

Indian market's fixation with fixed dose combinations

Fixed dose combination [FDC] are highly popular in the Indian pharmaceutical market and are particularly flourishing in the last few years. The rationality of FDCs should be based on certain aspects like:

- The drugs in the combination should act by different mechanisms.
- The FDC should have enhanced action compared to the additive effect of the individual ingredients (synergy).
- The pharmacokinetics must not be widely different.
- Also important is that the combination should not have supra-additive toxicity of the ingredients.

The World Health Organization's [WHO] Model List of Essential Drugs provides examples of some rational FDCs such as:

- Sulfamethoxazole + Trimethoprim.
- Antitubercular FDCs like Rifampicin + Isoniazid, Isoniazid + Ethambutol, etc.
- Antiparkinsonism FDCs like Levodopa + Carbidopa.

Unfortunately, FDCs being introduced in India are usually irrational. The most pressing concern with irrational FDCs is that they expose patients to unnecessary risk of adverse drug reactions. For instance, pediatric formulations of Nimesulide + Paracetamol can induce severe hypothermia in small children and lead to shock. FDCs of Diclofenac + Serrapeptase do not offer any particular advantage over the individual drugs despite vigorous claims that Serrapeptase promotes more rapid resolution of inflammation. On the other hand, the patient is exposed to greater risk of gastrointestinal [GI] irritation and serious bleeding from unsuspected peptic ulceration. FDCs of quinolones and nitroimidazoles (e.g. Norfloxacin + Metronidazole, Ciprofloxacin + Tinidazole, Ofloxacin + Ornidazole) have not been recommended in any standard books, but continue to be heavily prescribed drugs in GI infections, pelvic inflammatory disease, dental infections, etc., to cover up for diagnostic imprecision and the lack of access to laboratory facilities. Such injudicious use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource-poor country. A glaring example is the emergence of Ciprofloxacin-resistant *Salmonella typhi* strains which have made treatment of typhoid fever a difficult and expensive proposition in India today.

Over the years the Indian drug control authority has issued banned notifications on many FDCs like Analgin + Pitofenone, Vitamins B1 + B6 + B12, Cyproheptadine + Lysine, etc. But are these measures sufficient? Obviously not, since these notifications have not deterred manufacturers from coming out with new irrational FDCs. At this crucial juncture, when the global community represented by WHO is making an all out effort to propagate the concept of essential drugs amongst consumers throughout the world, our official stance could be viewed as too meager. India being the world's second most populous country we should expect much more of ourselves and not pay mere lip service to the global campaign.

Irrational FDCs also impose unnecessary financial burden on consumers. Medical practitioners who patronize such combinations could be the center of controversy when subjected to litigation in consumer forums, as these combinations do not find mention in standard text or reference books and reputed medical journals. Pharmaceutical manufacturers, however, continue to reap the benefits of huge sales, and therefore continue promoting them with vigor.

Time has come for all of us, as practitioners and consumers, to raise this matter vociferously through all possible avenues. The campaign against meaningless FDCs must be carried on to every nook and corner of the country. The power vested in state-level drug regulatory authorities is often taken advantage of by pharmaceutical companies who push through irrational combinations without proper scrutiny. Therefore, in making this campaign a success we earnestly hope that our drug regulatory bodies would take urgent and stringent measures in mitigating such free flow of irrational FDCs.

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RATIONAL DRUG BULLETIN

A CDMU Quarterly Bulletin

Vol. 12, No. 1, Jan-Mar 2002

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Introduction

Iron deficiency is the most common and widespread nutritional disorder in the world.¹ Nearly half of all pregnant women in the world are estimated to be anemic: 52% in non-industrialized as compared to 23% in industrialized countries.² Anemia is particularly prevalent in South Asia. The Second National Family Health Survey in 1998-1999 [NFHS-II]³ showed that 54% of rural women of childbearing age are anemic as against 46% of women in urban areas. Kerala has only 23% prevalence of anemia as against 62% in many northeastern states of India.

