure that there are features that will authenticate the product pack or confirm that it is counterfeit. The first hurdle of the Company being suspected of being a "spurious drug manufacturer" is then averted.

The next step is the investigation. Investigation should as far as possible determine whether the counterfeit was as a result of a re-cycled product pack or a complete copy. If it is established that it is 're-cycled' then steps should be taken to identify the weakest link in the supply chain.

If the counterfeit is a complete copy, but a detectable one, then customer education may be needed to ensure that the end user is made aware of the overt features. More important than this would be to 'educate' the Wholesaler and the other Dealers in the chain so that they are not 'palmed off' counterfeit products.

GLOSSARY

Anti-counterfeiting:

Any measure which, when employed prevents counterfeiting or establishes whether the product is a counterfeit one.

Counterfeit:

Term commonly used in regulated markets. A product / pack that is not manufactured by the original manufacturer. A fake made by a counterfeiter with the deliberate intention of passing it off as the original. The product may not (or may) contain the active ingredient/s printed on the label.

Counterfeiting:

A deliberate action that enables the manufacture and distribution of counterfeit drug products.

Primary Pack

The pack that is in direct contact with, and contains, the drug. Example is a liquid in a bottle.

Secondary Pack:

The pack that holds or contains the primary pack. Example is a carton with a primary pack of a bottle in it.

Spurious:

Term commonly used in India to describe counterfeit drug products. Refer to the Drugs & Cosmetics Act in which a detailed definition is provided under the act.