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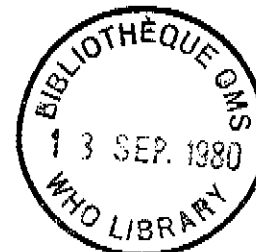
Technical Group on Use of
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RELATIONSHIP OF PRESENT PROJECT TO OTHER WHO ACTIVITIES
CONCERNING THERAPEUTIC SUBSTANCES

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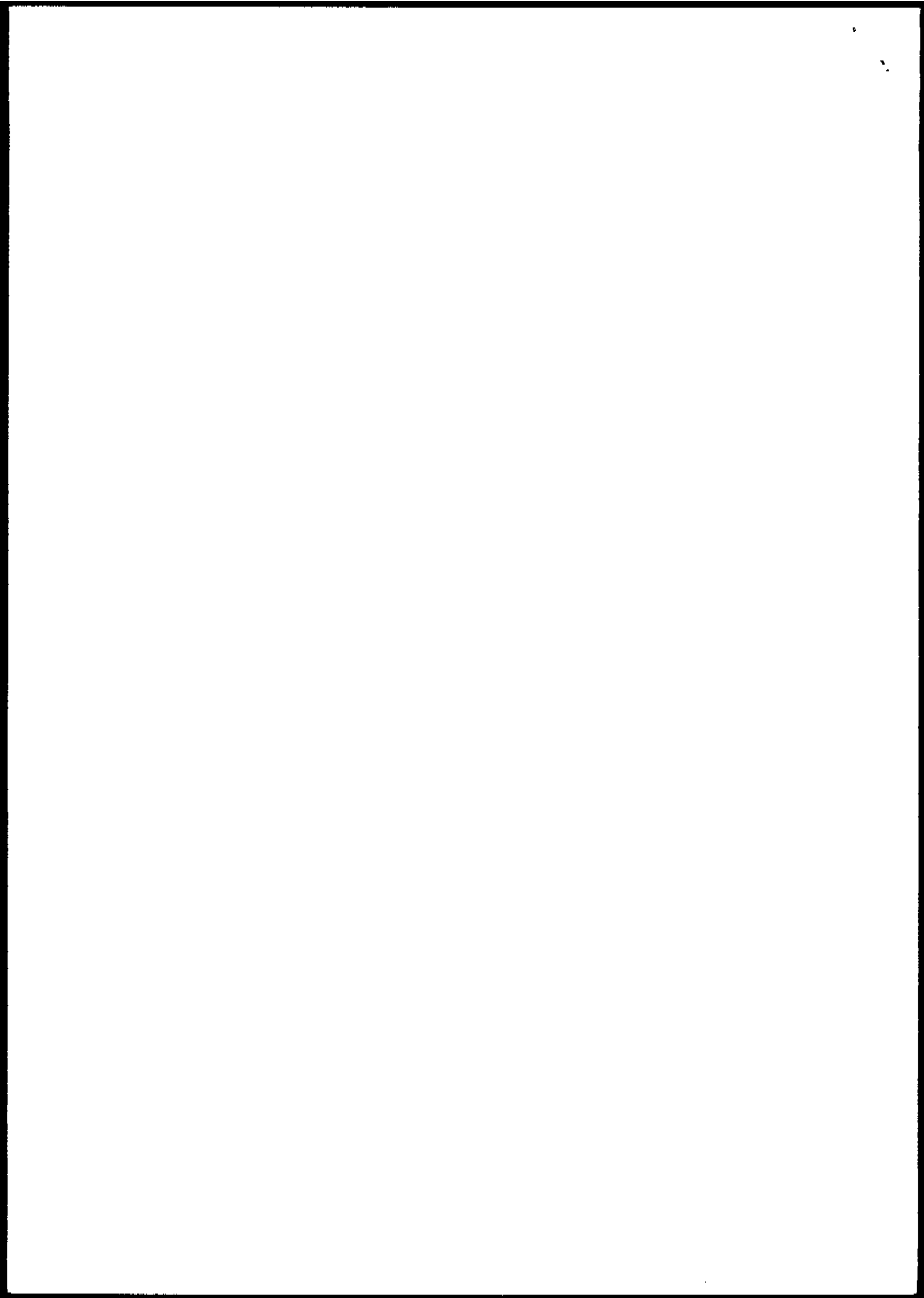
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A high proportion of technical activities conducted under the aegis of WHO is concerned, either directly or indirectly, with the effective, safe and rational use of drugs. Whereas some major programmes concerned with immunization, human reproduction, and tropical disease bear scant relation to the problems of the elderly, many others concerned, for instance, with cardiovascular disease, cancer, and mental health have immediate and specific relevance to the health of ageing populations. Drug use among the elderly also has inherent, if less specific, relevance to various other programmes devoted to wider therapeutic issues including the adoption of pharmacopoeial standards, drug usage surveys, surveillance of adverse drug reactions and drug abuse patterns, and related informational activities. Furthermore, article 21 (e) of the WHO Constitution which, as yet, remains unimplemented, is also pertinent in that it provides the Health Assembly with the authority to adopt regulations concerning advertising and labelling of biological and pharmaceutical products moving in international commerce.