Iron deficiency in childbearing women increases maternal mortality, prenatal and perinatal infant loss, and prematurity.^{4,5} Forty percent of all maternal perinatal deaths are linked to anemia. Favorable pregnancy outcome occurs 30-45% less often in anemic mothers, and their infants have less than one half of normal iron reserves.⁶

The woman in a developing country is always in a state of precarious iron balance during the reproductive years. The iron stores are not well developed because of poor nutritional intake, recurrent infections, menstrual blood loss and repeated pregnancies. Gender discrimination in a country like India ensures that the girl child lacks access to balanced diet, adequate health care and proper education. Thus the average Indian woman enters pregnancy with iron and folate deficiency.

Iron requirement during pregnancy

During pregnancy the maternal need for extra iron averages close to 800 mg (elemental iron), of which about 300 mg is for the fetus and the placenta and the rest for maternal hemoglobin [Hb] mass expansion. The placental and fetal requirement is obligatory and will be diverted to this end even if the mother is iron deficient. Approximately 200 mg more is shed via the gut, urine and skin. This total amount of 1000 mg quite exceeds the iron stores of most women, even in western countries. Practically all of this iron is used during the latter half of pregnancy. Therefore iron requirement increases from a minimal of 0.8 mg/day in the first trimester to 6-7 mg/day in the second half of pregnancy.⁷ Overall, the pregnant woman needs about 2 – 4.8 mg iron per day.⁸ The woman must consume 20 to 48 mg of dietary iron in order to absorb this quantity of iron daily. An average vegetarian diet does not provide more than 10 to 15 mg per day. Thus, the amount of iron absorbed from diet, coupled with that mobilized from body iron stores, is usually insufficient to meet the demands imposed by pregnancy. This is true even though the bioavailability of iron from the gastrointestinal tract is moderately increased during pregnancy and menstrual iron loss ceases.

Therefore, iron supplementation during pregnancy is recommended universally even in non-anemic women.

In developing countries, where average meals may be poor in iron, iron supplementation may be considered in pre-pregnant woman and adolescent girls as well. Women will then enter pregnancy with adequate iron reserves.

Lactation results in loss of iron via breast milk. Consequently, a deficiency developed during pregnancy may be perpetuated during lactation. In terms of iron balance, however, lactational amenorrhea more than compensates for iron loss through breast milk.

Prevention of iron deficiency anemia in pregnancy through food-based approaches

Food-based approaches can broadly be categorized into two – dietary improvement and food fortification.

The former should include strategies to

- Improved the year-round availability of micronutrient-rich foods.
- Ensured the access of households, specially those at risk, to such foods.
- Improve feeding practices with respect to these foods.

With respect to iron deficiency, efforts should be directed towards promoting the availability of and access to iron-rich foods. Examples include liver, meat, fish, poultry and non-animal foods such as legumes, green leafy vegetables, nuts, oilseeds, jaggery and dried fruits. In general, animal foods (other than egg and milk) tend to have higher iron content than non-animal foods.

Bioavailability of food iron is strongly influenced by enhancers and inhibitors in the diet [see Table 1]. Iron absorption can vary from 1% to 40% depending on the mix of such elements in the meal. Typical vegetarian Indian diets can contain large quantities of inhibitors. Therefore, focus should also be upon foods that enhance the absorption or utilization of iron. Examples include foods of animal origin (other than egg and milk) and non-animal foods, such as fresh fruits, green leafy vegetables and tubers, that are sources of vitamins A, C or folic acid. Finally, effective nutrition education and information on health and nutrition for both supply and demand aspects of programs may be needed to increase the demand for and consumption of such foods.

Examples of simple alterations in food habits that may improve iron bioavailability include:

- Inclusion in the meal fresh fruits or fruit juices and other sources of vitamin C such as

- tomatoes, spinach, cabbage, cauliflower, potatoes and other green leafy vegetables and tubers.
- Consume milk, cheese and other dairy products as between-meal snacks rather than at mealtimes.
- Separate tea drinking from mealtime by at least 2 hours.
- Consume foods containing inhibitors of iron absorption at those meals that are inherently low in iron e.g. breakfast of a low iron cereal (e.g. bread, cornflakes) with tea or milk.

