06 - 5. Drug approval

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© SPMM Course 5. Drug approval Any drug must undergo the following steps before approval is granted by regulatory agencies such as FDA in the US and MHRA in the UK.

1. Preclinical Animal Studies: The pathway a drug must undergo before approval and marketing start with animal studies where the molecule is demonstrated to have specific actions. These extensive preclinical animal studies must be carried out at least on two different animal species. Mutagenicity, carcinogenicity and organ system toxicity are studies at this phase.
2. Human trials – volunteers phase 1: (safety) An investigational new drug then enters human trials. The first phase consists of determining if the drug is safe for human subjects. It is administered to a small group of volunteers and safety; tolerability and pharmacokinetics of the drug are ascertained. They are usually open or uncontrolled studies.
3. Human trials – patients phase 2: (effectiveness) In phase 2 effectiveness is studied in hundreds of patients with target disease in comparison to placebo to see if it works at all against the disease. The main methods are controlled trails or small randomized controlled trials.
4. Human trials – patients phase 3: (superiority or equivalence to standard looking for comparative efficacy) and tolerance profile) In phase 3 the drug undergoes extensive doubleblind RCT to determine how well does it work and what are the common side effects.
5. Human trials – post-marketing surveillance phase 4: Phase 4 takes place if all the previous phases are successfully crossed – the drug undergoes an approval process by regulatory bodies and post-marketing surveillance ensues. Less common side effects, which sometimes could lead to drug withdrawal, can be picked up when large scale prescribing takes place during postmarketing surveillance observations. Psychotropic Drugs Adverse effects detected by post marketing surveillance
6. Nefazadone Hepatotoxicity
7. Droperidol, Thioridazine QT prolongation on ECG
8. Sertindole Sudden cardiac death
9. Thalidomide (analgesic) Phocomelia
10. Nomifensine Hepatotoxicity
11. Zimeldine Hypersensitivity reactions and Guillain-Barre syndrome
12. Remoxipiride(sulpiride group) Aplastic Anaemia
13. Mianserin Blood dyscrasias

14. MAOIs Cheese reactions
15. Clozapine Agranulocytosis

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