Much scope for coordination with established programmes consequently exists if specific projects are to be developed on the use of drugs by the elderly and this paper identifies some possible areas of collaboration.

Formulation of Medicinal Products

Realisation that wide and clinically significant variations existed in the release characteristics of nominally equivalent marketed brands of digoxin tablets has attracted much attention over the past few years to bioavailability as an important consideration in the formulation of solid dosage forms of many drugs. This concern is now reflected in proposed revisions in the International Pharmacopoeia. The adequacy of the recommended tests of disintegration and dissolution as in vitro indicators of bioavailability will be retained under review, particularly in relation to clinical evidence of inadequacy in drug performance, and the interests and requirements of elderly subjects on long-term medication may require specific consideration in some cases.

The influence of drug formulation on compliance among elderly subjects

has received relatively little attention, but this is another factor that might well be considered in the development of official monographs in the international pharmacopoeia.

Drug usage

Information concerning patterns of drug usage in a number of countries situated in North-Western and Eastern Europe have been obtained under the aegis of WHO over a period of several years. Wide local and national variations are evident in prescribing practice that cannot be ascribed to natural variations in the incidence of disease. For the most part the data do not, at present, allow usage patterns to be determined within specific age groups. Nonetheless, in principle, specific studies on drug use of the elderly could be accommodated within the terms of reference of the existing programme.

Drug surveillance

For more than a decade WHO has fostered an international approach to surveillance of adverse drug reactions. More than 200,000 individual reports of reactions voluntarily notified by clinicians to some twenty-two national collaborating centres are collated in a central data-bank. Nonetheless, the reliability of this type of approach in providing early warning of previously unanticipated reactions has been questioned.

The detection of delayed adverse drug reactions resulting from long-term treatment is particularly challenging within an aging population of patients with a relatively high incidence of intercurrent morbidity and mortality. Various alternative approaches to the detection of drug toxicity under these circumstances have been widely canvassed including intensive hospital monitoring, case control studies, postmarketing clinical trials, cohort studies and linkage of medical records. Whereas each of these has some specific advantage in offering information on the safety of new medicines during normal clinical use, no single method can provide fully comprehensive information.

Collaborative studies

Whatever approach may be selected to investigate the performance of drugs in routine practice, adequacy of scale is frequently the dominant problem in the design of studies. Success is frequently contingent upon multi-centre collaboration and an efficient coordinating mechanism, and collaborative clinical research is gaining momentum at both national and

international levels.

The experience of WHO in this context is most highly developed in the field of human reproduction. It is notable, however, that the impact upon practising clinicians, drug regulatory authorities and pharmaceutical manufacturers of a WHO-sponsored multi-centre international trial on the effect of long-term clofibrate treatment was greater than might have been anticipated from an analogous national study.

Independent central coordination of clinical investigation serves not only to promote the influence of a project; it can confer needed stability of operation to long-term studies, and it may provide the only means to obtain answers to therapeutic questions that, on logistic grounds, are beyond the capacity of a single centre or even a single country to address.