Table 1. Dietary elements that affect the bioavailability of oral iron

Enhancers	Inhibitors
<ul style="list-style-type: none"> ▪ Heme iron, present in liver, meat, fish, poultry and seafood. ▪ Ascorbic acid (Vitamin C) present in citrus fruits, fruit juices, green leafy vegetables, cabbage, cauliflower, tubers, etc. ▪ Some germinated or fermented foods (germination or fermentation reduces phytate content) e.g. soya sauce. 	<ul style="list-style-type: none"> ▪ Phytates present in cereal bran, cereal grains, high extraction flour, legumes, nuts and seeds. ▪ Calcium, particularly in milk and milk products. ▪ Tannins present in tea, coffee, cocoa. ▪ Phosphates in egg yolk. ▪ Oxalates in vegetables. ▪ Excess of dietary fibers.

Food fortification is increasingly being recognized as an effective long-term approach to improving the iron status of populations.² An effective fortification program will require the cooperative efforts of governments, the food industry (producers, distributors and retailers) and the consumers. The range of possible food vehicles identified for iron fortification is wide and include wheat flour, maize flour, bread, pasta, sugar, salt, haldi (turmeric), curry powder and soy sauce. Ferrous sulfate is the most commonly used fortificant for cow milk or infant formulas where this is practiced. Rice fortified with a standard ferrous sulfate mix has been used successfully in the Philippines.² Curry powder has been successfully fortified with iron-EDTA in South Africa. Prema reported that the technology for fortifying common salt with iron has been developed indigenously in India.⁹

The technical, logistical, financial, and social feasibility of a fortification program will have to be carefully considered before recommending fortification. The dietary habits of the population is an important consideration in selecting a suitable vehicle. For instance processed foods would be inappropriate for low income rural areas. Bread would not be able to meet the iron demands of infants and young children who do not take bread. Combined fortification with multiple nutrients (e.g. iron with vitamin C and iodine) may be considered depending on the anticipated risks of deficiency and the local circumstances. However, it must be remembered that fortified foods require processing and are more expensive and fortification should not be at the cost of reduction of overall food supplies or delays in delivery.²

Iron supplementation²

Iron supplementation is the most common strategy currently used to control iron deficiency in developing countries. It is important to distinguish between prophylactic and therapeutic supplementation. The latter aims at rectifying

established and manifest iron deficiency, and thus necessarily has to be more intensive.

Preventive supplementation is particularly well catered to by strategies that combine multiple micronutrient interventions. Thus programs that involve supplementation of iron, folic acid, vitamins A & C, and are directed, in particular, towards infants, children, expectant and nursing mothers, are particularly desirable. Universal supplementation has been recommended by WHO in pregnant women and low birth weight babies. Under universal supplementation, all pregnant women should be given at least 60 mg elemental iron and 400 mcg folic acid daily during the second half of pregnancy. In areas or communities where the anemia prevalence is severe (i.e. above 40%), the supplementation should continue during lactation, at the same dosage, for at least 3 months. In such areas, its is recommended that non-pregnant women of childbearing age, pubertal (adolescent) girls and even adolescent boys, if indicated by > 40% prevalence of anemia among them, should also receive supplementation with 60 mg elemental iron and 400 mcg folic acid daily for 3 month periods. Low birth weight infants should be universally given supplemental iron in a dose of 2 mg/kg per day from 2 months to 23 months of age. Other children in this age group should also receive routine supplementation at 2 mg/kg day if the anemia prevalence exceeds 40% among them. Older children up to 12 years of age in high prevalence areas may be supplemented with iron 30 mg/day and folic acid 250 mcg/day in 3 month courses.

In settings where there are multiple causes of anemia, iron supplementation may only partially correct the Hb deficit. In Indonesia, for instance, combined iron and vitamin A supplementation was needed in areas where both deficiencies were common.¹⁰ Concurrent intervention programs will thus have to include other micronutrients, depending upon the risks of deficiency, as also

control of malaria, hookworm and other chronic or recurrent infections.

Assessing the effectiveness of iron supplementation²

A question that is often asked is how to monitor the effectiveness of supplementation. The established simplest means is to serially monitor changes in Hb or hematocrit. With oral iron supplementation a minimum change of 1 g/dL of Hb is to be expected in 1 to 2 months time. Improvement slower than this usually indicates that the supplementation is ineffective. The response to parenteral iron is not greater but is more certain. Once manifest deficiency in the form of low Hb or hematocrit is corrected, the supplementation needs to be carried on for several months more (at least 3 months) to replenish the depleted body iron stores. This can only be monitored by measuring the markers of body iron status such as serum ferritin. This marker is now regarded as the best indicator of iron deficiency in the absence of infection and is being used in population based studies. The generally accepted cut-off level for serum ferritin, below which iron stores are considered to be depleted, is < 15 mcg/L. Other markers, such as low transferrin saturation conjointly with high erythrocyte protoporphyrin, are less used now. Bone marrow iron staining is, for obvious reasons, restricted to specifically indicated cases and rigorous small group research studies.

Among the red cell indices, which nowadays can be automatically estimated by electronic blood cell instrumentation, the mean corpuscular volume [MCV] and the mean corpuscular hemoglobin [MCH], are also sensitive indicators. However, reduction of MCV and MCH, occurring in parallel with anemia, is a relatively late phenomenon in the development of iron deficiency.

Which preparations to use for prophylactic supplementation and treatment¹¹

A number of iron preparations are currently available in the Indian market – ferrous, ferric as well as various iron complexes – for the prevention and treatment of iron deficiency anemia. Table 2 lists several iron compounds with equivalent elemental iron content. It may be noted that the WHO Model List of Essential Medicines recommends a ferrous salt. For oral supplementation, any preparation can be used provided it has sufficient oral bioavailability considering average Indian meal habits. The choice therefore depends to a large extent on cost and subjective adverse events. Some experimentation may be necessary in the individual subject to find the most suitable preparation.

Much of the reported poor compliance with oral iron therapy is due to the associated adverse drug reactions [see Table 3]. Gastrointestinal (GI) side effects are particularly common and if these

appear, taking the supplements after meals may help although at the potential cost of reduced bioavailability.

Table 2. Quantity of different iron salts supplying 60 mg of elemental iron.

Salt	Quantity
Ferrous ascorbate (anhydrous)	437 mg
Ferrous aspartate (tetrahydrate)	422 mg
Ferrous carbonate (anhydrous)	125 mg
Ferrous chloride (tetrahydrate)	214 mg
Ferrous fumarate (anhydrous)	183 mg
Ferrous gluceptate (anhydrous)	544 mg
Ferrous gluconate (dihydrate)	518 mg
Ferrous lactate (trihydrate)	310 mg
Ferrous oxalate (dihydrate)	193 mg
Ferrous succinate (anhydrous)	185 mg
Ferrous sulfate (dried)	200 mg
Ferrous sulfate (heptahydrate)	300 mg
Ferrous sulfate (hemipentahydrate)	268 mg

Source: Reynolds JEF, editor. Martindale: The Extra Pharmacopoeia. London: The Royal Pharmaceutical Society, 1996.

Increasing the number of tablets daily is also likely to invite non-compliance. A single daily dose of a preparation containing sufficient iron therefore may be preferred in subjects prone to non-compliance and is best given at bedtime.

Table 3. Side effect of oral iron medication

- Upper abdominal discomfort, nausea, diarrhea, constipation – often appear at daily doses > 60 mg elemental iron.
- Black stools – not harmful.
- Oral iron, particularly modified release preparations, may exacerbate diarrhea in inflammatory bowel disease. Care also needed in patients with intestinal strictures and diverticulae.
- Constipation may lead to fecal impaction, specially in elderly individuals.

Many oral preparations of iron available in the Indian market contain ascorbic acid to aid absorption or is in the form of a chelate which has been shown experimentally to produce a modest increase in iron absorption. However, the clinical advantage is minimal and the cost can be substantially increased. For instance, the currently popular iron(III) hydroxide polymaltose complex, is a chelate which has a pleasant chocolate-like taste and does not cause prominent GI irritation. Unfortunately, most rigorous clinical studies have shown that it has variable and generally poor bioavailability. The cost of this preparation therefore does not justify its use. Intravenous formulations of this complex, available in South-East Asian countries, is of great advantage in parenteral iron therapy as the risk of serious toxicity present with conventional preparations is

absent and the IV route precludes bioavailability problems. However, the IV formulation is not yet available in India. There are also very many preparations containing cocktails of iron, vitamins and minerals. Most of them provide too low an iron content to be of any use in supplementation, even for prophylactic purpose.

Modified release [MR] preparations, often in 'Spansule' formulation, are designed to release iron gradually as the preparation traverses the GI tract so that at any given time, only a small amount of iron is present in the lumen. The advantages claimed are less GI irritation and a long duration of action permitting once or twice daily dosage. However, these preparations are likely to carry the iron beyond the first part of the duodenum where the conditions for iron absorption are optimal and the lower incidence of intolerance may well be due to the fact that a smaller quantity of iron is actually released and absorbed. Furthermore, technical failure of the preparation can lead to dose-dumping and even to entire tablets being passed out in stool. Whatever, be the preparation, it must be remembered, that iron can hinder the absorption of several other drugs, such as tetracyclines and cotrimoxazole, if administered concurrently.

The elemental iron dose required for treatment of iron-deficiency anemia (as opposed to prevention) is 120 mg/day as per WHO estimation.² The earlier WHO recommendation was 120 – 240 mg/day.¹² The objectives of treatment are correction of Hb deficit and subsequent replenishment of body iron stores. Both objectives can be achieved with simple iron preparations – like ferrous sulfate, fumarate or gluconate – that provide a daily dose of about 200 mg iron. Once Hb is restored treatment should be continued for at least three months more. If the woman cannot tolerate oral iron or is non-compliant otherwise, parenteral therapy can be considered. The response to parenteral iron, as already said, is not greater or faster but is more certain. A detailed discussion of parenteral iron therapy is beyond the scope of this article.

The public health program in India

The National Anemia Prophylaxis Program has been in place since 1972. This aimed at distribution of 100 FOLIFER tablets (each containing 60 mg elemental iron as ferrous sulfate and 500 µg folic acid) to each identified pregnant woman. For logistical and other reasons, the response to the program was unsatisfactory and revisions followed. In the current program, after screening for anemia, all women who are not anemic are given FOLIFER tablets for at least 100 days during pregnancy. Women with Hb between 7 – 11 g/dL receive 2 FOLIFER tablets for at least 103 days. Those with

Hb < 7 g/dL are sent to a first referral level hospital for investigation and treatment.¹³

Conclusion

In medical science, the morbidity and mortality is high in such diseases where the cause is unknown or where there is no specific treatment. In nutritional anemia, not only is the cause known, but there are simple interventions to both prevent and treat the problem. The cost too is well within our means. The continuing prevalence of nutritional anemia in India is thus a neglected tragedy as it continues to exact a heavy toll of suffering and death. We know what is needed. The challenge lies in putting this knowledge effectively into practice.

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Stevens-Johnson syndrome induced by amantadine

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Amantadine is used in the treatment of Parkinson's disease and drug-induced extrapyramidal reactions. It enhances extracellular concentrations of dopamine by increasing dopamine release or decreasing reuptake of dopamine into presynaptic neurons. It may also stimulate dopamine receptors or drive the postsynaptic dopaminergic system to a more dopamine sensitive status. Recent work has shown that it exhibits indirect anticholinergic activity in some experimental animals like rats but not in others like dogs. Clinically, it exhibits anticholinergic-like side effects such as dry mouth, urinary retention, and constipation.¹

Amantadine also exerts antiviral activity in influenza. The mechanism is not clearly understood. It appears to mainly prevent the release of infectious viral nucleic acid into the host cell by interfering with the function of the transmembrane domain of the viral M2 protein. In certain cases, amantadine is also known to prevent virus assembly during virus replication. It does not appear to interfere with the immunogenicity of inactivated influenza A virus vaccine.¹ Variable activity had been reported in vitro against other virus like herpes zoster.²

Most adverse drug reactions [ADRs] associated with amantadine therapy appear to be dose-related and relatively mild; some resemble those of antimuscarinic drugs. Anorexia, nausea, gastrointestinal disturbances, dizziness, inability to concentrate, insomnia, feelings of detachment, hallucinations, blurred vision, and peripheral edema have been reported. These ADRs may be reversed by withdrawing therapy but many resolve despite continuation. Amantadine is also reported to cause skin reactions like pruritus, skin rashes, including livedo reticularis, and diaphoresis. However, serious skin reactions have not been reported so far with amantadine or with the chemically related tricyclic amine rimantadine, that is also used as antiviral agent. Literature searches on Medline and with standard references like Physician's Desk Reference¹ and Martindale² will not unearth serious adverse skin reactions.

WHO Data: Recently, 8 suspected cases of Stevens-Johnson syndrome have been reported from various countries to the WHO Centre for International Drug Monitoring, Uppsala, Sweden, with amantadine. In 2 of these cases amantadine was administered alone, while in the rest it was administered along with other drugs. The profile of these ADRs is summarized in the table. The reaction appears to be more common in females (7 cases) of older age group. Only one female patient

was aged 39 years and others were above 50. This may not be surprising since Parkinsonism is primarily a disorder of later life. It is observed in more than 1% of individuals over the age of 65.³ However, there are no reports to suggest higher incidence of Parkinsonism in females. More reports related to the association of amantadine with SJS may provide definite information whether its incidence is higher in older females or not.

Table 1: Profile of reports of Stevens Johnson syndrome associated with amantadine

Countries (Incidence)	USA (4) Germany (1) Finland (1) UK (1) Israel (1)
Patient age range	39 - 79 years
Sex distribution	Male - 1, Female - 7
Outcome	Recovered without sequelae - 2 Not yet recovered - 1 Unknown - 5
Dechallenge	Positive - 3, Rest unknown
Rechallenge	Unknown - 6, Not performed - 2

In the two patients who used amantadine as a single agent, SJS appeared after one day (75 y old patient) and 5 days (39 y old patient) of starting therapy. In those where amantadine was given concomitantly with other drugs, the SJS appeared after one day (2 cases), 7 days (1 case) and 14 days (1 case) of therapy. In two cases the time of onset remains unknown.

From the above reports, it appears that there is correlation between SJS and amantadine with a higher incidence of occurrence in females. The use of amantadine in India [available as Cap AMANTREL from Cipla and Cap NEAMAN from Nestor Pharmaceuticals] is not widespread in India. However, Indian practitioners should remain alert to the possibility of serious skin reactions caused by amantadine and the related drug rimantadine.

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Survey of member organizations

During July-August, 2001, CDMU Documentation Centre [DC] conducted a survey of CDMU's member organizations [MOs] throughout the state of West Bengal by sending a questionnaire through post. The objectives behind this exercise were to evaluate CDMU's own performance in the supply of low-cost essential drugs and medical devices, so that future operation can be streamlined, and to gather information about the workings of its member organizations so that modifications in CDMU's pharmaceutical procurement and distribution policy can be made accordingly. The CDMU DC could utilize the data to decide upon its future thrust areas and campaign on rational drug use. Finally, it was also anticipated that the survey would enable the c to assess what proportion of CDMU's member organizations are currently utilizing the various value-added services it provides, like using the 'Rational Drug Bulletin' [RDB], attending training program / workshops / seminars and accessing the drug information service rendered by the DC.

The questionnaire requested information on the contact details of the MO, details in relation to health care services & facilities, annual healthcare budget, budgetary allocation for drugs, years of association with CDMU, various aspects of CDMU's drug supply activity, price, quality of service with respect to the concerned organization, and the utilization of various value added services provided by the DC.

Our members appreciated this effort which will strengthen their goodwill bond with CDMU. We received 68 responses to the questionnaire, from across the state, till the deadline for receiving a reply. Based on this, we have prepared a brief report. Table 1 gives the districtwise distribution of the responses received while Table 2 presents the range of healthcare activity of our MOs.

We also analyzed the patient attendance in different MOs and how they avail CDMU's services in terms of purchase of medicines, attending training programs, regular use of the quarterly RDB and whether they have received a copy of the National Essential Drug List [NEDL] from CDMU.

It was found, of 6964 patients attending clinics in these 68 organizations every day, 6126 patients are attending out-patient departments [OPDs] and 838 patients are being admitted as indoor cases. It was also noted that 86.76% of these 68 organizations regularly purchase low-cost and satisfactory quality medicines from CDMU; 23.53% have attended training programs conducted by CDMU in the past. Regarding RDB, around 18% of MOs regularly subscribe to this bulletin. A quarter of all MOs responding have received the NEDL from CDMU.

The most satisfactory aspect of this survey was the feedback on the quality of services rendered by CDMU to its MOs in terms of quality of medicines, cost-effectiveness and promptness in medicine

supply. It was noted that 78% of MOs are fully confident about the quality of medicines received from CDMU, about 80% have agreed that medicines supplied are cost-effective, and 70% feel that CDMU is quite prompt in supplying on time. Overall, the survey has revealed that about 81% of the MOs are benefiting from the services rendered to them.

Table 1. Locational distribution of the responses

District	No. of responses
24 Parganas North	5
24 Parganas South	6
Birbhum	2
Burdwan	1
Darjeeling	8
Dinajpur North	2
Dinajpur South	1
Hooghly	3
Howrah	2
Jalpaiguri	11
Kolkata	15
Medinipur	3
Murshidabad	2
Nadia	4
Purulia	3

Table 2. Fields of activity of our member organizations

Field of healthcare activity	No. working [%]
Acute respiratory infection	32 [47.06]
Ear, Nose, Throat problems	1 [1.47]
Eye problems	1 [1.47]
Gastrointestinal related problems	45 [66.18]
Leprosy	9 [13.24]
Malaria	22 [32.3]
Mother & child health [specifically]	16 [23.53]
Mental disorders	3 [4.41]
Occupational diseases	1 [1.47]
Polio vaccine	1 [1.47]
Tuberculosis	18 [26.47]
Others [dental, skin, STDs, diabetes, hypertension, etc]	35 [51.47]

This survey also gives much food for thought. Almost 75% of the total number of MOs to which the questionnaire was mailed have not responded. In a postal survey reminders are necessary. This was not done in this case, so that the picture is incomplete. The figures regarding quality of service rendered by CDMU are impressive but still 20-30% short of the ideal 100%. We cannot satisfy everybody all the time, but there is considerable scope for improvement. This endeavor was the first of its kind by CDMU. We hope that MOs will continue to give us much-needed feedback on the scope and quality of our services, so that future surveys would narrow the gap between actual and ideal.

New drugs approved by Drugs Controller General of India in the period July to December, 2001

Name of drug	Therapeutic category	Name of drug	Therapeutic category
Ebastine	Antiallergic	Decapeptide	Vitiligo therapy
Leflunomide	Antiarthritic [Rheumatoid arthritis; Immunosuppressant disease modifying drug]	Oxcarbazepine	Antiepileptic
Citalopram	Antidepressant [Selective serotonin reuptake inhibitor]	Desloratidine	Antiallergic
Gatifloxacin	Antibacterial [Fluoroquinolone]	Zoledronic acid	Biphosphonate for hypercalcemia of malignancy
Linezolid	Antibacterial [Oxazolidinone]	Ropinirole	Antiparkinsonian [Dopaminergic agonist]
Genirelix	Fertility agent	Esomeprazole	Antiulcer [Proton pump inhibitor]
Racecadotril	Antidiarrheal	Etanercept	Antiarthritic [Rheumatoid arthritis; Recombinant fusion protein with TNF α receptor decoy activity]
Cefdinir	Antibacterial [Cephalosporin]	Valsartan	Antihypertensive [Angiotensin receptor antagonist]
Iobitridol	Contrast medium	Meningococcal Type C conjugate vaccine	Immunizing agent
Exemestane	Anticancer [Steroidal androstenedione analog aromatase inhibitor]	Rabeprazole	Antiulcer [Proton pump inhibitor]

Source: Office of State Drugs Control – West Bengal

It is to be noted that approval of a new drug does not necessarily result in immediate introduction of the corresponding formulation in the Indian pharmaceutical market, whether imported or indigenously manufactured. Even if available, prescribers should exercise due caution in the use of these drugs for obvious reasons, particularly for those drugs which are new in the global pharmaceutical market too.

Recent additions to our library

- CD-ROM. Malaria: an information resource. Perth: Royal Perth Hospital, 2001.
- CD-ROM. WHO Medicines Bookshelf – A global virtual collection of information resources on access and rational use of essential drugs, quality and safety of medicines and traditional medicine. Prototype version. Geneva: Division of Essential Drugs and Medicines Policy, World Health Organization, 2001.
- CD-ROM. International Family Planning Perspectives on CD – Articles published in The Alana Guttmacher Institutes' peer-reviewed journal 1990-1999. Alan Guttmacher Institute & Johns Hopkins University School of Public Health, 2000.



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Our International Standard Serial Number is ISSN 0972-3064

**PUBLISHED BY: Community Development Medicinal Unit (CDMU) Documentation Centre
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E-mail: cdmudocu@giasc101.vsnl.net.in Electronic version.**